



ACT EU webinar on contractual agreements

16 April 2026





Landscape analysis

Teresa Calandri (*EMA*)

16 April 2026

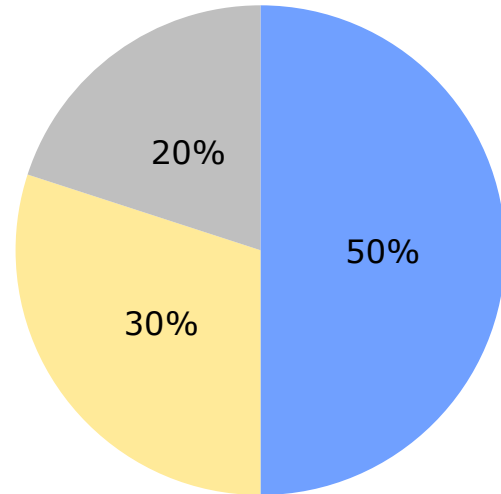


Input received from CTCG

- Starting point → to understand the current contractual landscape across Member States
- To determine whether clinical site agreements are in place and what their scope is:
 - whether these are templates applied on a per-trial basis or at a regional or national level
 - whether they cover both commercial and non-commercial sponsors
 - whether their use is mandatory or simply customary practice
- Survey conducted in February/March to CTCG members
- 24 Member States provided answer

Contract templates

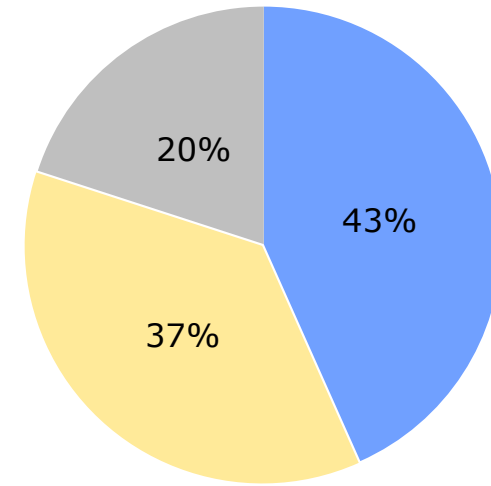
Commercial sponsors



■ Yes ■ No ■ No response

Austria	Croatia	Czech Republic
Belgium	Ireland	Cyprus
Germany	Italy	Estonia
Denmark	Netherlands	Finland
Spain	Norway	Hungary
France	Poland	Luxemburg
Greece	Sweden	Latvia
	Slovakia	Portugal
		Slovenia

Non-commercial sponsors



■ Yes ■ No ■ No response

Austria	Italy	Belgium	Hungary
Germany	Netherlands	Czech Republic	Ireland
Denmark	Norway	Cyprus	Luxemburg
Spain	Poland	Estonia	Latvia
France	Sweden	Finland	Portugal
Greece	Slovakia		Slovenia
Croatia			

Contract templates with commercial sponsors

Customary		Mandatory	
Austria	Per hospital (established best practice by trial site)	Germany	National (but may be waived if all partners agree)
Belgium		France	National
Denmark	Per trial	Greece	National
Spain	Regional/ per hospital	Ireland	Per Health Service Executive (public) hospitals
Croatia	Per trial	Italy	National
Netherlands	Per trial (between sponsor and site/ also if CRO is involved)		
Norway	Per trial		
Poland	Per trial (template developed by Polish Clinical Trials Network)		
Sweden	Per trial		
Slovakia			

Contract templates with non-commercial sponsors

Customary		Mandatory	
Austria	Per hospital (established best practice by trial site)	Greece	National
Germany	National	Italy	National
Denmark	Per trial		
Spain	Regional/ per hospital		
France	Variable (depends on sponsor and institution)		
Croatia	Per trial		
Netherlands	Per trial		
Norway	Per trial		
Poland	Per trial (template developed by Polish Clinical Trials Network)		
Sweden	Per trial/ trial site		
Slovakia			

Conclusions

- Mapping exercise → lack of harmonization, different types of contracts, varying obligations regarding applicability and use, and different scopes, as some are regional, national while others are trial based.
- Contract negotiations remain a major bottleneck delaying clinical trial start-up across Europe.
- Shows a strong need to learn from national experiences and share best practices across Member States.

Joint Action of Academia, CRO and Industry

DEUTSCHE HOCHSCHULMEDIZIN E.V.



VERBAND DER
UNIVERSITÄTSKLINIKA
DEUTSCHLANDS



medizinischer
fakultätentag

BPI Bundesverband der
Pharmazeutischen Industrie e.V.

BV Med Bundesverband
Medizintechnologie e.V.



KKS Netzwerk
Koordinierungszentren für Klinische Studien

vfa Die forschenden
Pharma-Unternehmen



Update Germany: Standard CTA Templates based on Binding Standard Contract Clauses

Sebastian Klammt
Clinical Trial Center (KKS)
University Hospital Würzburg

Joint Action of Academia, CROs and Industry

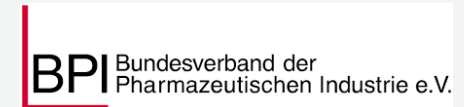
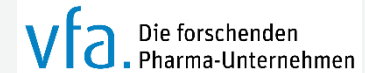
Academia



CROs



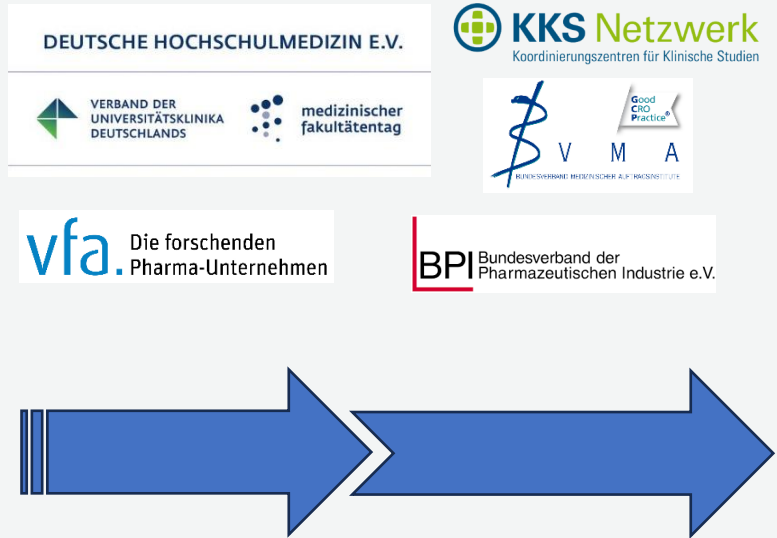
Pharmaceutical Industry and MedTech



KKS/ZKS:

Coordinating centers for clinical trials and
Competence hubs for quality-oriented academic clinical research
at **Medical Faculties** or **University Medical Centers**

The way to commonly agreed CTA-Templates for Sponsor Initiated Trials



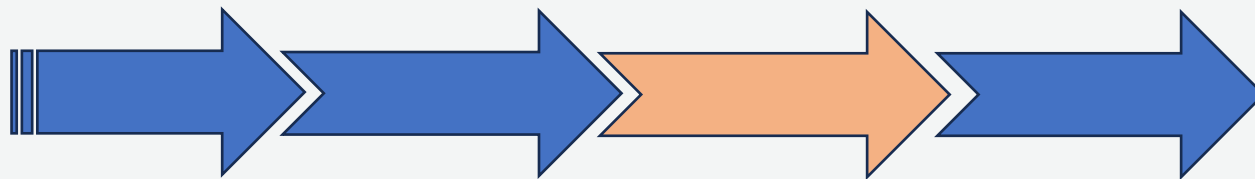
2019
Model
Contract
Clauses v1

2023
Model Contract
Clauses v2 with
Intellectual Property
clauses and annex on
data protection -
joint controllership
(Annex 2)

Model contract clauses for clinical trials with drugs, conducted under the responsibility of a pharmaceutical company (industrial sponsor)
 Version 2.0
 (10/30/2023)

<https://www.bvma.de/en/templates/>

The way to commonly agreed CTA-Templates for Sponsor Initiated Trials



2019
Model
Contract
Clauses
v1

2023
Model Contract
Clauses v2 with
Intellectual
Property clauses
and annex on data
protection - joint
controllorship
(Annex 2)

2024
Binding Standard
Contract Clauses
(Medicinal
Product Acts –
AMG) – in force
since December
2025

2025
Contract
Templates
based on the
new German
binding
Standard
Contract Clauses



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 (StandVKIV)

Status December 8th, 2025

<https://www.kks-netzwerk.de/en/study-support/model-contract-clauses/>

Legally binding Standard Contractual Clauses in Germany

Medicinal Products Act (Arzneimittelgesetz – AMG):
§ 42d

Standard Contractual Clauses for the performance of
clinical trials

Medical Devices Implementation Act (MPDG):
§ 31c

Standard Contractual Clauses for the performance of clinical
investigations and performance studies

Effective since 18th December 2025 for CTR/AMG trials

**Ordinance
on Standard Contractual Clauses for the Conduct of Clinical Trials (Standard
Contractual Clauses Ordinance)
(Standardvertragsklauselverordnung – StandVKIV)**

Section 1

Stipulation of standard contractual clauses

(1) For the contractual provisions on specific rights and obligations of the sponsor and the trial site when conducting a clinical trial as defined in Article 2 (2) (2) of Regulation (EU) No 536/2014 in the version of 6 September 2022, the standard contractual clauses laid down in Annexes 1 and 2 are established. The standard contractual clauses laid down in Annex 2 are established only for contractual provisions in which the sponsor and the trial site agree their obligations as joint controllers of personal data as set out in Article 26 (1) sentences 2 and 3 as well as subsection (2) sentence 1 of Regulation (EU) 2016/679, provided that the actual stipulations of the purposes and means of the processing of personal data by the sponsor and the trial site do not require other contractual provisions.

(2) The standard contractual clauses included in Annexes 1 and 2 are not established for contractual provisions that are agreed to conduct a clinical trial which is commissioned by a non-commercial sponsor and does not pursue any commercial intent.

**Ordinance
for Medical Devices/IVDR
is expected in 2026**

https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/3_Downloads/Gesetze_und_Verordnungen/GuV/K/Ordinance_on_Standard_Contractual_Clauses_for_the_Conduct_of_Clinical_Trials.pdf

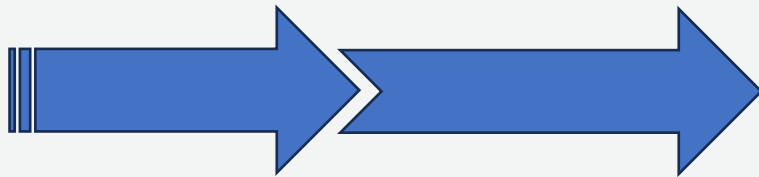
Reduction of contracting times already by optional contract clauses



Survey in academic institutions

2023: before publication of Model Contract Clauses V2 (28 institutions)

2025: after publication of Model Contract Clauses V2 and **before binding** Standard Clauses (29 institutions)



2019
Model
Contract
Clauses v1

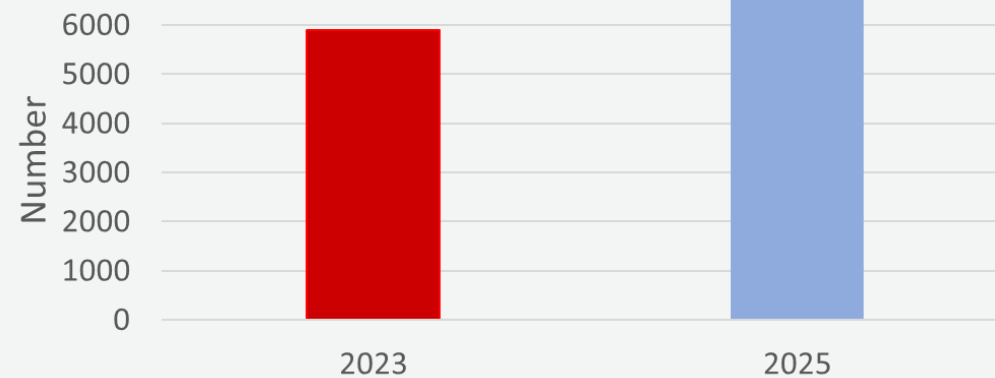
2023
Model Contract Clauses
v2 with **Intellectual
Property** clauses and
annex on **data
protection - joint
controllership**

Survey 2023

Survey 2025

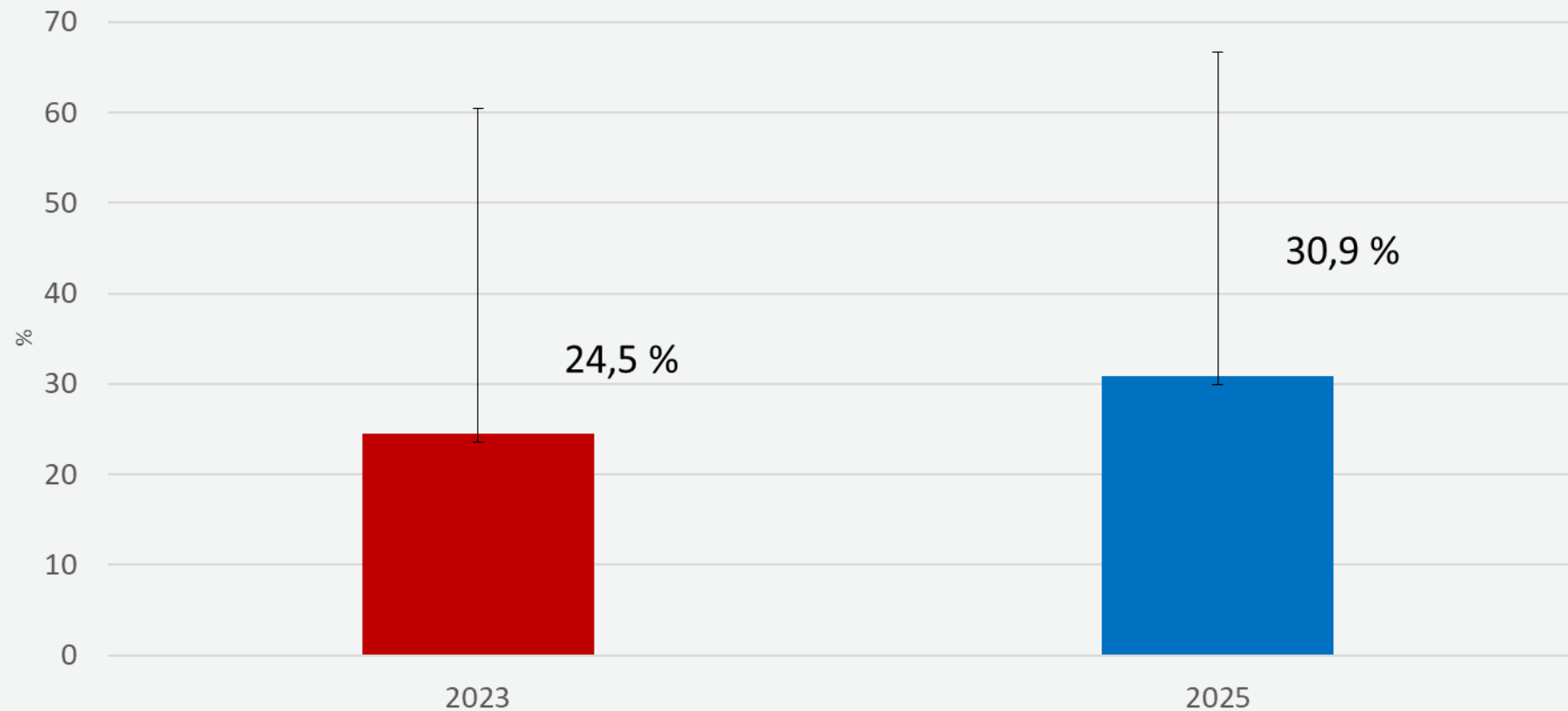
~ 6.000 CTAs are basis for each survey

Number of Clinical Trial Agreements concluded



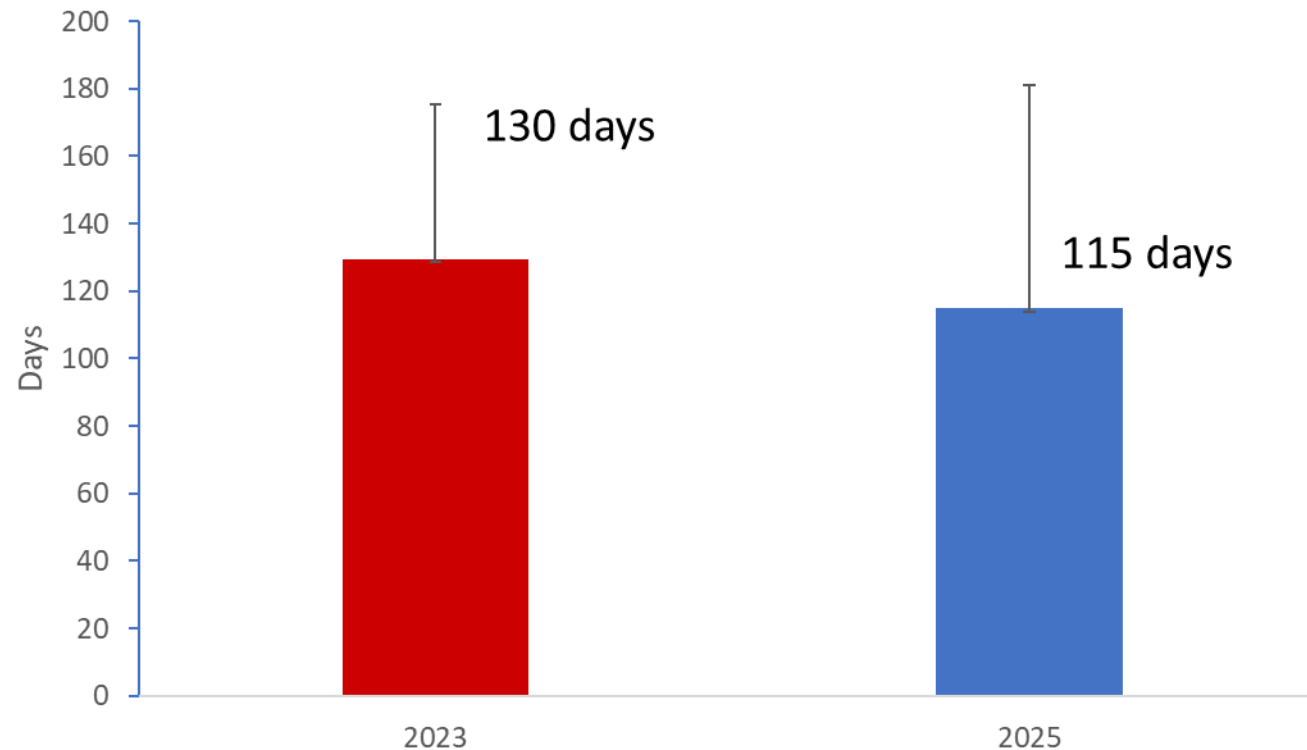
Increasing Use of commonly agreed optional Model Contract Clauses

CTAs concluded with optional Model Contract Clauses (in full or in part)



Reduction of contracting times already by optional contract clauses

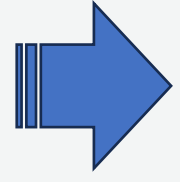
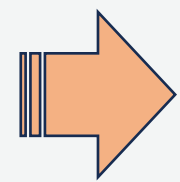
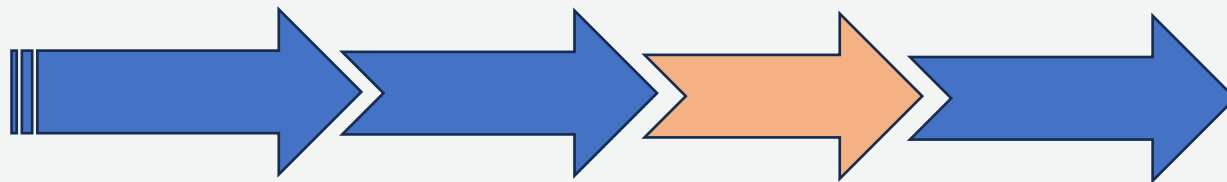
(Mean) Time for Contractual Agreements with industry (academic institutions surveys)



Reduction of **12%** by offering **optional Model Contract Clauses**

Further **reduction of timelines** due to the new **binding Standard Contract Clauses** in Germany (since 2026) is expected.

The way to commonly agreed CTA-Templates: Next Steps



2019
Model
Contract
Clauses v1

2023
Model Contract
Clauses v2 with
Intellectual
Property clauses
and annex on data
protection - joint
controllership
(Annex 2)

2025
Binding
Standard
Contract
Clauses
(Medicinal
Product Acts
AMG)

2025
Contract
Templates
based on the
new German
binding
Standard
Contract
Clauses

2026 (expected)
Ordinance on
Binding Standard
Contract Clauses
for **Medical
Devices (MDR)**

2026 (expected)
Contract Templates
based on the new
German **binding**
Standard Contract
Clauses
for **CTR and MDR**

Joint Action of Academia, CROs and Industry: Cost Calculation



DEUTSCHE HOCHSCHULMEDIZIN E.V.

vfa. Die forschenden Pharma-Unternehmen



**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)

<https://www.vfa.de/de/englische-inhalte/recommendations-for-a-total-services-calculation-in-clinical-trials>

WORK in PROGRESS

Harmonised structure for cost calculation - including:

patient-related expenses

- (most common) study related procedures
- (most common) events

non-patient-related (administrative) expenses

- One-off activities
- Ongoing activities
- Events

Academia: adopted Standard Template for Cooperation in academic Clinical Trials



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UNIVERSITÄTSKLINIKA
DEUTSCHLANDS



mft



KKS Netzwerk
Koordinierungszentren für Klinische Studien



NUM

Network of University Medicine

Standard Template for Cooperation in Academic Clinical Trials (Investigational Site Contracts in academic research)

Sponsor / Prüfarzt 1 Studientitel Version 1.0

**Vertrag über die gemeinsame
Durchführung einer klinischen Prüfung
mit dem (Kurz-)Titel.....**

zwischen

der **[Einsetzen Institution]**,
vertreten durch
[Einsetzen Juristische Vertretung, Adresse]

Verantwortlicher Projektleiter/-in¹:.....

Durchführende Stelle/Klinik/Institut (Standortbez. Anschrift):

Updated version is planned
for July 2026, also in English

<https://medizinische-fakultaeten.de/themen/forschung/pruefzentrumsvertraege/>

Improving Contractual Agreements in Germany by various measures

- **Optional** Model Contract Clauses has been developed by a **Joint Action of Academia, CROs, Pharmaceutical Industry and MedTech**
- Commonly developed and adopted Optional Model Contract Clauses **reduced contracting times**
- **Binding Standard Contract Clauses** has been implemented in German Law (AMG; effective 18.12.2025) and MPDG
- **Standard Contract Templates** based on the binding Standard Contract Clauses has been published by Joint Action, a **more pronounced reduction of time on contract conclusion is expected**
- **Joint Recommendations for Cost calculation/remuneration** in clinical trials are in place to foster contractual agreements between pharmaceutical industry and academia
- a harmonised **structure for cost calculation** in clinical trials **is currently under development** by Joint Action group
- Furthermore, **standard templates for academic clinical trials** has been adopted by German Associations of Medical Faculties (MFT), University Medical Centers (VUD), KKS-Network and Network University Medicine (NUM); an English version will be available shortly

Downloads:

Binding German Standard Contract Clauses (as implemented by the German government since December 17th, 2025):

https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/3_Downloads/Gesetze_und_Verordnungen/GuV/K/Ordinance_on_Standard_Contractual_Clauses_for_the_Conduct_of_Clinical_Trials.pdf

Standard Contract **Templates** (based on the **binding** German Standard Contract Clauses):

<https://www.kks-netzwerk.de/en/study-support/model-contract-clauses/>

Joint recommendations for **Cost Calculations/Remuneration**:

<https://www.vfa.de/de/englische-inhalte/recommendations-for-a-total-services-calculation-in-clinical-trials>

Standard Template for **academic clinical trials** (currently in German only)

<https://medizinische-fakultaeten.de/themen/forschung/pruefzentrumsvertraege/>

CONTACT

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University Hospital Würzburg
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Tel.: +49 931 201 39340
Klammt_S@ukw.de



**MINISTÈRE
DE LA SANTÉ, DES FAMILLES,
DE L'AUTONOMIE
ET DES PERSONNES HANDICAPÉES**

*Liberté
Égalité
Fraternité*

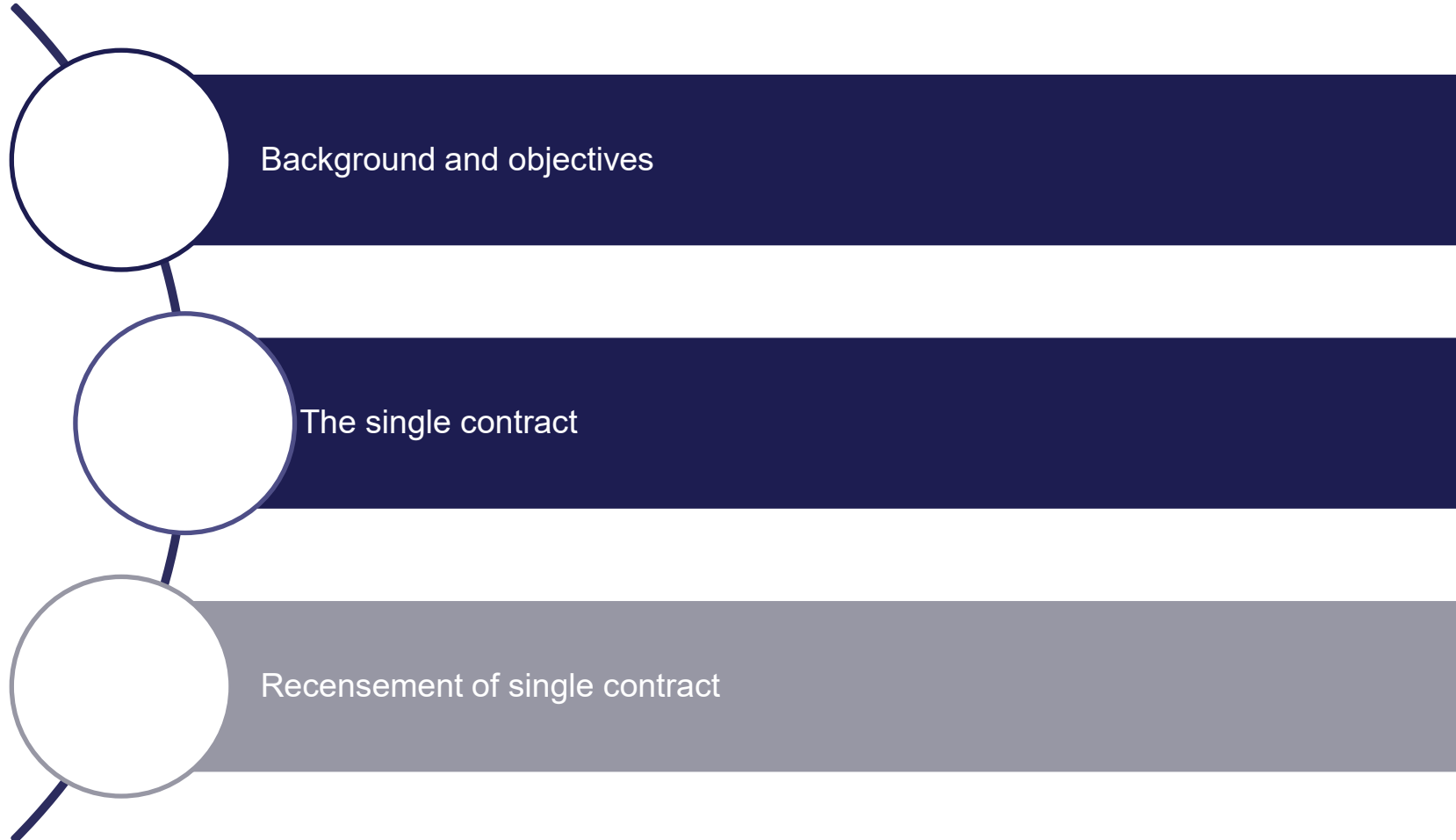
THE FRENCH SINGLE CONTRACT FOR INDUSTRY-SPONSORED CLINICAL RESEARCH

Teddy LEGUILLIER

Office for the Organization and Funding of Research

Single Contract Lead : **Ornellia MOPHAWE**

Summary





Background and objectives

Background and Legal Framework

Before 2017

- Multiple type contracts per site
 - Long and heterogeneous negotiations between industrial sponsors and hospitals
 - Lack of predictability for sponsors
- **Introduction of a standardized national contract by DGOS**

Legal framework

- Introduced in 2017
 - Based on the French Public Health Code
 - Updated by ministerial decrees
- **Mandatory under French Public Health Code**



Objectives of the Single Contract



Reduce the time required to set up clinical research projects → a key driver of France's attractiveness



Simplify the procedures required to implement industry-sponsored research involving human participants



Ensure transparency of financial flows related to these studies



Overview of the Single Contract

Scope of application and Contracting Parties

Scope of application	Who signs the contract
<p data-bbox="112 525 835 571">Industry sponsored clinical research</p> <p data-bbox="112 604 891 649">Research involving human participants</p> <p data-bbox="112 758 555 803">Conducted in hospital</p>	<p data-bbox="1296 525 1661 571">Industrial sponsor</p> <p data-bbox="1296 604 1465 649">Hospital</p> <p data-bbox="1296 758 1477 803">Possible:</p> <p data-bbox="1296 836 1666 882">Delegation to CRO</p> <p data-bbox="1296 915 1860 961">Involvement of third parties</p>

Key features of the contract

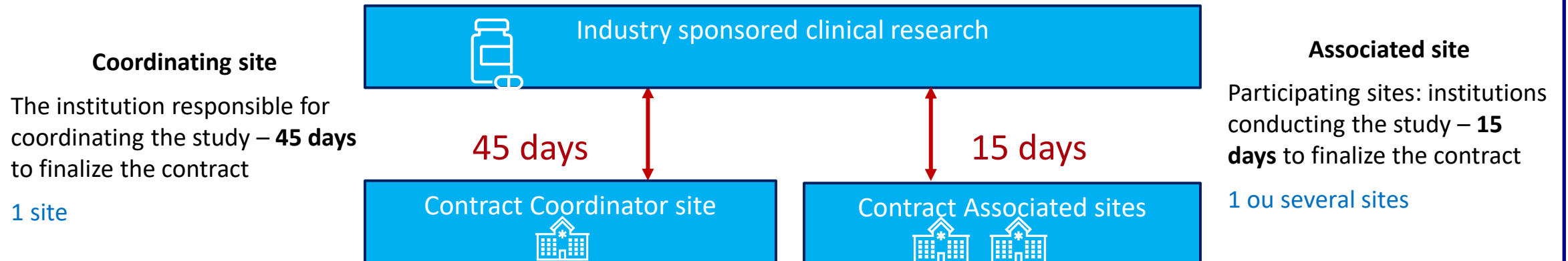
A standardised national template

National contract template

Core text cannot be modified

3 mandatory annexes and 3 annexes can be adapted

Target timelines



Used as a national benchmark

Reference documents

Available on the French Ministry of Health website [ministère de la santé, des familles, de l'autonomie et des personnes handicapés](https://www.solidarites-sante.gouv.fr/)

Official contract template in French and English

- Coordinating
- Associated

Information note and Q&A

Financial annex in French and English


Note d'information

La DGOS met à disposition une note d'information

 N° DGOS/RI1/2024/120 du 1er août 2024 [Téléchargement du pdf \(604.1 kio\)](#)

ainsi qu'une [foire aux questions](#) (FAQ) relative à l'utilisation de la convention unique.

 [Foire aux questions sur la convention unique - juillet 2025](#) [Téléchargement du pdf \(415.9 kio\)](#)

 [Annexe 2.1 – Convention unique v.sept2024 et mode opératoire v.juil 2025](#) [Téléchargement du xls \(129.5 kio\)](#)

 [Annexe 2.1 – Convention unique - english version v.sept2024 - instruction \(...\)](#) [Téléchargement du xls \(96.6 kio\)](#)

Modèles de convention

 [Modèle de convention associé - août 2024](#) [Téléchargement du docx \(142.2 kio\)](#)

 [Modèle de convention associé - english version - septembre 2024](#) [Téléchargement du docx \(130.4 kio\)](#)

 [Modèle de convention coordonnateur - août 2024](#) [Téléchargement du docx \(141.6 kio\)](#)

 [Modèle de convention coordonnateur - english version - septembre 2024](#) [Téléchargement du docx \(134.1 kio\)](#)



Monitoring of the single contract

Monitoring

National monitoring

Annual national data collection on « Démarche numérique »

Used for:

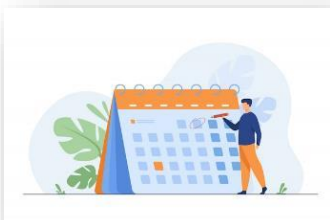
- Monitoring implementation
- Allocation of funding €20M allocated across hospitals



Measure

Impact on contracting (Compliance with the template and completeness) €

Time to contract between sponsor and site (observational indicator)



Monitoring page

Available on the French Ministry of Health website [ministère de la santé, des familles, de l'autonomie et des personnes handicapés](https://www.solidarites-sante.gouv.fr/)

Annual fundings result for each hospital

[+ Recensement de l'usage 2023 de la convention unique](#)




[+ Recensement de l'usage 2022 de la convention unique](#)

[+ Recensement de l'usage 2021 de la convention unique](#)

[+ Recensement de l'usage 2020 de la convention unique](#)

Q&A, procedure and guide document

Documents

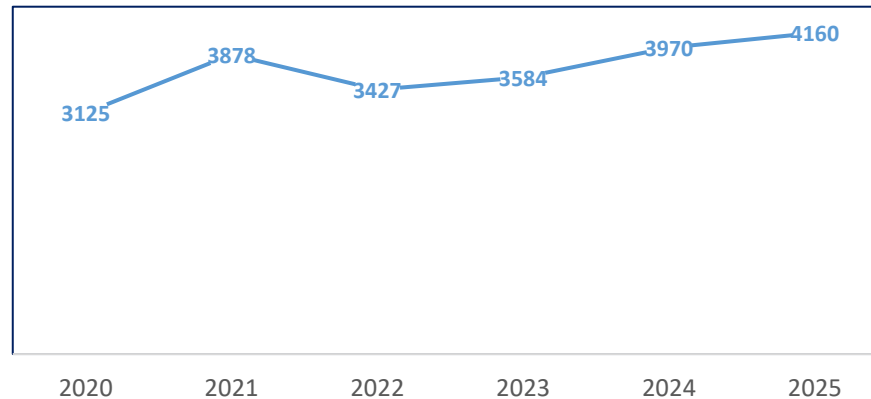
-  **FAQ - recensement convention unique** Téléchargement du pdf (432.8 kio)
-  **Guide utilisateur recensement 2024** Téléchargement du pdf (880.5 kio)
-  **Modalités de recensement 2024** Téléchargement du pdf (216.2 kio)

Key results 2025

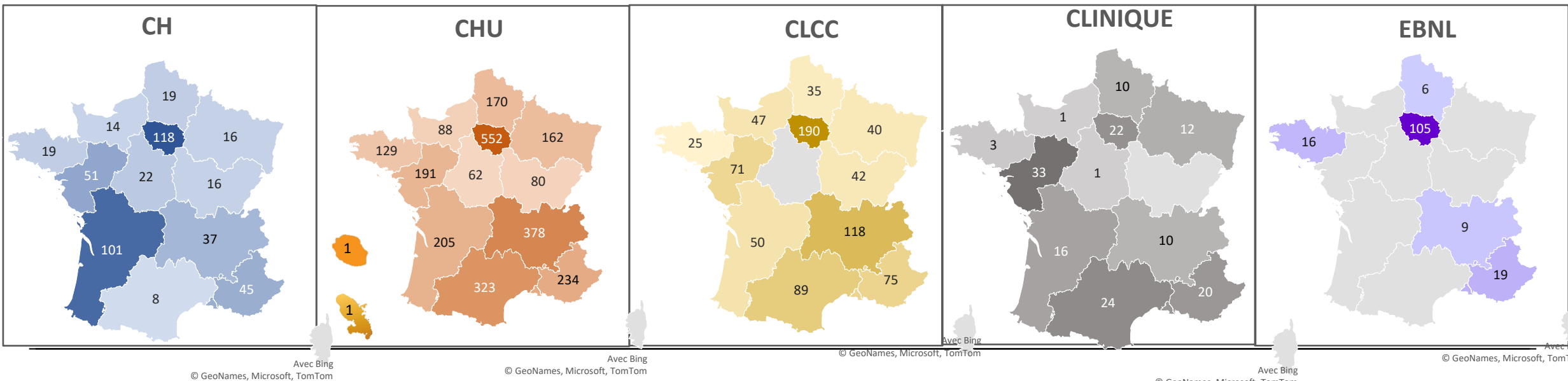
Result

Contract included in the monitoring	4160
-------------------------------------	------

Contrats included in the monitoring by year

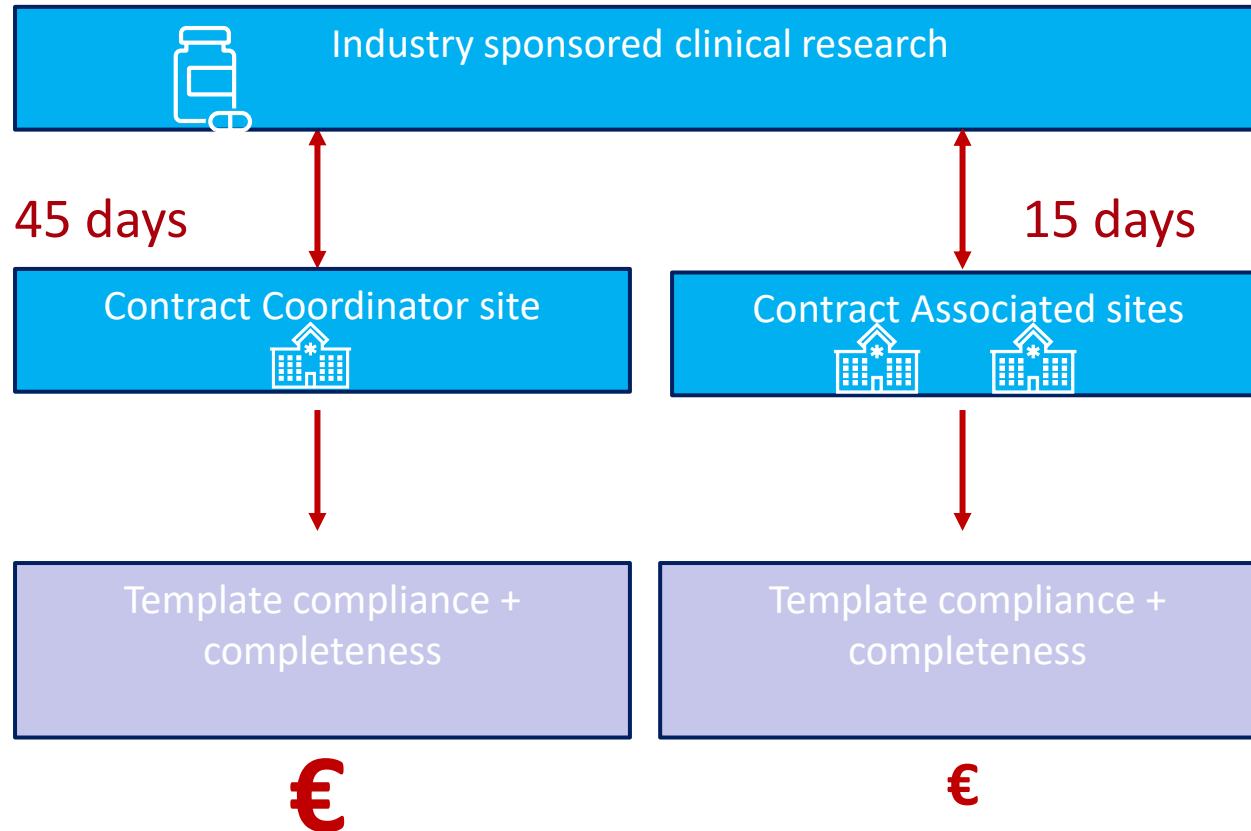


209 French healthcare institutions



Summary

Legal framework



Funding
allocation



MEDICAL
RESEARCH
AGENCY



Polish
Clinical Trials
Network

Medical Research Agency

Our experience in developing a template clinical trial agreement

Medical Research Agency

Through research to health

The Medical Research Agency (MRA) is a government-based Agency, operating under the *Act of 21 February 2019* and reporting to the Minister of Health. Responsible for development of scientific research in the field of medical and health sciences.



35 Clinical Research Support Centres 19 Regional Digital Medicine Centres



Polish
Clinical Trials
Network



REGIONALNE
CENTRUM
MEDYCYNY
CYFROWEJ

First comprehensive support for Polish public facilities conducting clinical trials



MEDICAL
RESEARCH
AGENCY

CRSC CRSC+RCDM

Clinical Research Support Centers Development – III Pillars

Pillar I

- Infrastructure
- IT systems

Pillar II

- Document templates
- Quality support

Pillar III

- Education
- Promotion

The idea behind developing a template agreement



Support for the contracting process.



Harmonisation of agreement execution between sponsors and sites.



Building a foundation for relationships between sponsors and sites.



Promotion of the PCTN among sponsors.

The process behind developing a template agreement

Step 1

- May 2022 – conceptual work
- June 2022 – development of the process framework

Step 2

- July 2022 – commencement of collaboration with an expert – subject matter expert
- July 2022 – drafting of the first version of the tripartite agreement

Step 3

- August – September 2022 – 3 consultation rounds
- Consultations were held with representatives of the pharmaceutical industry, organisations supporting clinical trials in Poland, and research centres.

The process behind developing a template agreement

First version

- October 2022 – publication of the first version
- Publicly available document published on the MRA website

Step 4

- Verification of the document's implementation
- Comments: the terms of the contract are not always clear to the parties; concerns about upcoming law changes; the need for a four-party agreement

Changes in the law

- Entry into force of the Act of 9 March 2023 on clinical trials of medicinal products for human use
- Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC

The process behind developing a template agreement

Step 5

- August 2023 – work begins on updating the tripartite agreement and the template for the four-party agreement
- September 2023 – draft versions of the documents

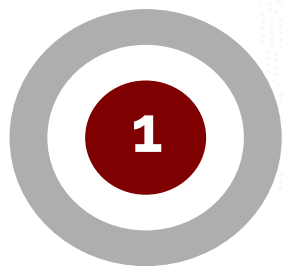
Step 6

- September – October 2023 - consultation rounds
- October 2023 – pre-final version of updated documents

Second version

- February 2024 - Publicly available document published on the MRA website
- Tripartite agreement template and the template for the four-party agreement

Agreement template – Key challenges



When drafting a contract template, conflicting comments will inevitably arise – it is essential to weigh up the options and reach a decision.

The mandatory implementation of a standard contract template always involves some disruption, as the parties will need to adapt to the new circumstances.



A contract template will not speed up the financial negotiations; in Poland, these currently take the longest.

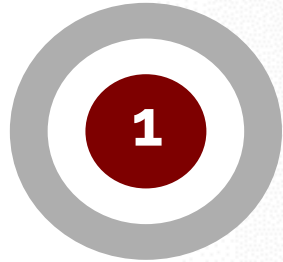
The contract template must be flexible enough to allow it to be used in increasingly complex research projects, yet rigid enough to actually serve as a template.



Agreement template – Key areas covered by the document

Section 1	Subject matter of the Agreement
Section 2	Investigational Medicinal Product
Section 3	Responsibilities of the CRO/Sponsor
Section 4	Responsibilities of the Principal Investigator
Section 5	Responsibilities of the Site
Section 6	Personal data, confidentiality and intellectual property
Section 7	Financing health care services and Study insurance
Section 8	Remuneration and payment terms
Section 9	Term and termination
Section 10	Final provisions

Agreement template – 4 Basic principles



Template is intended to support the trial contracting process.

Template is intended to address as many cases as possible;
User should to read it thoroughly and adapt it to individual needs.



User is free to introduce any kind of modification to the wording of this document.

Any appendices must be developed by User.



Agreement Templates in PCTN

Homepage > Files > Documents

Documents

FILTERS

Sort by...

Document kind

Document type(pdf/template)

Template or template converted to pdf

Name

Name that must appear in the title
(capitalization does not matter)

Description

Text that must appear in the document description
(capitalization does not matter)

Search

FILES TO DOWNLOAD



Wzór umowy o przeprowadzenie badania klinicznego - wersja trójstronna (PL)



UMOWA O PRZEPROWADZENIE BADANIA KLINICZNEGO trójstronna PL



Wzór umowy o przeprowadzenie badania klinicznego - wersja czterostronna (ENG)



UMOWA O PRZEPROWADZENIE BADANIA KLINICZNEGO czterostronna akademička EN



Wzór umowy o przeprowadzenie badania klinicznego - wersja trójstronna (ENG)



UMOWA O PRZEPROWADZENIE BADANIA KLINICZNEGO trójstronna EN



Wzór umowy o przeprowadzenie badania klinicznego - wersja czterostronna (PL)



UMOWA O PRZEPROWADZENIE BADANIA KLINICZNEGO czterostronna akademička PL

WZORY

PLIKI DO POBRANIA

Wzór umowy **trójstronnej** na realizację badania klinicznego

Umowa_PL
Umowa_ENG

Wzór umowy **czterostronnej** na realizację badania klinicznego

Umowa_PL
Umowa_ENG

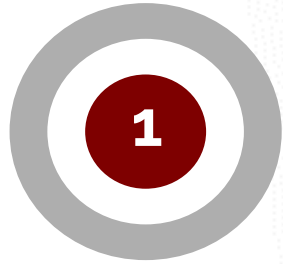


Scan to visit
a page with files!

Contract negotiation time (days) – Mean

N.	CALL.	CLINICAL RESEARCH SUPPORT CENTER	TIME in DAYS (MEAN)
1.	I E D I T I O N	Medical University 1	190
2.		Medical University 2	101
3.		Medical University 3	97
4.		Medical University 4	53
5.		Medical University 5	181
M		University MEAN	124,4
6.		Medical Institute 1	59
7.		Medical Institute 2	36
8.		Medical Institute 3	73
9.		Medical Institute 4	29
10.	Medical Institute 5	42	
M	Institute MEAN	47,8	
Total MEAN			86.8

Agreement template – Lessons learned



If the model is to apply nationwide, it must be introduced by an Act, a regulation or another relevant legal document. Otherwise, it serves as a supporting measure or a collection of legal provisions.

Stakeholders in the clinical trials market who have already established standard operating procedures are generally reluctant to introduce further regulations. New entrants to the market, however, are keen to see such measures implemented.



Simply introducing the template without systemic support (training, implementation support, a transition period) will not, in the long term, lead to a faster contracting process.

It may be appropriate to stipulate only those provisions required by law, such as those relating to insurance and data protection, whilst leaving the remaining provisions to be agreed between the parties



Clinical Trial Agreements The Dutch Model Understanding agreement structures in clinical research 16 April 2026



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The Dutch Clinical Research Landscape

Clinical research collaboration Academic and peripheral hospitals collaborate with research networks, industry, and patient organisations.

Contractual bottlenecks Variations in contract processes and legal interpretations caused long negotiations and delays.

Harmonisation and predictability The Netherlands promoted CTA harmonisation to reduce timelines and increase predictability.

National CTA Model The Dutch CTA model resulted in widely supported contract templates for clinical research.

Ongoing alignment CTA models through DCRF Working Groups



From Fragmentation to National Harmonisation

2007 Initiative for alignment by industry and Central Committee on Research Involving Human Subjects (CCMO)

In 2007 initiative was launched to promote contractual alignment in clinical research by involving hospitals, researchers, patients, companies, and other parties directly engaged in the process of clinical drug and medical device research

2010-2013 National CTA-template

Between 2010 and 2013, facilitated by the Ministry of Health, Welfare and Sports and the Dutch Clinical Research Foundation (DCRF) the first national CTA template was developed, based on an US model provided by Industry and adapted for the Netherlands

2017-2019 Expansion

Process expanded to include CRO's, networks and academic centers, resulting in a harmonised national CTA template

2025

Updated CTA template aligned with Clinical Trials Regulation practice.

<https://dcrfonline.nl/werkgroepen/clinical-trial-agreement/>



DCRF as National Contract Alignment Platform

Central consultation platform DCRF serves as a permanent platform for the joint discussion of contractual issues and best practices.

Broad stakeholder involvement Input from various organisations such as the Central Committee on Research Involving Human Subjects (**CCMO**), the Dutch Association of Medical Research Ethics Committees (**NVMEETC**), Dutch Patients Federation and the national network of university medical centers (**UMCNL**) and hospitals strengthens dialogue and decision-making.

Improved research climate Focus on shortening start-up times, developing templates, and strengthening governance and compliance.

Adaptive and forward-looking model A continuous mechanism for updating, sharing experiences, and addressing new legislation and regulations.



Overview Dutch templates

Wide range of CTA templates

The Netherlands has various CTA templates for industry- and investigator-initiated clinical research, including inter-institutional collaboration.

Additional agreements

Joint Registry, CDA, MTA, and DSA agreements have also been developed to meet diverse research needs.

Consensus-based development

The templates were developed through intensive consultation among stakeholders and aligned with industry standards.

Future medical device templates

Work is underway on a separate CTA template for clinical research involving medical devices, despite sector-specific challenges.



Benefits of National Harmonisation

Uniformity and predictability

National templates provide clear contractual principles, significantly reducing negotiation time.



Higher quality and compliance

Standardization leads to less errors and better compliance with CTR, national law and CCMO guidelines in clinical studies.



Flexibility for foreign sponsors

Use of national templates is not mandatory, allowing flexibility and study specific terms for foreign sponsors with their own contracts.

Central platform and collaboration

The DCRF platform resolves bottlenecks and updates templates, facilitating faster contract cycles.



Challenges within the Dutch System

Local variations and risk perceptions

Institution-specific differences and local governance affect consistency within the Dutch system.

Deviating contractual arrangements

Research networks sometimes require alternative contracts, which can create complications.

National versus international templates

Differences between national and international templates may lead to discussions and delays.

Impact on foreign sponsors

Mandatory use of national templates could discourage foreign academic sponsors from conducting studies in the Netherlands.





Relevance of the Dutch model

The Dutch model serves as an example in EU discussions on contract harmonization, with a focus on study start-up times.



Risk of fragmentation

Mandatory national templates without European alignment could lead to fragmentation within the EU market.



EU-wide collaboration

There is a need for European cooperation through CTA templates or common guidelines to reduce discrepancies.

What the Netherlands Demonstrates

Collaboration and consensus

The Netherlands demonstrates that long-term collaboration and consensus-building are essential factors in accelerating clinical research.

National templates and platform

A broad range of national templates and an active platform support the structured discussion of contractual issues.

Example within Europe

The Dutch approach contributes to predictability, quality, and efficiency, serving as a valuable European example.

Building block for European alignment

National harmonization provides a starting point for further European alignment of clinical research contracts.



Recommendations for the EU Landscape

Develop **EU-harmonised CTA** templates for non-commercial and commercial studies

Second best: introduce **EU-level guidance** for resolving differences between national laws (including GDPR!)

Stimulate cross-border collaboration to reduce negotiation bottlenecks

Strengthen **feedback** loops between regulators, sites, and sponsors

Have EU regulators, together with all relevant stakeholders, resolve the current fragmentation by implementing a single CTR-linked EU CTA template and, failing that, establish practical guidance that parties can rely on during negotiations.





ERA4HEALTH, WP 16 : Clinical site agreement
(EU model template)

Mihaela Matei- Legal manager and DPO
ECRIN

ERA4HEALTH, WP 16: What do we want to achieve?

- Develop an EU model template for clinical site agreements (CSA) related to clinical trials on medicines

- **EU model** : accepted and endorsed by a large number of partners across the EU

- **Context of use** :
 - Any multinational clinical trial on medicines (EU based Sponsor(s) or involving EU organisations/clinical trial participants
 - Not specific to a type of funding

□ Steps and methods:

- 1. Identify the legal aspects and constraints that must be considered prior to developing an EU template for clinical site agreements**
 - through a Survey and Legal task force

- 2. Preparation of the 1st draft of the template : content, structure**

- 3. Review and validation steps**
 - Cross countries review of the first template (completed)
 - National/EU level Validation (in progress)
 - Implementation across the EU

□ Countries : 15

1. France
2. Germany
3. The Netherlands
4. Czech Republic
5. Poland
6. Norway
7. Italy
8. Spain
9. Danmark
10. Ireland
11. Hungary
12. Slovakia
13. Belgium
14. Greece
15. Switzerland

ERA4Health - Task 16.4

Task 16.4 . Harmonization of the Clinical site agreement contract

SURVEY (completed in December 2024)

- Overview of the existing documents at national and European levels
- Issues encountered by sponsors and other relevant actors
- Non-negotiable specificities

LEGAL TASK FORCE

- Consensus on the template
- Implementation
- Endorsement

For reasons of privacy, the names of the contributors to the development of the CSA are not listed on the slides, but they will be mentioned in the relevant publication subject to their consent.

Survey

Main questions and findings

□ Survey questions :

- **Check if such models exist and who developed them**
 - What models of Clinical site agreement templates exist in your country?
 - Who developed them? (Sponsor, Clinical sites, central administration, law firm, etc.)
- **Check how these models work in practice and if they are fit for multinational projects**
- **Check if there are national requirements that cannot be avoided**
 - Please specify in more detail the legal issues you have encountered.
 - Which aspects/sections of the clinical site agreement used in your country cannot be subject to negotiation
- **Who can support us with our task**
 - Are you aware of any networks or associations of academic Sponsors in your country that could support our task?

Survey findings

COUNTRY FACTS

Existing models of CSA in your country

- **National template:**

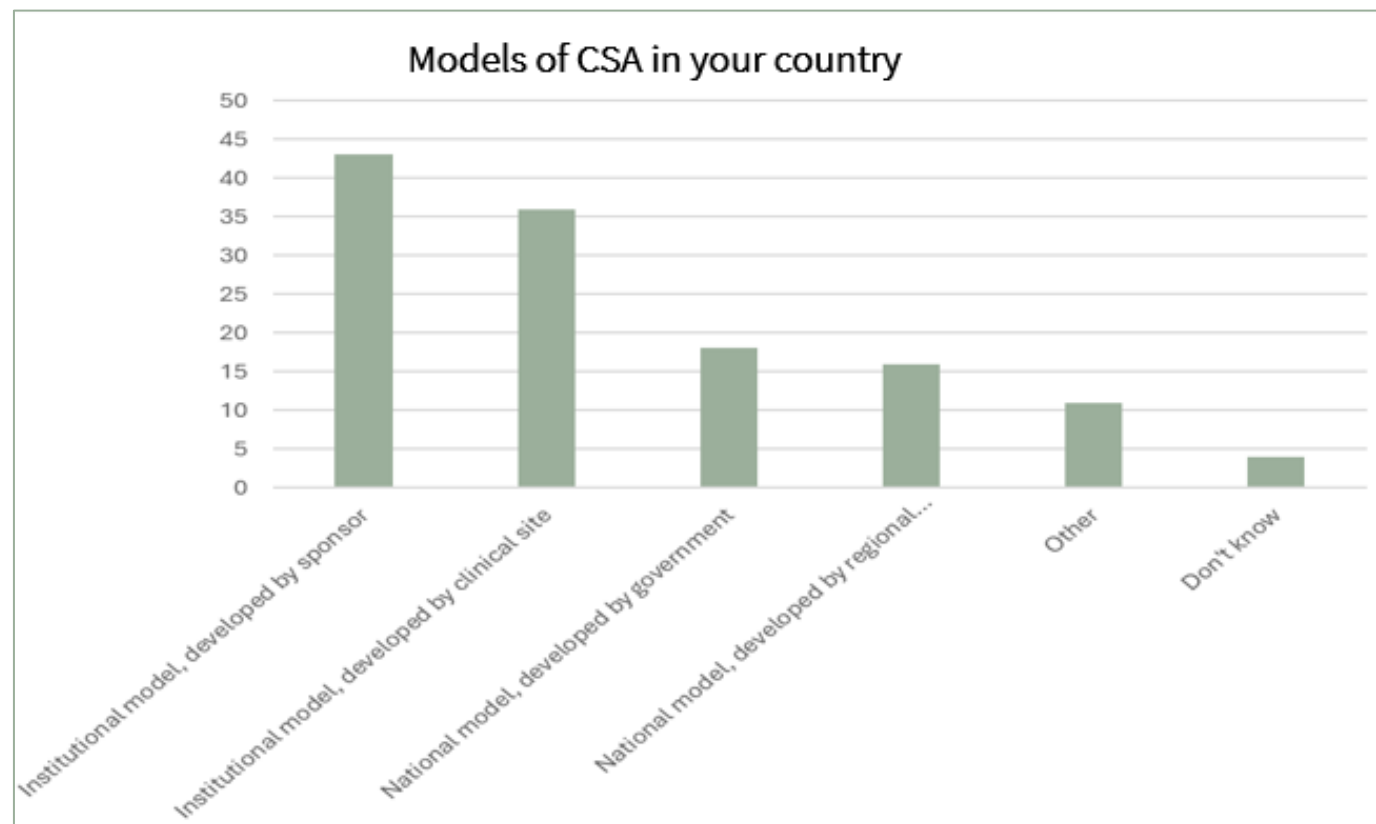
France, Czech Republic,

Switzerland, Greece

- **Regional Template:**

Spain, Italy, etc

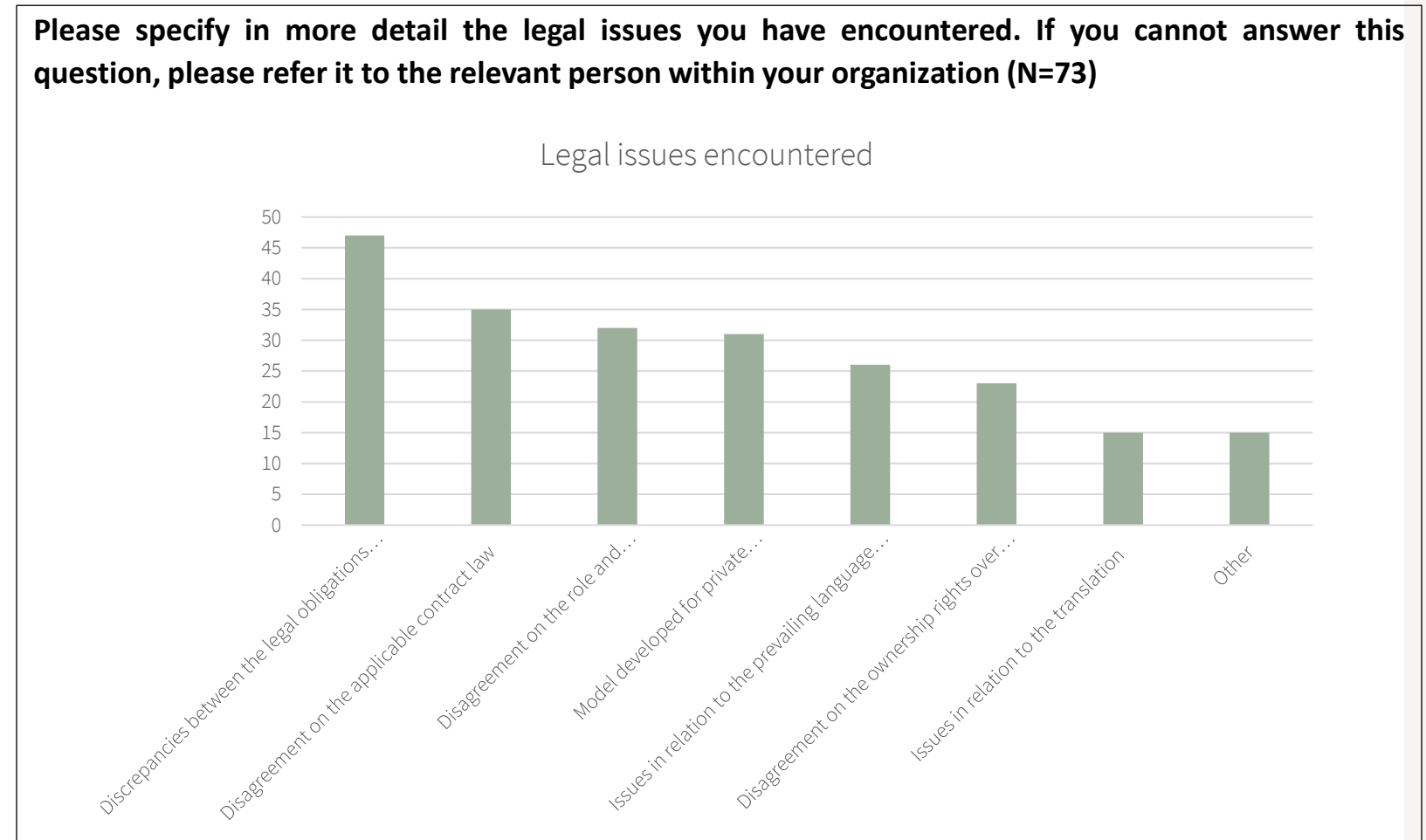
- **Not adapted specifically for cross countries trials**



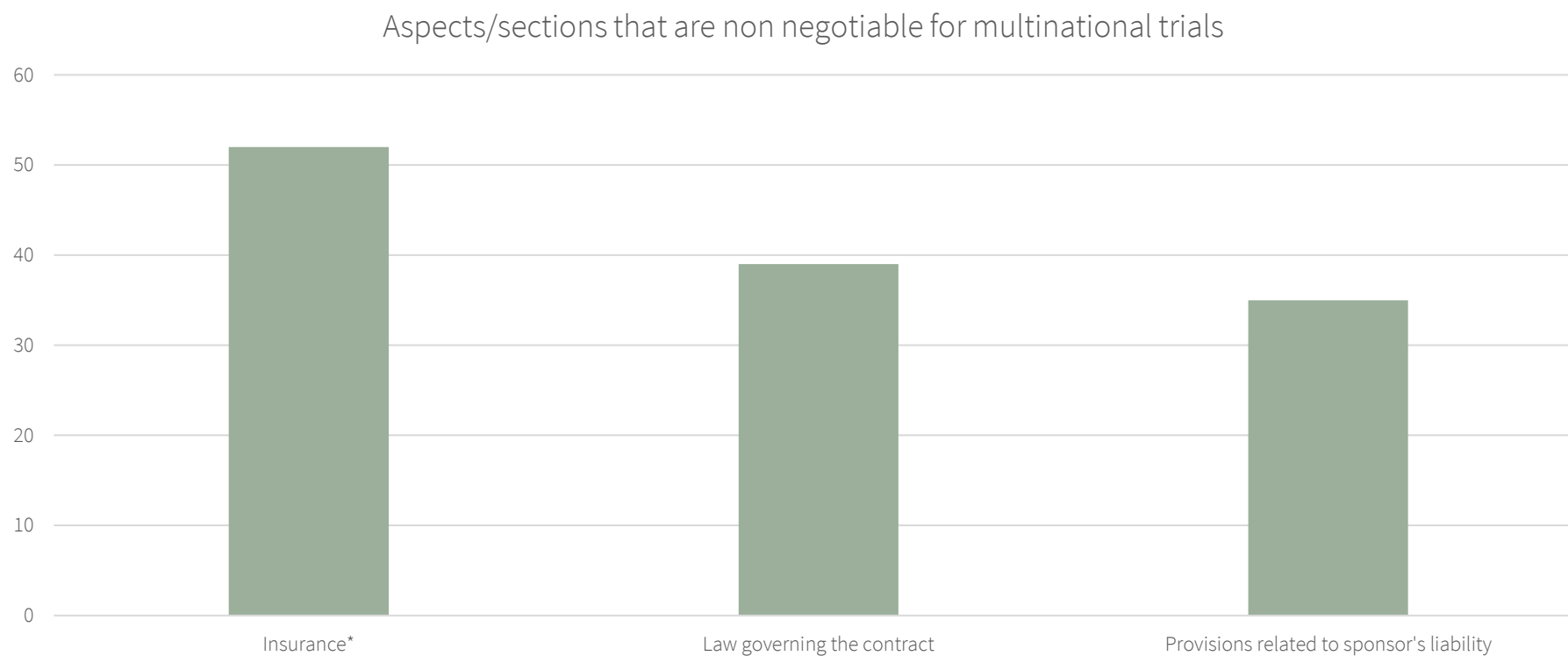
LEGAL BOTTLENECKS

Please specify in more detail the legal issues you have encountered. If you cannot answer this question, please refer it to the relevant person within your organization (N=73)

Main bottlenecks when using these templates in the context of EU/Multinational projects



Which aspects/Sections of the CSA used in your country cannot be subject to negotiation in the context of multinational trials? (N=70)



LEGAL TASK FORCE

**□ Questions
further explored
through the legal
task force**

- 1. Can we generate a “generic” template escaping the national specificities (references to national laws, codes, etc) similarly to the CA DESCAs?**
- 2. Are there any national specificities that cannot be avoided and are not subject to negotiation?**
- 3. Possible structure and content of an EU template**
- 4. How can we ensure cross country reviews and validation of the templates?**
- 5. How can we achieve implementation? Through a specific EU funded project? Are Sponsors willing to participate in a pilot study?**

□ Structure and content of the CSA

■ CSA template

I. The core terms of the agreement : standard clauses/ not controversial in contract law

- Description of Responsibilities (e.g. Description of action)
- Status of the Parties (e.g. Under EU GA)
- Financial rules (EU funded projects, other funding sources)
- Non-disclosure of information, etc

II. Appendix/ Specific clauses : National legal specificities

- Include references to national laws into the agreement as attachments
- Any references to national pieces of legislation should be translated into clear duties
- The appendices should be validated at national level beforehand to avoid negotiation
- Any additional agreements required by national laws and regulations should be attached to the main agreement (data processing agreement; financial agreement)
- Only some aspects can be subject to negotiation (e.g. financial agreement)

Updates and Next steps

TASKS COMPLETED

- CSA Annotated version (it includes instructions and options)
- Deliverable is provisionally published in ERA4Health website and CORDIS website
- Presented at the Clinical Trials Coordination Group (CTCG HMA) (few comments)
- Updated annotated version on-line (Zenodo)

NEXT STEPS

- **Pilot studies : Platform trial (22 countries)** : in progress
- Other pilot studies are being considered
- Transform the annotated version into a simplified form : internal discussions
- Publication : in progress

Thank you !

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Cross-Industry Site and Investigator Contracting Survey

Siard Houtzager, PhD.

Associate Director Regulatory Policy EMEA, Global Regulatory Affairs, J&J



ACT EU Webinar on contractual
agreements
16 April 2026



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Site and Contracting Process Survey

EFPIA and EUCROF conducted a cross-industry survey in November 2025 to understand the challenges and opportunities of the site and investigator contracting process in European Member States.



- * What are the challenges in the site contracting process?
- * What can we learn from different Member State processes?
- * Proposals to improve the contracting process.

BACKGROUND:

New targets for clinical trials in Europe

In 5 years:

- * An additional 500 multinational clinical trials authorized (i.e. an estimated 100 per year)
- * Two thirds (66%) of clinical trials should begin recruiting patients within 200 calendar days or less from the date of application submission. (50% of clinical trials today).
- * Improved Regulatory / Ethics Assessment process – currently in the Bio Tech Act proposals
- * Improved Site Contracting process is needed to make Europe an attractive place to run clinical trials.

EFPIA / EUCROF

Survey on Site and Investigator contracting process.



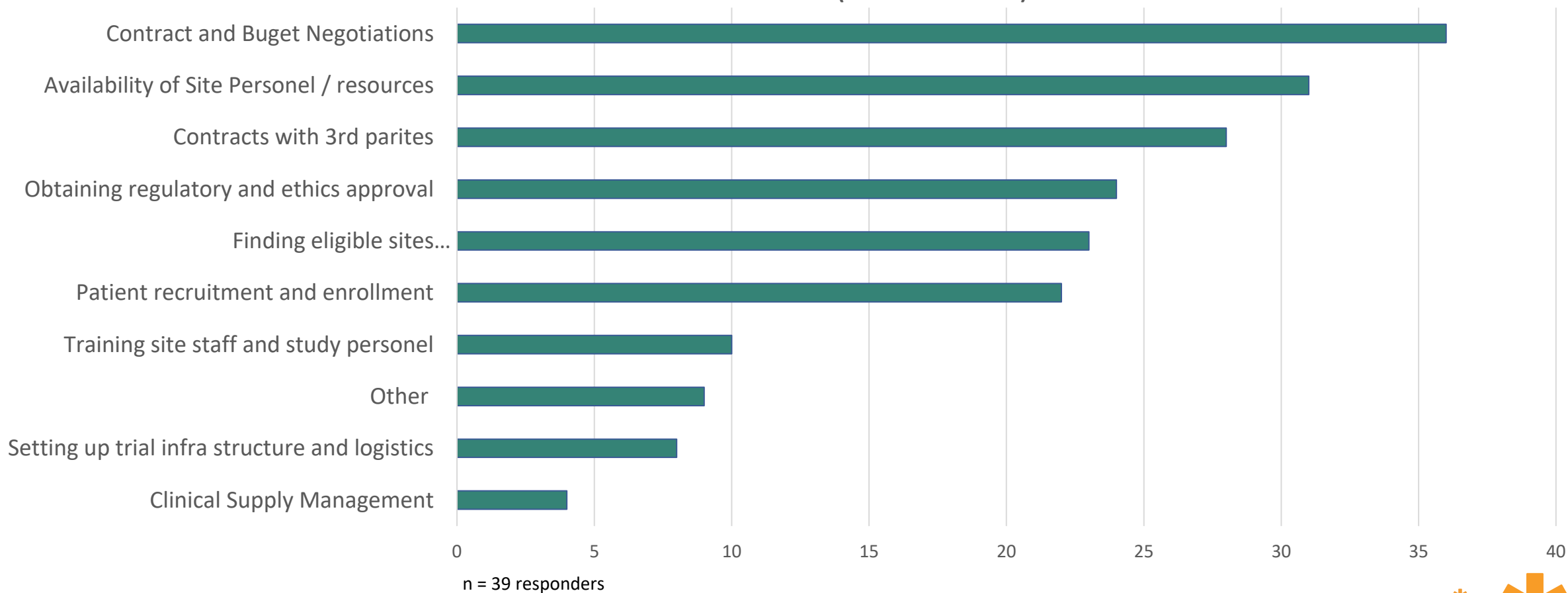
The objective of this survey was to gather industry feedback on the current site contract process and identify potential improvements.

- Survey conducted in November 2025
- 40 Company responses
- 50% EFPIA members, 40% CROs, 10% SME

Challenges in Study Start up

#1: CONTRACTING!

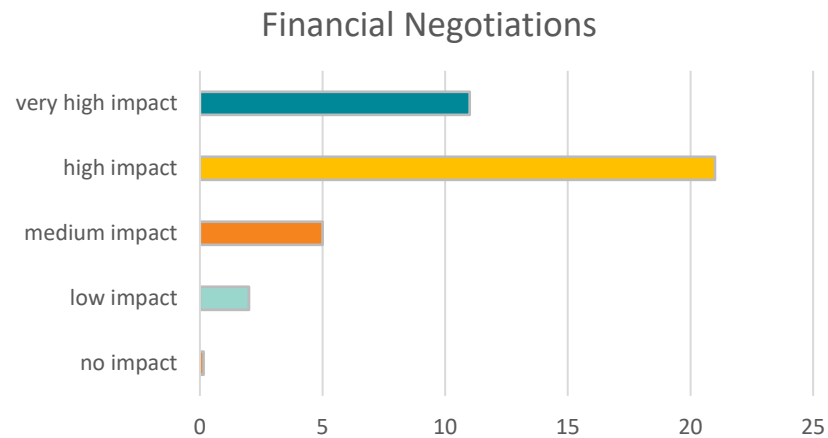
Q1: Which Study Start-up Steps are most challenging / time consuming to accomplish (select 5 out of 10)



HIGH IMPACT HURDLES:

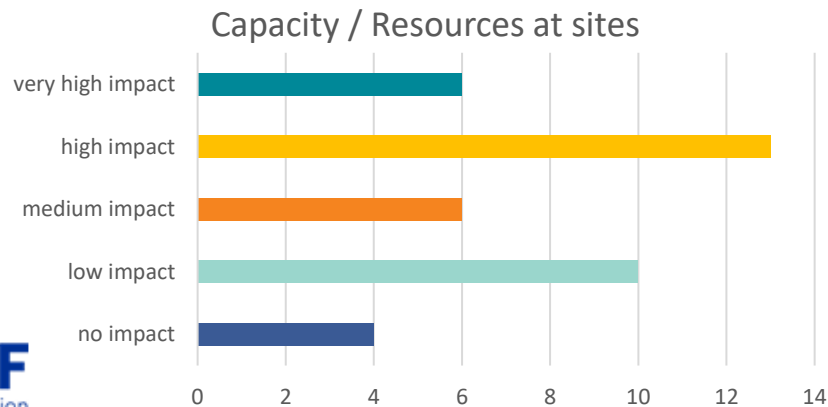
Financial negotiations and the capacity at the sites to review the contracts

Q2: Rate the impact of the following challenges which occur most frequent during the contracting, causing delay in finalizing the site contracts.



“Contract finalization is prolonged due to budget negotiations.”

“A standardized prize catalogue, based on the specific tasks in handling a trial could be helpful to provide fitting budgets.”



“Lack of resources of dedicated expertise for clinical trials contracts, especially around data privacy.”

“Sponsors need to spend a lot of time following up with the sites to finalize the contracts.”

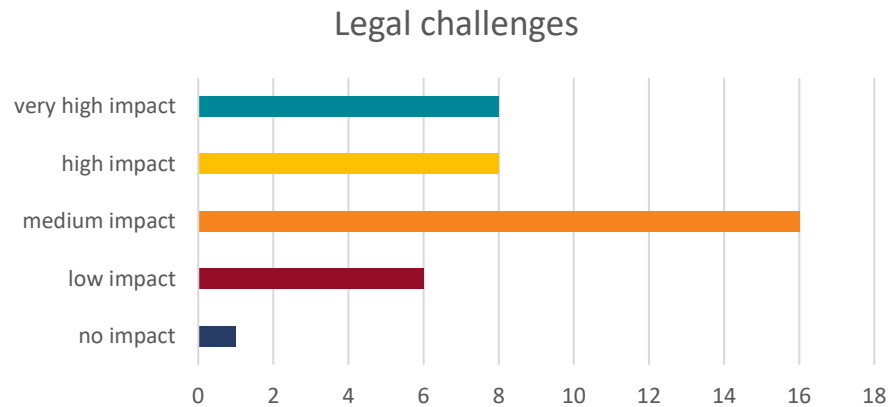
n = 39 responders



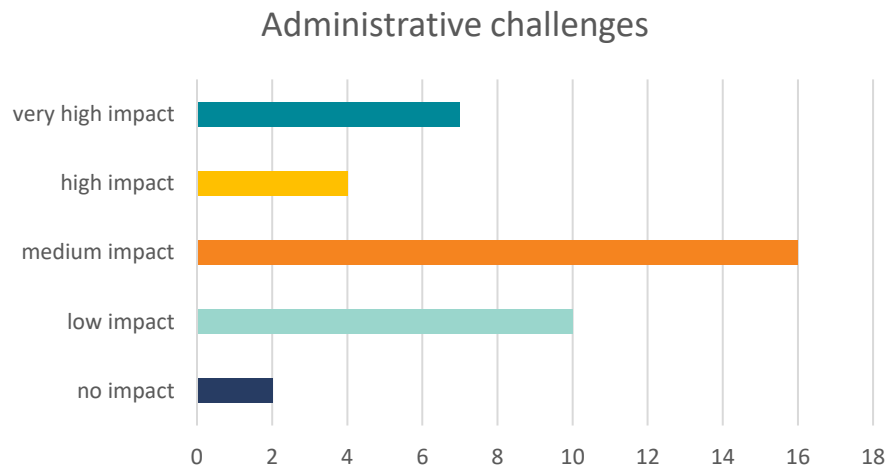
MEDIUM IMPACT HURDLES:

Legal text and Administrative challenges

Q2 (cont) Rate the impact of the following challenges which occur most frequent during the contracting, causing delay in finalizing the site contracts.



“High level of complexity compared to other Country or Regions around legal terms for data privacy requirements.”



“Each site has a specific administrative process for contract negotiation and authorization.”

“Multiple layers of approval slows down the process”

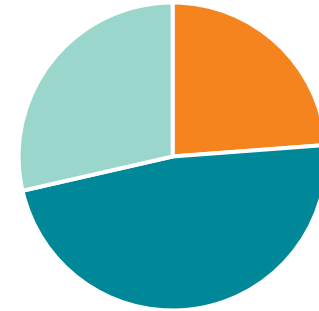
n = 39 responders

Sponsor's Experience in Different Member States

Substantial differences between Member States and more work needs to be done to achieve harmonisation and predictable, shorter timelines.

Timelines:

In 75 % of the Member States, the contracting process takes longer than 90 days



■ < 3 months ■ 3-6 months ■ > 6 months
n=32 responders, sample of 21 MS.

Identified hurdles in the process:

- * Long review process
- * Multiple layers of approvals
- * Limited flexibility in negotiations

Smooth contracting process has:

- * Standardized contract templates
- * Reasonable timelines
- * Efficient and fast legal review process

POTENTIAL SOLUTIONS:

Templates, e-Signature and a Smooth Process

Q6: Based on your experience please rate (on a on a scale of 1 to 5 (1 = unlikely to be helpful, 5 = very helpful) the potential preferable solution to improve the contract negotiation process?

A mandatory country specific template?

4.18 

Harmonized rules for e-signature?

3.95 

Agreed process to facilitate contract negotiations?

3,75 

Unified budgeting tools?

3,75 

Central negotiation in a MS?

3.5 

A mandatory European template?

3.50 

Additional (regulatory) guidance?

2,8 

n = 39 responders

Key Messages from the Survey

Contract and Budget negotiations is listed as #1 challenge in study start-up

Long contracting process:
75% of MS the process will take longer than 3months.
In some MS longer than a half year!



Streamlined, harmonized process for the contract review and negotiations **in parallel** with the regulatory / ethical review of the CTA*

*CTA: Clinical Trial Application

KEY FOR SUCCESS:

Member State (“central”) negotiations with a **Member State specific contract template** with agreed legal text and agreed **“fair market value” price catalogue** which will be made mandatory for use.

Ensure harmonization of rules on the use of **e-signature** across the EU.



European Federation of Pharmaceutical
Industries and Associations



Thank you



Questions?



Thank you

