Welcome to our Webinar:

Standard Contractual Clauses (SCC) for Clinical Trials in Germany – A New Approach

KKS Netzwerk
Koordinierungszentren für Klinische Studien

DEUTSCHE HOCHSCHULMEDIZIN E.V.

VERBAND DER UNIVERSITÄTSKLINIKA DEUTSCHLANDS

medizinischer fakultätentag

vfa. Die forschenden Pharma-Unternehmen

BPI Bundesverband der Pharmazeutischen Industrie e.V.

VMA
BUNDESVERBAND MEDIZINISCHER AUFTRAGSINSTITUTE

Good CRO Practice®

BVMed
Bundesverband Medizintechnologie e.V.

PHARMA DEUTSCHLAND

Programm for today

Wednesday, July 1st, 2026, 4 – 5.30 pm Berlin time (CEST)

(respectively 10 – 11.30 am EDT or 7 – 8.30 am PDT)

Welcome/Introduction

The new Standard Contractual Clauses for Clinical Trials in Germany
(Dr. Thorsten Ruppert; vfa)

Why is this important for industrial sponsors, and why does this German approach differ from US law?
(Christoph Bertsch; Senior Counsel Drug Development & Regulatory Law; Bristol Myers Squibb)

How do universities and study centres in Germany view the Standard Contractual Clauses?
(Dr. Frank Wissing; DHM)

Open round for discussion and your questions on SCC in Germany

Closing remarks and Farewell

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Standard CTA Contracting – the new German Approach

Dr. Thorsten Ruppert

SCC-webinar July,1st 2026

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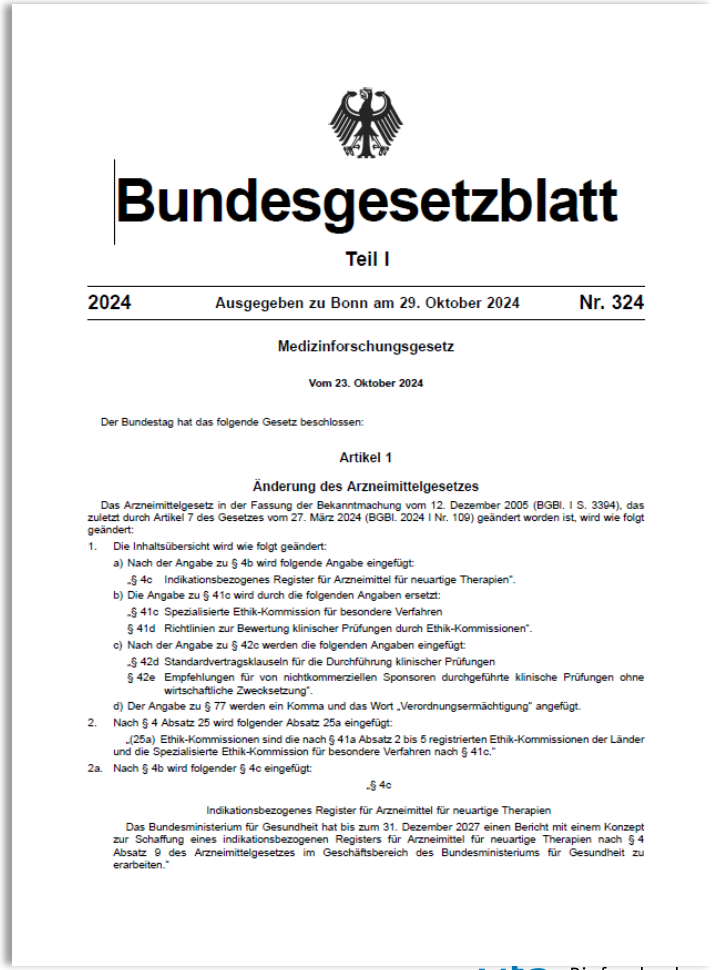
Research-Based Pharmaceutical Companies

Medicines Research Act introduced various improvements – examples…

Trial Location Germany

Improvements for clinical research through the new Medical Research Act **(entered into force on October 30th 2024) - Background:**

- Medical Research Act is the **first outcome of a broader pharma strategy** to improve Germany as a location for pharma companies. The government is showing that it is backing the research-based pharmaceutical industry as a key sector.
- The Medical Research Act will **speed up and reduce bureaucracy** in approval procedures for clinical trials and authorization procedures for medicinal products, medical devices and research-related radiation applications, while at the same time maintaining high standards for patient safety.
- **More than 40 "improvements"** regarding clinical trials with medicines and medical products are implemented with this Medical Research Act.



Bundesgesetzblatt

Teil I

2024 Ausgegeben zu Bonn am 29. Oktober 2024 Nr. 324

Medizinforschungsgesetz

Vom 23. Oktober 2024

Der Bundestag hat das folgende Gesetz beschlossen:

Artikel 1

Änderung des Arzneimittelgesetzes

Das Arzneimittelgesetz in der Fassung der Bekanntmachung vom 12. Dezember 2005 (BGBl. I S. 3394), das zuletzt durch Artikel 7 des Gesetzes vom 27. März 2024 (BGBl. 2024 I Nr. 109) geändert worden ist, wird wie folgt geändert:

1. Die Inhaltsübersicht wird wie folgt geändert:
   a) Nach der Angabe zu § 4b wird folgende Angabe eingefügt:
   „§ 4c Indikationsbezogenes Register für Arzneimittel für neuartige Therapien".
   b) Die Angabe zu § 41c wird durch die folgenden Angaben ersetzt:
   „§ 41c Spezialisierte Ethik-Kommission für besondere Verfahren
   § 41d Richtlinien zur Bewertung klinischer Prüfungen durch Ethik-Kommissionen".
   c) Nach der Angabe zu § 42c werden die folgenden Angaben eingefügt:
   „§ 42d Standardvertragsklauseln für die Durchführung klinischer Prüfungen
   § 42e Empfehlungen für von nichtkommerziellen Sponsoren durchgeführte klinische Prüfungen ohne wirtschaftliche Zwecksetzung".
   d) Der Angabe zu § 77 werden ein Komma und das Wort „Verordnungsermächtigung" angefügt.
2. Nach § 4 Absatz 25 wird folgender Absatz 25a eingefügt:
   „(25a) Ethik-Kommissionen sind die nach § 41a Absatz 2 bis 5 registrierten Ethik-Kommissionen der Länder und die Spezialisierte Ethik-Kommission für besondere Verfahren nach § 41c."
2a. Nach § 4b wird folgender § 4c eingefügt:

„§ 4c

Indikationsbezogenes Register für Arzneimittel für neuartige Therapien

Das Bundesministerium für Gesundheit hat bis zum 31. Dezember 2027 einen Bericht mit einem Konzept zur Schaffung eines indikationsbezogenen Registers für Arzneimittel für neuartige Therapien nach § 4 Absatz 9 des Arzneimittelgesetzes im Geschäftsbereich des Bundesministeriums für Gesundheit zu erarbeiten."

Improvements for clinical research through the new Medical Research Act - **Examples :**

Specialized Ethics Committee for Special Procedures (SEKbV)
A specialized ethics committee will be set up at the BfArM (e.g. clinical trials discussed in the EMA's Emergency Task Force, platform studies, highly complex master protocol studies, first-in-human studies and advanced therapy medicinal products). (**Application from July 2025**)

SEKbV as the central authority for certain study types
Creation of the Specialised Ethics Committee is a fundamentally good approach, especially for Phase I studies. Cave: Cooperation with AKEK?

Directive authority for AKEK (Working group Medical ethics committees)
Working group Medical ethics committees can issue binding guidelines - e.g. on the application of the requirements for informed consent referred to in Section 40b (1) or for the documentation and working methods of study coordinators.

AKEK can set standards
AKEK is given more powers through the authority to issue guidelines - this allows national standards to be formed for certain areas, which must be observed by all stakeholders.

Radiation protection
The notification and authorization procedures under radiation protection law are largely integrated into the clinical trial authorization procedure to reduce bureaucracy. Authorization periods for certain projects (radiation exposure above 6 mSV) follow the requirements of EU Regulation 536/2014 on clinical trials. (**Application since July 2025**)

Relief for CTs under radiation protection regulations
BfS is only required in a few authorization cases; >90% notification procedure. In the remaining few authorization procedures, clear shorter deadlines.

Standard contractual clauses
The Federal Government is given the opportunity to define binding standard contractual clauses by ordinance. This can significantly speed up contract negotiations between sponsors, trial centres and investigators. (**Application since December 2025**)

Acceleration of contract negotiations
Standard contractual clauses are to be used in accordance with the regulation - deviation possible. As a result, longer recruitment phase and inclusion of more patients possible.

Improvements for clinical re… …he new Medica…

Initial experiences with the SEKbV point in the right direction and are fundamentally positive; the ethics committee is approachable and open to discussion. It remains to be seen how this ethics committee will continue to establish itself.

Specialized E…
A specialized ethi… Emergency Task … studies and advar…

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AKEK is working on this. First guidelines on the qualification of examiners and examination centres since July 12th, 2025 - based on the update of the curricular training courses (basic, advanced and refresher course).

In April 2026 an additional guidance regarding sample texts for ICF was published.

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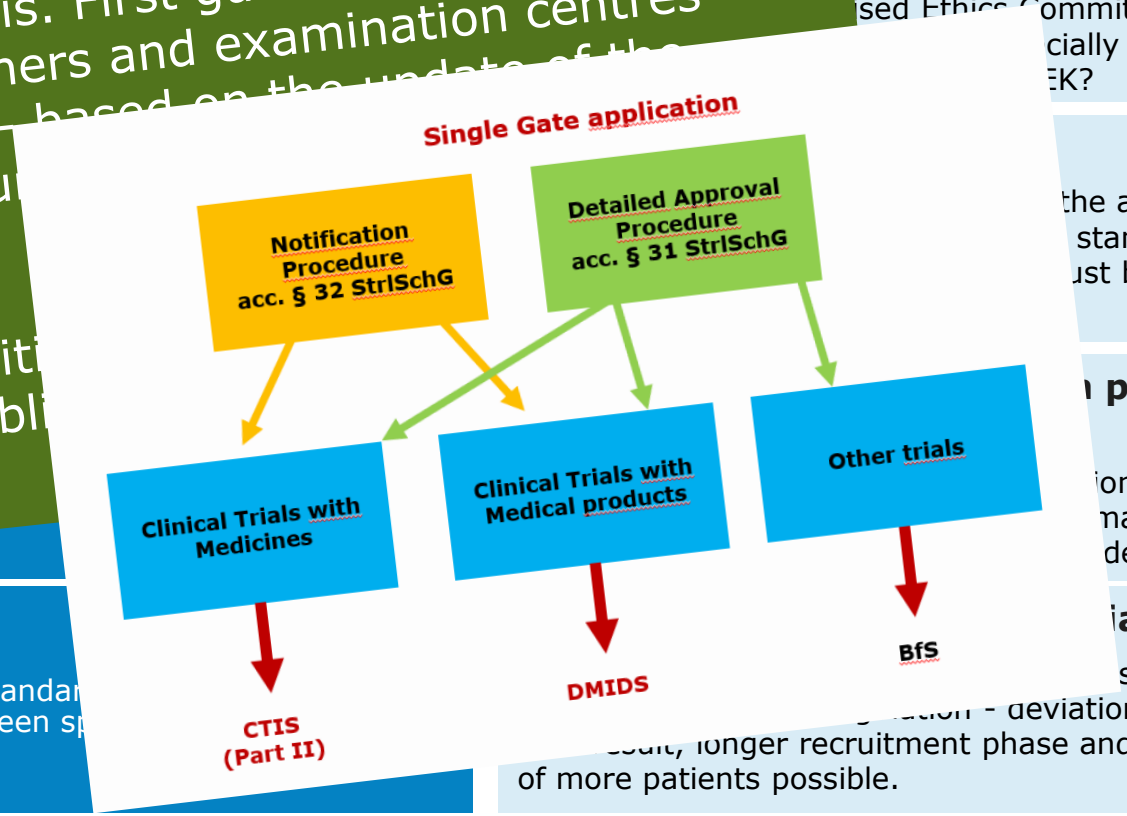

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Medicines Research Act introduces standard contract clauses for clinical trials in Germany

Trial Location Germany

Contracts and Remuneration for Clinical Trials…

… a crucial factor for early study start up and site selection:

- The conduct of clinical trials is often subject to time pressure, with the factor “time” playing an important role internally but also in the international competition. Long contracting timelines particularly leading up to a delayed start of a clinical trial.
- Currently contracting with clinical sites is probably the biggest rate-limiting step that sponsors have in operationalizing clinical trials.
- In order to be able to begin a clinical trial as early as possible, it should be possible to conclude the underlying contracts between the parties involved (e. g. Sponsor and Site) quickly and smoothly. This process starts with the NDAs and goes on until final trial contract or even further.
- So: Contracting as essential selection criteria for or against a trial center. So, it's one essential element when a company/CRO is making the decision where to conduct a clinical trial.

Clinical Trial Contracting in Germany – a long story…

Model contract clauses for clinical trials with drugs, conducted under the responsibility of a pharmaceutical company Version 2.0

(published in November 2023)

https://www.vfa.de/download/model-contract-clauses.pdf

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Model contract clauses for clinical trials with drugs, conducted under the responsibility of a pharmaceutical company (industrial sponsor)

Version 2.0

(10/30/2023)

Disclaimer:
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If you notice any inconsistency in this translation, please send your comments to info@vfa.de

- *Preamble*

Germany was well positioned as a location for conducting clinical trials and was internationally competitive. This was demonstrated, among other things, by its position as number 1 in Europe and number 2 worldwide, behind the USA, in terms of the number of clinical trials conducted. This is no longer the case and many countries, also in the European environment, have overtaken Germany. It is in the common interest of all those involved in clinical research, the patients, the trial sites and the sponsors of clinical trials to regain a good position as a trial location.

The conduct of clinical trials is often subject to time pressure, with the factor of time playing an important role in international competition, particularly in the period leading up to the start of a clinical trial. In order to be able to begin a clinical trial as early as possible, it should be possible to conclude the underlying contracts between the parties involved quickly and easily, with comprehensive content. As such, it would be useful if guidelines, in the form of model contract clauses providing examples of specific contractual provisions that regularly recur in contracts governing the conduct of clinical trials, were available to potential contractual partners during their respective negotiations; this would result in simplified negotiations in these areas.

To pursue these common goals, representatives from the Medizinischer Fakultätentag (MFT, German Association of Medical Faculties), the Verband der Universitätsklinika Deutschlands (VUD, German Association of University Clinics), the Koordinierungszentren für Klinische Studien (KKS network, Coordinating Centres for Clinical Trials) and the Verband forschender Arzneimittelhersteller (vfa, Association of Research-based

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Model contract clauses…

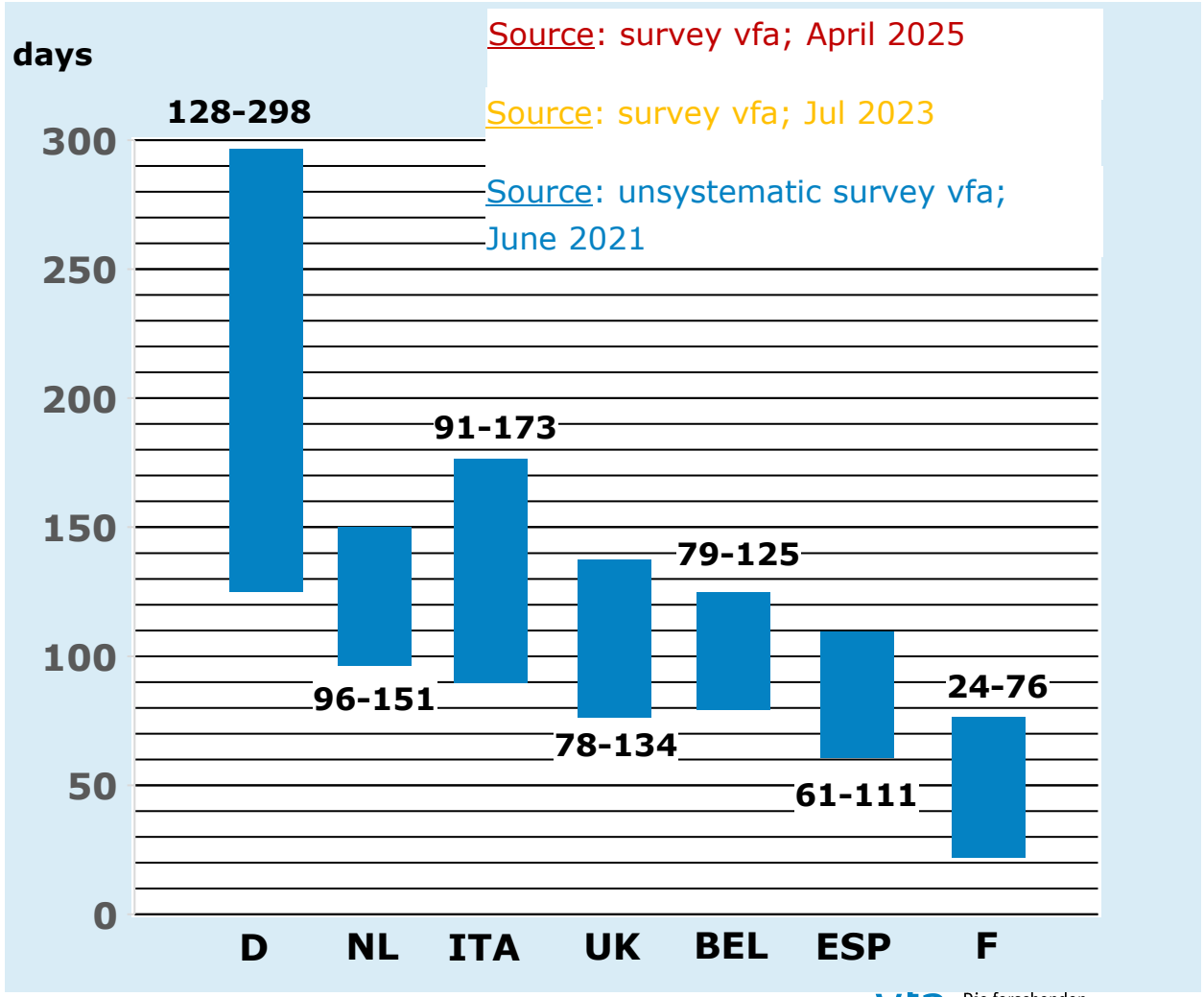
Model contract clauses for Inventions and property rights and responsibilities for data protection have been added with version 2.0.

- **Elements include** – e.g.: Publications, Confidential information, Liability, Audits/inspections, Archiving, Termination/cancellation of the contract.
- Trial contracts are typically concluded either between the sponsor and the trial site (institution/contractor) or between the trial site, investigator and sponsor (three-party contract). The German model contract clauses are based on a **two-party contract model**. For trial contracts involving one or more CROs, it is advisable to clearly delineate the areas of responsibility and services between the parties involved.
- It’s necessary for the investigator and other medical members of the investigating team to accept certain obligations in the form of a declaration – e.g. data protection, confidentiality, financial disclosure. **Corresponding model texts covering this aspects are annexed**.
- **BUT: Model contract Clauses were not mandatory!**

Contracts and Remuneration for Clinical Trials in Hospitals/University Clinics…

… a crucial factor for early study start up:

- Current surveys confirms long duration of contract negotiations in Germany in comparison!
- Long duration in Germany for the conclusion of contract negotiations in EU comparison.
- Large "range" for the duration of contract negotiations makes it difficult for sponsors to plan the start of a study!
- BUT at least a positive trend: average duration fell from 156 to 130 days!



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Research-Based Pharmaceutical Companies

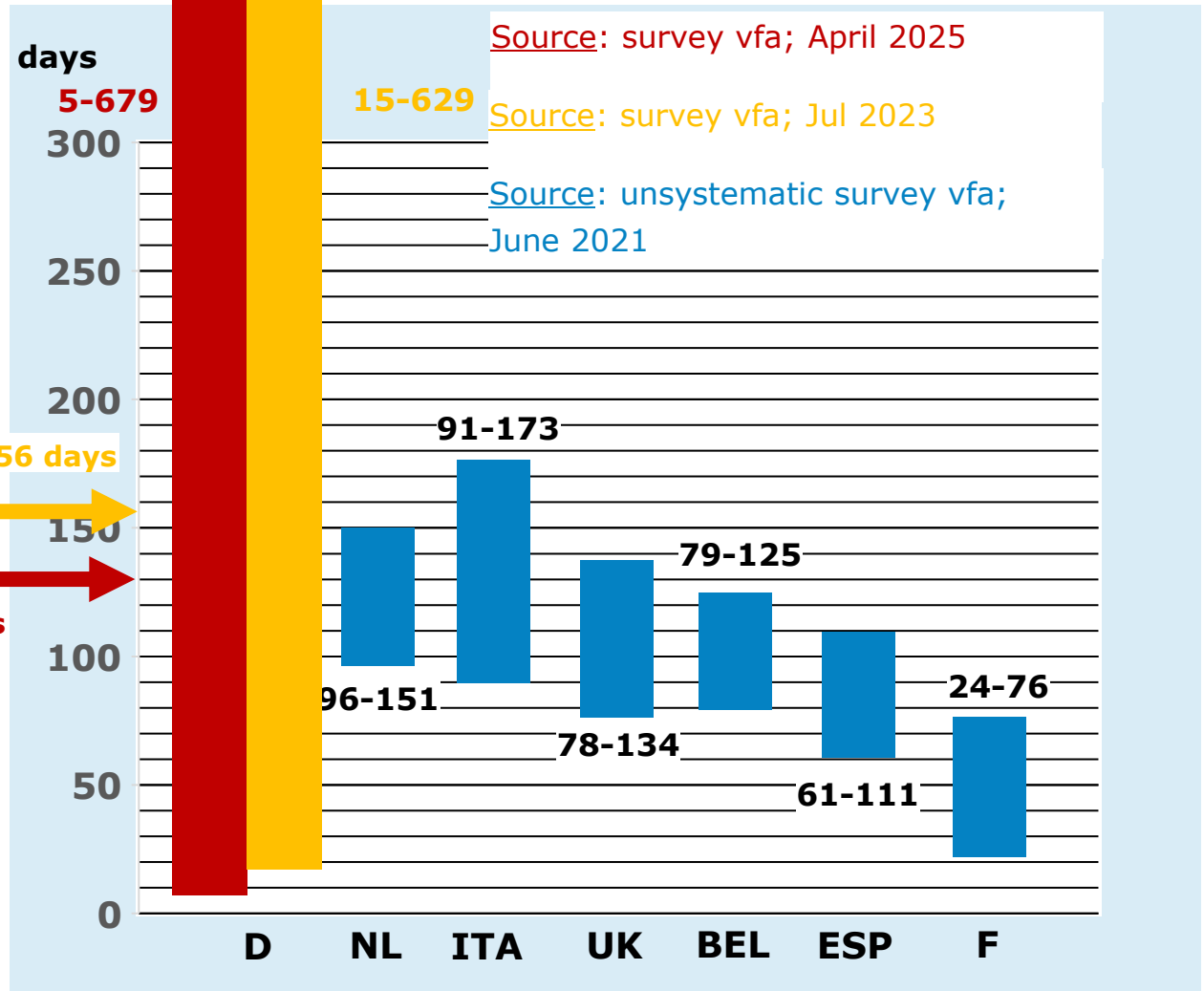
Contracts and Remuneration for Cli Trials in Hospitals/University Clinics…

… a crucial factor for early study start up:

- Current surveys confirms long duration of contract negotiations in Germany in comparison!

The problem:
High site quality, but historically slow activation of site in Germany!

- BUT at least a positive trend: average duration fell from 156 to 130 days!



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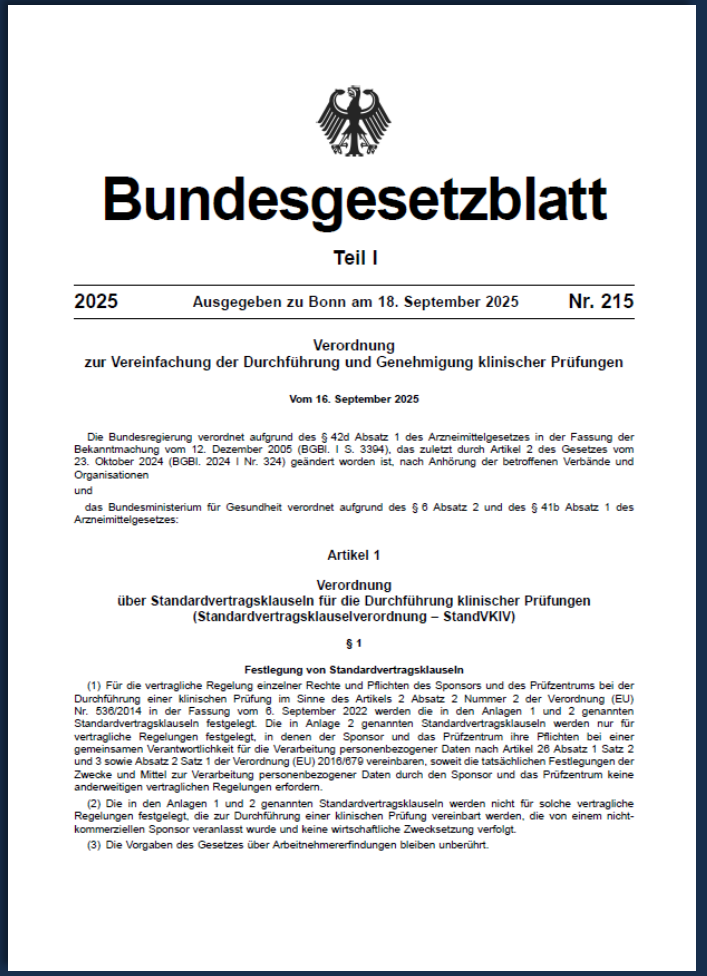
Our Model contract clauses paved the way for binding Standard Contract Clauses in Germany -
German Standard Contractual Clauses Ordinance – *„Standardvertragsklausel-Verordnung (StandVKlV)*“
(since December 2025)



Bundesgesetzblatt

Teil I

2025 Ausgegeben zu Bonn am 18. September 2025 **Nr. 215**

Verordnung
zur Vereinfachung der Durchführung und Genehmigung klinischer Prüfungen

Vom 16. September 2025

Die Bundesregierung verordnet aufgrund des § 42d Absatz 1 des Arzneimittelgesetzes in der Fassung der Bekanntmachung vom 12. Dezember 2005 (BGBl. I S. 3394), das zuletzt durch Artikel 2 des Gesetzes vom 23. Oktober 2024 (BGBl. 2024 I Nr. 324) geändert worden ist, nach Anhörung der betroffenen Verbände und Organisationen

und

das Bundesministerium für Gesundheit verordnet aufgrund des § 6 Absatz 2 und des § 41b Absatz 1 des Arzneimittelgesetzes:

Artikel 1

Verordnung
über Standardvertragsklauseln für die Durchführung klinischer Prüfungen
(Standardvertragsklauselverordnung – StandVKlV)

§ 1

Festlegung von Standardvertragsklauseln

(1) Für die vertragliche Regelung einzelner Rechte und Pflichten des Sponsors und des Prüfzentrums bei der Durchführung einer klinischen Prüfung im Sinne des Artikels 2 Absatz 2 Nummer 2 der Verordnung (EU) Nr. 536/2014 in der Fassung vom 6. September 2022 werden die in den Anlagen 1 und 2 genannten Standardvertragsklauseln festgelegt. Die in Anlage 2 genannten Standardvertragsklauseln werden nur für vertragliche Regelungen festgelegt, in denen der Sponsor und das Prüfzentrum ihre Pflichten bei einer gemeinsamen Verantwortlichkeit für die Verarbeitung personenbezogener Daten nach Artikel 26 Absatz 1 Satz 2 und 3 sowie Absatz 2 Satz 1 der Verordnung (EU) 2016/679 vereinbaren, soweit die tatsächlichen Festlegungen der Zwecke und Mittel zur Verarbeitung personenbezogener Daten durch den Sponsor und das Prüfzentrum keine anderweitigen vertraglichen Regelungen erfordern.

(2) Die in den Anlagen 1 und 2 genannten Standardvertragsklauseln werden nicht für solche vertragliche Regelungen festgelegt, die zur Durchführung einer klinischen Prüfung vereinbart werden, die von einem nicht-kommerziellen Sponsor veranlasst wurde und keine wirtschaftliche Zwecksetzung verfolgt.

(3) Die Vorgaben des Gesetzes über Arbeitnehmererfindungen bleiben unberührt.

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Standard contract clauses (SCC) in Germany…

- **A new paragraph was implemented with the German Drug Act - Article 42d AMG:** Legal basis for standard contractual clauses for the conduct of clinical trials.
- The Federal Government was authorized to provided an ordinance on standard contractual clauses.
- The causes can be implemented after consulting the associations and organizations concerned, to lay down standard contractual clauses on the rights and obligations of the sponsor and the trial site in the conduct of a clinical trial by ordinance subject to the approval of the Bundesrat.
- In September 2025 the final version of the ordinance on standard contractual clauses was agreed upon. Entry into force for all new contracts AFTER December 17th, 2025.
- **Possible exception:** If sponsor and trial site explicitly and unanimously agree by mutual consent to deviate from the standard contractual clauses.

Standard contract clauses (SCC) for CTs in Germany…

- **Elements include 10 areas addressed in the standard contract clauses:**

(1) Regulations on the sponsor's right of first publication and on the requirements for publications by the trial site
(2) Regulations on rights to results
(3) Regulations on confidential information
(4) Regulations on name and trademark rights
(5) Regulations on equipment and materials provided
(6) Regulations on inspections and audits
(7) Regulations on liability
(8) Regulations on the documentation of clinical trials and archiving of documentation
(9) Regulations on data protection
(10) Regulations on termination and cancellation of the contract.

Standard contract clauses (SCC) in Germany… main goals

- **Harmonization and acceleration**: The SVK are intended to create uniform contractual bases between sponsors (e.g. pharmaceutical companies) and trial sites nationwide to avoid lengthy and often tough contractual negotiations for each clinical trial.
- **More legal certainty**: Legally legitimized, standardized clauses are intended to avoid legal disputes and regulate clear responsibilities (e.g. on data protection, liability, remuneration, use of results, etc.).
- **More efficiency in trial start up timelines**: The use of SVK enables faster processing of the necessary contractual agreements in the context of the conduct of clinical trials in Germany.
- **Promotion of Germany as a research location**: Germany has been at a disadvantage in the competition for clinical trials - complex and time-consuming contract negotiations were a main reason. The SVK should make it easier to conduct clinical trials at German trial sites.

Standard contract template for clinical trials based on the German Standard Contractual Clauses Ordinance – Standardvertragsklausel-Verordnung (StandVKlV)

(published in December 2025)

https://www.vfa.de/standard-clinical-trial-template-en.pdf

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BPI Bundesverband der Pharmazeutischen Industrie e.V.

BVMA

Standard contract template for clinical trials with medicines under the responsibility of a pharmaceutical company (industrial sponsor) based on the German Standard Contractual Clauses Ordinance - Standardvertragsklausel-Verordnung (StandVKlV)

Status December 8th, 2025

- *Preamble/Foreword*

For many years, Germany was well positioned and internationally competitive as a location for conducting clinical trials. This was reflected, among other things, in its position as number one in Europe and number two worldwide, behind the United States, in terms of the number of clinical trials conducted. Unfortunately, this has not been the case for several years now, and several countries, including some in Europe, have overtaken Germany. Regaining a strong position at the top is in the common interest of all those involved in clinical research, patients, trial centres and sponsors of clinical trials.

The conduct of clinical trials is often subject to time pressure, and the factor of "time" plays an important role in international comparison, especially until the start of a clinical trial. To be able to start a clinical trial as early as possible, the underlying contracts between the parties involved should also be able to be concluded quickly, easily and comprehensively in terms of content.

Against this background, it is helpful if the potential contracting parties have guidance in the form of model contract clauses in their respective negotiations, in which certain, constantly recurring contractual provisions in contracts for the conduct of clinical trials are compiled as examples, thus simplifying contract negotiations in these areas. For this reason, model contract clauses have been jointly drafted by representatives of the German Association of Medical Faculties (MFT), the German Association of Academic Medical Centres (VUD), the Coordinating Centers for Clinical Studies (KKS Network) and the Association of Research-Based Pharmaceutical Companies (vfa), considering the different interests of all parties involved. The Federal Association of the Pharmaceutical Industry (BPI) and the Federal Association of Medical Contract Research Organisations (BVMA) have also contributed to version 2.0 of the model contract clauses for clinical trials with medicinal products.

As part of the discussions on the Medical Research Act, the Federal Ministry of Health (BMG) has now gone one step further and introduced "Standard Contract Clauses for the Conduct of Clinical Trials" into the German Medicines Act as Section 42d. Section 42d AMG created the legal basis for a regulation in this area.

On 18 September 2025, the "Regulation on the Simplification of the Conduct and Approval of Clinical Trials" was published, which contains Article 1, the "Regulation on Standard

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Standard contract template for clinical trials based on the German Standard Contractual Clauses Ordinance

- Since December 18th 2025, it has been mandatory for almost all new contracts between study sites and pharmaceutical companies to use the new standard contract clauses. This is intended to enable contracts to be concluded more quickly and thus also to enable studies to start more quickly.
- In order to simplify negotiations even further, we have developed a complete standard contract template that complies with the regulations - based on a **two-party contract model**.
- The standard contract template is intended as a guide for drawing up a specific contract for participation in a clinical trial. It is available for download in German and English.
- This standard contract template contains all standard contract clauses and is characterized by a balanced reconciliation of interests between the sponsor and the.
- The use of this contract template is not mandatory, but should support the implementation of the provisions by the new StandVKlV in Germany more quickly.

3-party standard contract template for clinical trials with medicines under the responsibility of a pharmaceutical company (industrial sponsor) and involvement of a CRO (contract research organization) based on the German SCC Ordinance

(published in June 2026)

https://www.vfa.de/standard-clinical-trial-template-3-party-en.pdf

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3-party standard contract template for clinical trials with medicines under the responsibility of a pharmaceutical company (industrial sponsor) and involvement of a CRO (contract research organization) based on the German Standard Contractual Clauses Ordinance - Standardvertragsklausel-Verordnung (StandVKlV)

As of June 23rd, 2026

- *Preamble/Foreword*

For many years, Germany was well-positioned and internationally competitive as a location for conducting clinical trials. This was reflected, among other things, in its position as number one in Europe and number two worldwide – after the United States – in terms of the number of clinical trials conducted. Regrettably, this has not been the case for several years, and a number of countries, including some in Europe, have overtaken Germany in this regard. Restoring its leading position is in the common interest of all stakeholders in the field of clinical research, patients, trial sites and sponsors of clinical trials.

The conduct of clinical trials is often subject to time pressure, and the factor of "time" plays a particularly important role in international comparison, especially in the phase leading up to the initiation of a clinical trial. In order to facilitate the earliest possible commencement of a clinical trial, the underlying contracts between the parties involved should be concluded quickly, easily and on a basis of comprehensive terms.

Against this background, it is helpful for prospective contracting parties to have guidance in the form of model contract clauses in their respective negotiations. These clauses provide examples of specific, frequently recurring contractual provisions in agreements for the conduct of clinical trials, thus expediting contract negotiations in these areas. For this reason, representatives of the German Association of Medical Faculties (MFT), the German Association of Academic Medical Centres (VUD), the Coordinating Centers for Clinical Studies (KKS Network) and the Association of Research-Based Pharmaceutical Companies (vfa drafted model contract clauses, which take the differing interests of all stakeholders involved into account. The Federal Association of the Pharmaceutical Industry (BPI) and the Federal Association of Medical Contract Research Organisations (BVMA) have also contributed to version 2.0 of the model contract clauses for clinical trials with medicinal products.

As part of the discussions on the Medical Research Act, the Federal Ministry of Health (BMG) has now gone one step further and introduced in accordance with Section 42d of the German Medicines Act the so-called "Standard Contract Clauses for the Conduct of Clinical Trials". Section 42d AMG created the legal basis for a regulation in this area.

On September 18th, 2025, the "Ordinance on the Simplification of the Conduct and Approval of Clinical Trials" was published, which contains the "Ordinance on Standard Contractual

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3-party standard contract template for clinical trials based on the German SCC Ordinance

- In addition to the 2-party contract template the associations involved in the SCC/model contract clauses published also a 3-party contract template based on the German SCC addressing the common situation where a site, a CRO and a sponsor are involved in the trial negotiations.
- This template will help to simplify negotiations even further also for this common constellation in clinical trials.
- The standard contract template is intended as a guide for drawing up a specific contract for participation in a clinical trial in the **three-party contract model**.
- It is available for download in German and English – https://www.vfa.de/standard-clinical-trial-template-3-party-en.pdf
- The new template was published on June 30th, 2026.

Summary

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Summary

- **Currently contracting and renumeration with clinical sites is probably the biggest rate-limiting step that sponsors have in operationalizing clinical trials – in Germany and worldwide.**
- **The new standard contractual clauses in accordance with Section 42d of the German Drug Law are a decisive building block for the simplification, harmonization and acceleration of clinical trials in Germany.**
- **They aim to strengthen Germany in international competition, increase legal certainty and significantly reduce the administrative burden for all parties involved.**
- **Their effectiveness will depend on how broadly and consistently they are implemented in practice - while at the same time remaining open to necessary exceptions in special study scenarios.**

Summary – important aspects for Clin Ops

- **What changes?** **Standardized CTAs in Germany are in place!**
- **When?** **Mandatory for new CTAs contracted <u>after</u> 17 Dec 2025!**
- **Why?** **Faster start-up, less negotiation for CTA contracting!**
  More predictable country-level planning!
- **Impact?** **Shorter timelines, more predictable delivery timelines!**
  Reduction in CTA contracting friction!
  Easier inclusion of multiple German sites!
- **Opportunity?** **Standardized CTAs enable faster start-up of CTs in Germany!**
  Opportunity to strengthen Germany's role in global trials!

Thank you!

https://www.vfa.de/de/forschung-entwicklung/klinische-studien/standardvertragsmuster-klinische-pruefung

Trial Location Germany

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Standard Contractual Clauses (SCC) for Clinical Trials in Germany – A New Approach

A legal context

July 1st, 2026

Christoph Bertsch

Disclaimer

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Constitutional context

Medizinforschungsgesetz/Medical Research Act	Regulation for the simplification of the conduct and approval of clinical trials
- In force since Octobre 30th, 2024 - Enacted by the German Parliament - National law - Includes a multitude of improvements for medical research in Germany - One of the improvements is the opportunity for the Ministry of Health to publish Standard Contractual Clauses for Clinical Trial Agreements.	- In force since September 19th, 2025 - Published by the Ministry of Health - Collection of most discusses clauses, not a full contract template - Standard Clauses are mandatory, except **both** parties agree to deviate - Clauses include alternatives and do not provide details (such as reimbursement for inventions)

Clinical Trial Agreement template

- Includes the mandatory Standard Contractual Clauses (SCCs) as published by the Ministry of Health (MoH).
- Transfer the Standard Contractual Clauses into a full contract template.
- Text of the contract template was developed and approved by a wide range of stakeholders, including university hospitals, industry associations, and clinical research networks.
- In the pipeline: template for CRO involvement and for medical devices.

Legal Focus – Intellectual Property

- No automatic transfer possible under German law on employee inventions.
- Site will inform the Sponsor about invention and site needs to accept the invention (otherwise it falls back to the site).
- Under German law a reimbursement in some kind must be made. SCCs offer two alternatives:
  - Later agreement (royalty or one-time payment)
  - Fixed fee at transfer (to be defined)
- Universities have a right to use results for own, non-commercial research, teaching and patient treatment purposes (SCCs extend this to all sites).

Legal Focus - Liability

- The MoH is using German civil law as a basis. For that reason the contract is only mentioning the limitations, but not the applicable standard rule.
- Applicable is §§ 276, 278, and 280 Germany Civil code (for **both** parties)
  - Liable for intent and negligence (but see limitation for slight negligence in the contract!)
  - Negligence is defined as not applying the care required in usual business. (medical standards and guidelines apply, violation of these is likely to result in gross negligence)
  - Liability includes representatives and agents that perform obligations on behalf of site, to the same extent
- This is no gap, but intended. Any attempt to include an additional liability regime will, most like, be pushed back.

Liability – relevant German law

Section 276
Responsibility of the obligor

(1) The obligor is responsible for intent and negligence if a higher or lower degree of liability neither is laid down nor is to be inferred from the other subject matter of the obligation, in particular the giving of a guarantee or the assumption of a procurement risk. The provisions of sections 827 and 828 apply accordingly.

(2) Anyone acts negligently who fails to exercise the care required in business dealings.

(3) The obligor may not be released in advance from liability for intent.

Liability – relevant German law

Section 278
Responsibility of the obligor for third parties

The obligor is responsible for fault on the part of their legal representative, and of persons of whose services they avail themselves in order to perform their obligation, to the same extent they are responsible for fault on their own part. The provision of section 276 (3) does not apply.

Liability – relevant German law

Section 280
Damages for breach of duty

(1) If the obligor breaches a duty arising from the obligation, then the obligee may demand compensation of the damage caused thereby. This does not apply if the obligor is not responsible for the breach of duty.

(2) The obligee may demand compensation of damages for delay in performance only subject to the additional prerequisite set out in section 286.

(3) Damages in lieu of performance may be demanded by the obligee only subject to the additional prerequisites set out in sections 281, 282 or 283.

DEUTSCHE HOCHSCHULMEDIZIN

Webinar: Standard Contractual Clauses (SCC) for Clinical Trials in Germany – A New Approach

How do universities and study centres in Germany view the Standard Contractual Clauses?

Frank Wissing, DPhil (Oxford)

Secretary general of the Association of German Medical Faculties (MFT)

German University Medicine (DHM)

German University Medicine represents a total of

40 medical faculties

and

37 university hospitals.

German University Medicine (DHM)

- ✓ ~ 2,2 Mio. inpatients p.a. (12,5% market share)
- ✓ ~ 12 Mio. outpatients p.a.
- ✓ ~ 33.000 hospital beds
- ✓ ~ 4.000 professorships
- ✓ ~ 40.000 scientists and MD
- ✓ > 200.000 employees in total

Clinical Trials in Germany: Some figures

- **WHO ICTRP: 7.609 running in Germany in 2025**

  (Source: Number of clinical trials by year, country, WHO region and income group (1999-2022))

- **German Trial Registry (DRKS) : 2.489 newly registered in 2025**

  (Source: BfArM - Deutsches Register Klinischer Studien (DRKS) – Statistik)

- **KKS-Network (2024): 1.125 in 2024**

  (Source: Zahlen und Fakten - KKS Netzwerk Koordinierungszentrum für Klinische Studien)

- **Clinical Trials led bei UMC: ~3.000 started between 2009-2017**

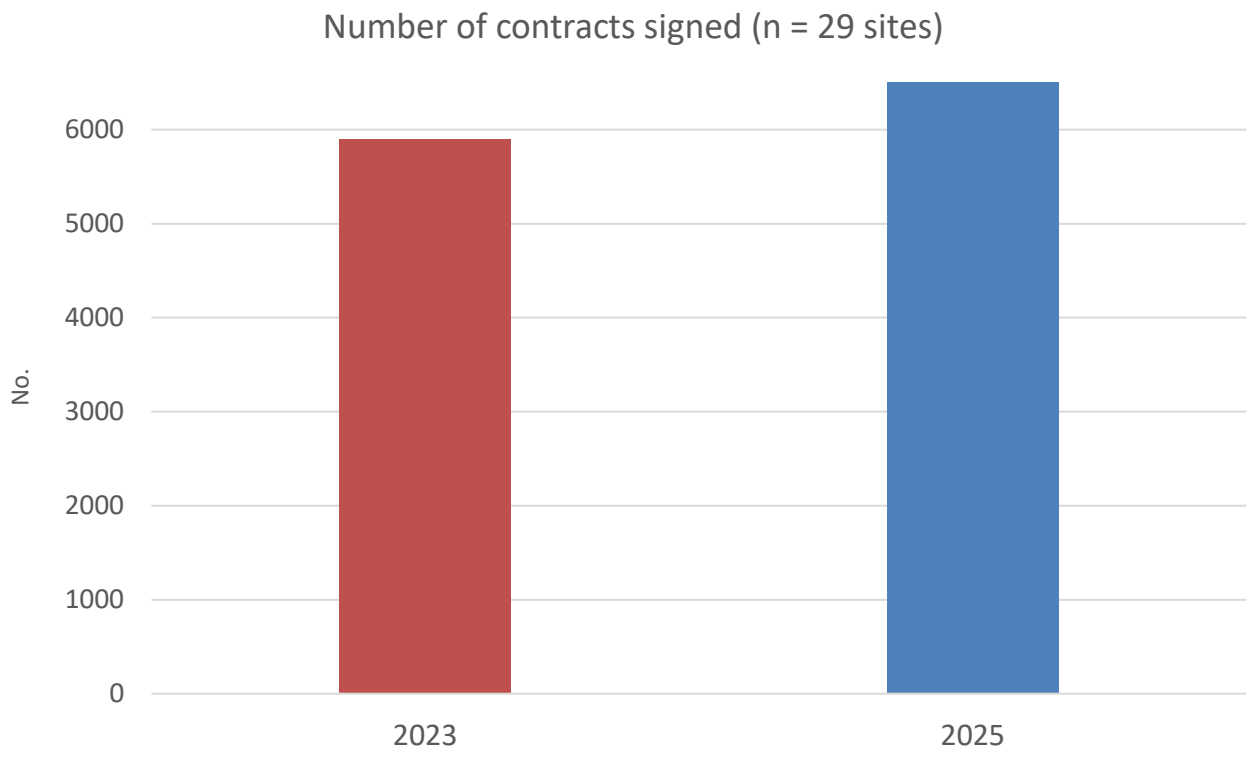
  (Source: Institutional dashboards on clinical trial transparency for University Medical Centers: A case study | PLOS Medicine)

- **Pharma-Trials in Germany (vfa, clinicaltrials.gov): 541 started in 2024**

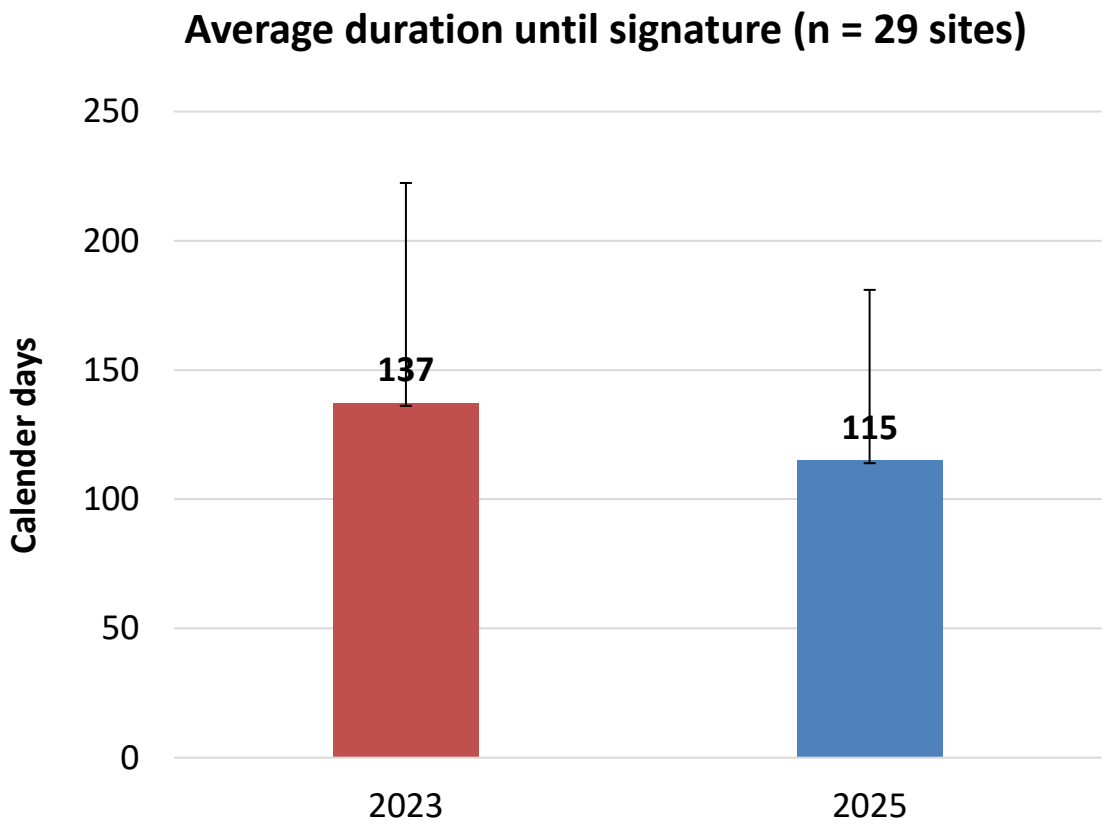
  (Source: welche und wie viele Studien Pharmafirmen in Deutschland durchführen)

Survey of voluntary SCC 2.0 in University Medicine (Jan ‘26)

Number of contracts has remained stable between 2023 and 2025 at around 6.000 at 29 sites that have answered the survey



Average duration until signature after voluntary SCC (2025)



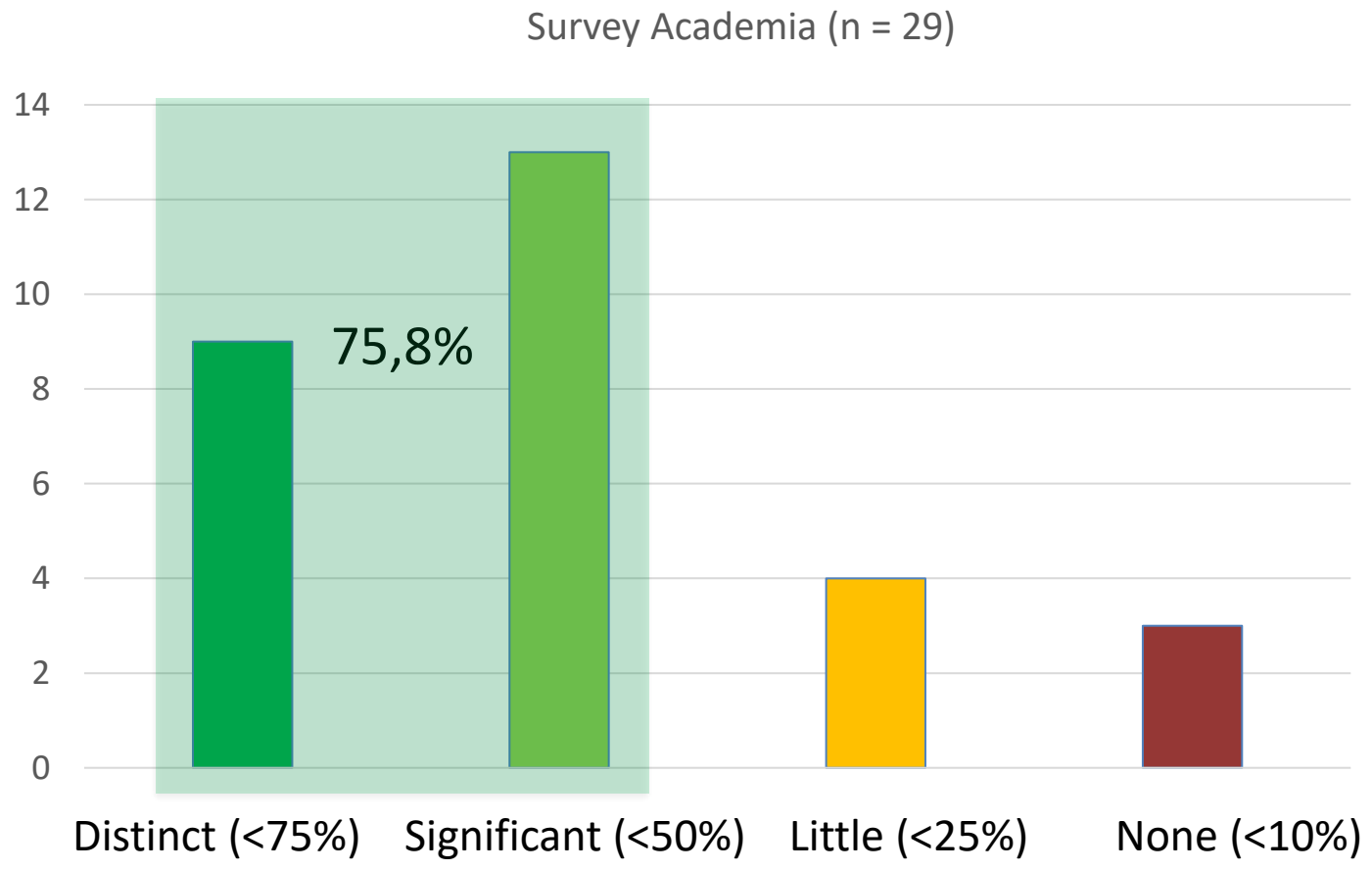
Fastest Agreements:

- 2023 Ø 24 days
- 2025 Ø 19 days

Slowest Agreements:

- 2023 Ø 378 Tage
- 2025 Ø 358 Tage

Estimated reduction on contractual agreement duration when SCC are used from the start (2025)



Perspective of University Medicine on SCC

Full support by University Medicine

- DHM ist part of the SCC platform since 2016
- SCC are fully supported by all DHM-CEOs
- Additional contract templates and services

Many sites offer fast track for SCC

- Condition: Full set of SCC or SCC-contract template is applied without changes
- Spacers/details in SCC are provided as needed

Deviations from SCC take time

- Please highlight changes/deviations from SCC
- Deviations or only SCC-parts provided: Need for individual contract negotiations (i.e. time)

Further Activities to Strengthen Clinical Trials in Germany

MEDICAL INFORMATICS INITIATIVE GERMANY

National Access to RWD from all UMC

NUM Network of University Medicine

Organises nationwide data and method platforms

Biobanking on Demand

High-Tech Agenda Germany

Thank you for your attention!

Frank Wissing, T. 030/6449 8559 0, verband@medizinische-fakultaeten.de

Joint recommendations for establishing a total services calculation for remuneration related to the conduct of a clinical trial in a trial center

(Version: May 2025)

https://www.vfa.de/download/empfehlungen-gesamtleistungsrechnung-en.pdf

KKS Netzwerk Koordinierungszentren für Klinische Studien

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BPI Bundesverband der Pharmazeutischen Industrie e.V.

VERBAND DER UNIVERSITÄTSKLINIKA DEUTSCHLANDS

medizinischer fakultätentag

BVMA Bundesverband Medizinischer Auftragsinstitute

Updated joint Recommendations for the preparation of a

total services calculation for remuneration related to the conduct of a clinical trial in a trial center

(updated version – as of May 5th, 2025)

Preamble

Carrying out clinical trials is often subject to time constraints. In order to start a clinical trial as soon as possible, it should be possible to finalize the underlying contracts between the parties quickly and easily while addressing all relevant issues. In this context, it is helpful if the potential partners in the contract have (in their respective negotiations) recommendations available that identify examples of recurrent cost items for the accurate determination of the remuneration. In this regard, representatives of the Association of Medical Faculties in Germany (MFT), the German Association of Academic Medical Centers (VUD), the Network of Coordination Centers for Clinical Trials (KKS Network) and the German Association of Research-Based Pharmaceutical Companies (vfa) have drawn up recommendations for the preparation of such a total services calculation for the first time in 2017. In 2025, the following revised version of the common recommendations was published in collaboration with the German Pharmaceutical Industry Association (BPI) and the German Association of Medical Contract Research Organizations (BVMA).

Instructions for use

These recommendations cannot be binding due to antitrust legislation, but they are intended to be a jointly adopted orientation for the negotiation of clinical trial contracts by members of the above-mentioned organizations and other third parties. The recommendations include tasks that may be performed depending on the project in the context of conducting a clinical trial and are not – or only insufficiently – described in relevant service specifications.

If the respective trial protocol and the recommendations are considered, these recommendations should enable comprehensive remuneration of all direct trial-related costs in a total services calculation based on the principle of fee for service. **The recommendations should be regarded as supplementary to the payments / activities listed in the trial protocol.**

General administrative costs and possibly other operational costs are to be considered in the respective total services calculation, provided that they are directly related to the conduct of the clinical trial. General administrative costs specific to the location (e.g. pro rata costs for electricity, room costs, use of equipment, etc.) should be included. In this case, a percentage surcharge (so called "overhead") would be contrary to the above-mentioned principle of fee for service.

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Joint recommendations for remuneration…

…core items:

- The services to be remunerated by the sponsor include **all services in <u>direct</u> connection with the clinical trial** that are provided to or with the patient, such as a consultation (patient information), blood draws, physical and instrumental diagnostics, ECG, etc., and the preparation of necessary trial-specific documentation (reports, certificates).
- **Other costs** also need to be considered; these are **likely be covered by lump sum payments** and include items such as electricity costs, telephone/fax/internet, office supplies and the use of other existing materials and facilities.
- If the remuneration is based on this recommendations, **no percentage lump sum surcharge (so called "overhead") should be demanded/accepted**.
- **Ban on possible double billing**: No additional remuneration would be made for standard of care activities that were already reimbursed by the German health insurance funds.
- **NOT MANDATORY!**

Thank you!

Questions?

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