White Paper

Optimizing Clinical Trial Startup Times: Competing on Contracting Efficiency

DR. KAI HÄNEL, Associate Director, Global Site Activation
MEIKE MADELUNG, Engagement Manager, EMEA Thought Leadership
DR. MARC ROHDE, Director, Strategic Site Solutions

Table of contents

Preface: Advancing Germany as a trial location — together!

Germany has long been well positioned and internationally competitive as a location for conducting clinical trials. This was reflected in its position as number one in Europe and number two worldwide, behind the USA, in terms of the number of clinical trials conducted. Unfortunately, this is no longer the case. Some indicators show that several countries, including in Europe, are overtaking Germany as a preferred location for clinical trials. It is in the common interest of all those involved in clinical research in Germany — patients, trial centers, CROs and clinical trial sponsors — to regain a leading position.

Representatives of various stakeholders in the field of clinical trials have joined forces to pursue these common goals: The Association of Medical Faculties (MFT), the Association of German University Hospitals (VUD), the Coordination Centers for Clinical Trials (KKS Network), the Federal Association of Medical Contract Research Organizations (BVMA), the Federal Association of the Pharmaceutical Industry (BPI) and the Association of Research-Based Pharmaceutical Companies (vfa). Together, they have published joint model contract clauses that consider the different interests of all parties involved.

With this joint, partnership-based approach, the parties involved aim to speed up the contract negotiations and start-up process for conducting clinical trials, thereby making Germany more attractive as a research location. As the study by IQVIA nicely shows, at the sites acceptance for using model contract clauses grows substantially. However, too often the first draft contracts provided by industrial sponsors do not yet refer to these model clauses due to the global specifications within the companies. To address this issue, nationally binding standard contracts or contract clauses should be the next step forward. We are therefore also pleased that German politicians have taken up this approach and have paved the way for binding standard contractual clauses for clinical trials in Germany.

However, we still have many topics to address jointly. Currently, the associations are collaborating to further develop the model contract clauses and their contracting party options, prepare an easily usable full model contract template based on the upcoming standard contract clauses, and review options to further harmonize the budgeting approach in Germany.

Improving competitive conditions is a common interest, which is why we are pleased to emphasize this joint approach once again with this preface. At the same time, however, we would like to point out that we have already taken and will continue to take further urgent initiatives to make Germany a more attractive place for sponsors to initiate and conduct clinical trials.

PD Dr. med. Sebastian Klammt, KKS-Netzwerk e.V., Netzwerk der Koordinierungszentren für Klinische Studien
Dr. Frank Wissing, Deutsche Hochschulmedizin e.V.
Dr. Thorsten Ruppert, vfa. Die forschenden Pharma-Unternehmen
Prof. Dr. Jens Peters, Bundesverband der Pharmazeutischen Industrie e.V. (BPI)
Martin Krauss, Bundesverband Medizinischer Auftragsinstitute (BVMA)

Executive summary

Across the globe, countries are competing to attract international clinical trials. In this competition, contracting cycle times are increasingly recognized as key contributor to a country's attractiveness as clinical trial location. This is particularly true for European countries where the regulatory landscape was harmonized when the Clinical Trials Regulation (CTR EU 536/2014) came into full effect, leaving start up times as one of the few differentiators. To address contracting cycle times, more and more countries are harmonizing clinical trial agreements and in part also budgeting and costing.

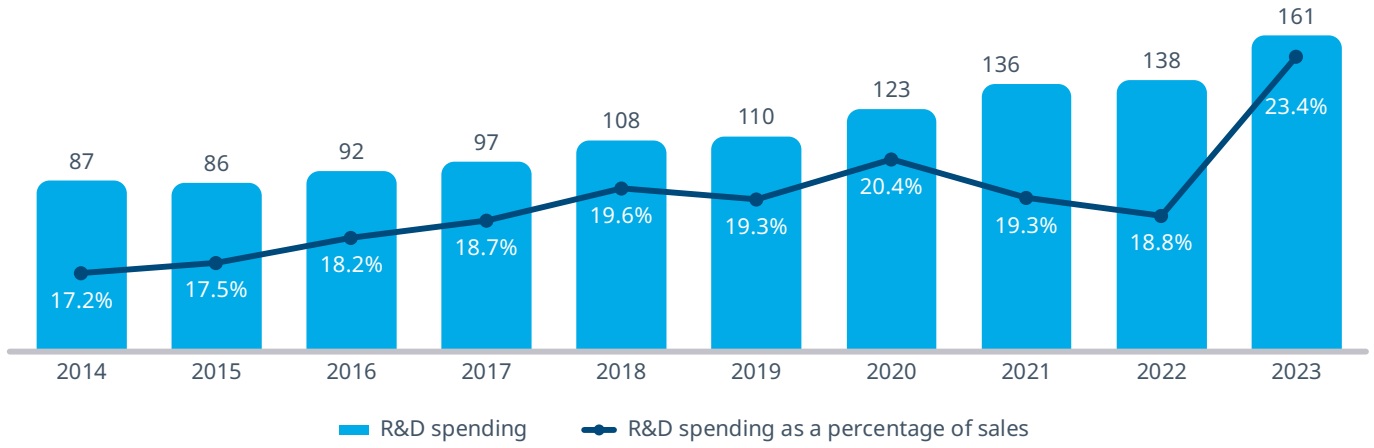
This white paper is studying the introduction of mandatory and optional contract templates across key European trial locations. As IQVIA data shows, the introduction of contract templates may result in significantly decreased cycle times. This applies, for example, to France which introduced a mandatory national contract template as well as a harmonized budgeting process in 2014 and saw a reduction of cycle times by over 40% in the following year. On the other hand, the introduction of national contract templates is not sufficient, since further factors such as the freedom to deviate from the template, negotiation of functional department agreements, budget negotiation, Covid-19, and other mega trends may influence national cycle times. Further, we find that among countries with optional contract templates, clinical trial agreements based on the national template tend to be negotiated faster than those agreements not adopting the national template.

Finally, we take a closer look at Germany as clinical trial location which is currently in the process of introducing national standard contract clauses which are optional so far but are planned to be made mandatory through a statutory order by the Federal Government. In order to drive adoption, IQVIA Germany conducted a strategic site survey with 14 of its key research sites between October 2023 and January 2024. The results show that the majority of sites support adopting the standard contract clauses with no or minor adaptations. Sponsors looking to decrease contracting cycle times are well advised to broadly adopt the standard contract clauses, while German policy makers aiming to drive national study location competitiveness should learn from international experience and make standard contract clauses compulsory.

Country trends in clinical trials

Pharmaceutical research is a significant economic factor, with large pharma spending 161bn US$ on R&D in 2023.[1] Countries around the globe vie to attract clinical trials to boost their position as research leaders, to attract pharma as a driver of economic growth, and to ensure patients get early access to innovative therapies.

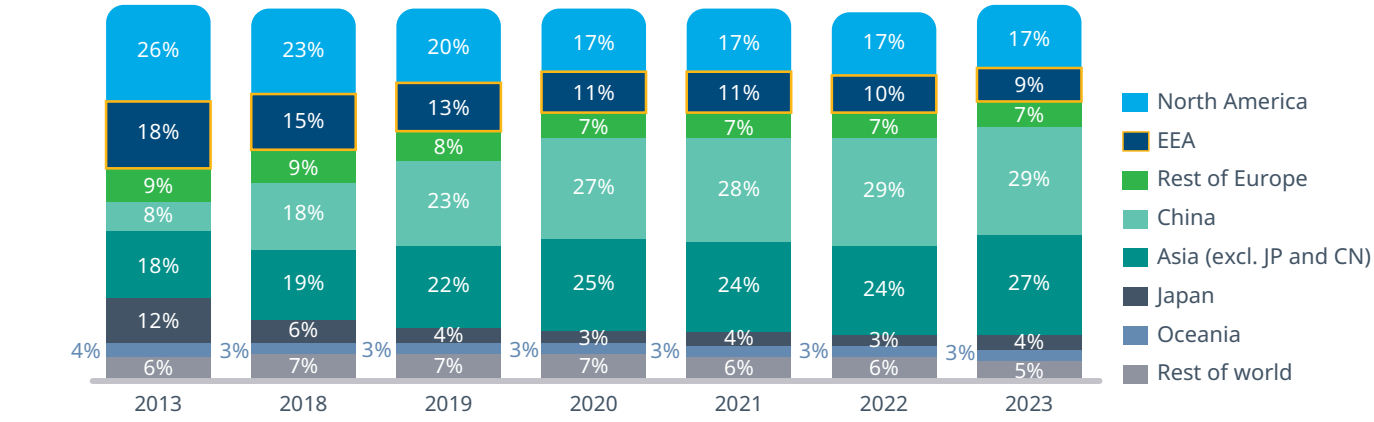
Figure 1: Increase in large pharma R&D spending



Source: Global Trends in R&D 2024[1]

Pharma companies select trial locations based on a complex set of criteria including commercial return from the country, trial performance, clinical expertise network, regulatory framework, disease prevalence and operational attractiveness, i.e. factors like start-up times, bureaucracy, and cost.[2] In multi-country trials, patient recruitment often is competitive across the countries involved so long start-up times may mean countries and research sites lose out on the benefits associated with trial participation.

Figure 2: Development of clinical trial starts in global comparison (all sponsor types)

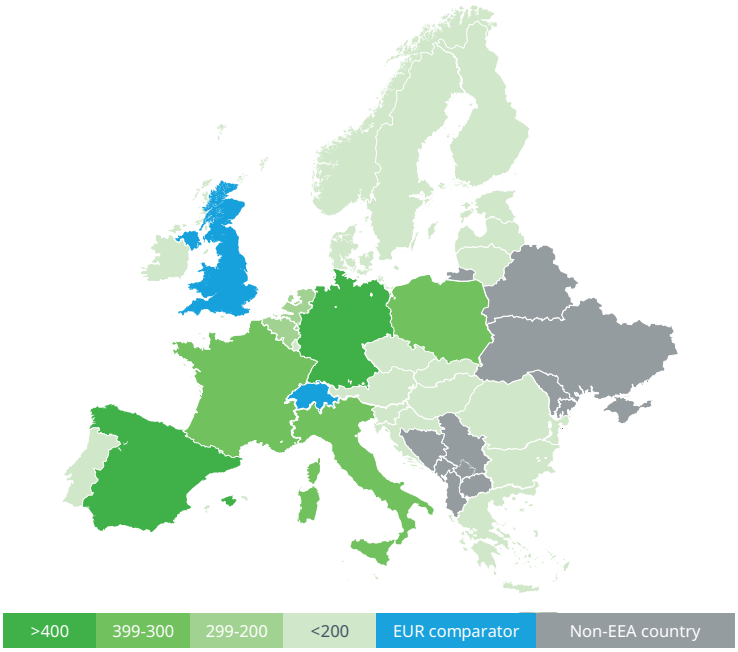


Trial starts in EEA:	2,424	2,662	2,622	2,737	2,983	2,449	1,978

Source: Assessing the clinical trial ecosystem in Europe[3]

However, the global trial landscape is evolving. In the last ten years, Europe has lost ground in absolute and relative terms against the US and Asia. While the total number of trials has increased, the number of trial starts in the European Economic Area (EEA) was lower in 2023 than it was in 2013 and the share of trial starts in Europe has dropped from 27 to 16% (EEA and rest of Europe combined). While much late-stage trial activity in China is focused on local and regional approvals, the US' share increase could be driven by trial start-up times.[3]

Figure 3: Development of commercial clinical trial starts in European countries



	2018	2023	CAGR
	491	**485**	-0.2%
	618	**417**	-7.6%
	439	**389**	-2.4%
	378	**343**	-1.9%
	332	**300**	-2.0%
	305	**218**	-6.5%
	282	**210**	-5.7%
	205	**161**	-4.7%
	199	**147**	-5.9%
	156	**118**	-5.4%
	573	**439**	-5.0%
	120	**107**	-2.3%
	1,253	**920**	-6.0%

Source: Assessing the clinical trial ecosystem in Europe[3]

Within Europe, country performance is also shifting: Spain has pulled ahead of Germany and is now the country with the highest number of commercial trial starts. Some smaller countries, notably Denmark and Belgium, are also performing well in terms of number of trials per capita, whereas the larger countries are lagging behind by this measure. However, all countries had fewer trial starts in 2023 than in 2018, and trial starts in the EU overall were down 27% in the same time period. The relatively lower attractiveness of Germany as a trial location has been attributed to long negotiation timelines as well as slower patient recruitment due to stringent data protection laws.

Table 1: Commercial clinical trials in EEA countries per capita (100,000) in 2023

	COUNTRY	#TRIALS PER CAPITA
1	Denmark	2.00
2	Belgium	1.84
3	Bulgaria	1.72
4	Estonia	1.71
5	Hungary	1.68
6	Latvia	1.58
7	Czech Republic	1.35
8	Slovakia	1.28
9	Austria	1.22
10	Netherlands	1.17
11	Lithuania	1.14
12	Norway	1.04
13	Greece	1.02
14	Spain	1.00
15	Finland	0.96

	COUNTRY	#TRIALS PER CAPITA
16	Sweden	0.84
17	Portugal	0.82
18	Poland	0.82
19	Croatia	0.79
20	Slovenia	0.67
21	Ireland	0.60
22	Italy	0.58
23	France	0.57
24	Germany	0.49
25	Romania	0.42
26	Luxembourg	0.29
27	Cyprus	0.08
UK		0.64
Switzerland		1.22
US		0.51

Note: Limited data coverage on Lichtenstein, Malta and Iceland; Phase 1-4 commercial trials considered. Medical device trials and terminated/suspended trials were excluded; Source: Clinical Trial Repository (Access Date: April 30th 2024)/IQVIA expertise.

Political environment

The significance of pharmaceutical R&D for overall economic competitiveness has been recognized both at the EU and the national level. The European Commission's recent report on the future of European competitiveness[4] devotes an entire chapter to this topic and includes multiple suggestions for improving the EU's standing as a trial location, including streamlining the set-up and management of multi-country trials. Introducing and incentivizing the adoption of model templates is one of the proposed measures.

In Germany, the government adopted the National Pharmaceutical Strategy in December 2023 which is intended to strengthen Germany's attractiveness as research and production location for the pharmaceutical industry. The recently passed Medicine Research Act with the stated goal of improving the framework for development, approval, and production of pharmaceuticals and medical devices is a cornerstone of this strategy, along with the Health Data Utilization Act and the Digitalization Act. Proposed measures include the use of standardized contract clauses to shorten negotiating times and thereby trial startup times. Specifically, the federal government is authorized to establish mandatory contract clauses for conducting clinical trials by statutory order and with consent of the Federal Council. Industry and scientific associations and organizations are to be involved in developing these contract clauses.

Spain's rise to top trial performer is no accident either — from 2016 onward, the country has taken targeted measures to attract clinical trials with a focus on streamlining and harmonizing trial approval and easing the bureaucratic burden. These measures include requiring a single approval submission per trial, a single ethic commission vote even for multi-centre trials, pricing catalogues, and model contract clauses.

Initiatives to increase attractiveness as a trial location are not limited to EU members. In 2023, the Lord O'Shaughnessy review into commercial trials in the UK which had been commissioned by the UK government

issued a range of recommendations to improve the UK's attractiveness as a trial location. The government responded to these recommendations by, among other measures, reaffirming its commitment to a mandatory national approach to costing and contracting[5] involving national commercial trials contracting documents. An already implemented interactive costing tool ensures costing transparency and shortens negotiation times.

The impact of contracting templates and harmonized budgeting on cycle times across Europe

While the European clinical trial market has seen the development of contract templates and harmonized budgeting approaches as early as 2003, it has been characterized by a significant increase of further national contract templates over the last five years with little harmonization across countries (Magnin et al., 2021).[6] In order to assess the impact of the introduction of national contract templates, IQVIA has performed an analysis of start-up cycle times in multiple European countries following the introduction of such templates (see ***Table 2 — Start-up cycle times and contracting templates across Europe***). This analysis is based on > 15.000 contracts being negotiated by IQVIA RDS from 2005 onwards across the UK, Ireland, France, Italy, Spain, Belgium, the Netherlands, and Denmark.

Table 2: Start-up cycle times and contracting templates across Europe

COUNTRY	YEAR CTA TEMPLATE IMPLEMENTED	MANDATORY CTA TEMPLATE?	CENTRALIZED COSTING APPROACH?	CYCLE TIME PERFORMANCE FOLLOWING INTRO OF CTA TEMPLATE
The UK	2003	✓ (National, mandatory for NHS sites)	✓ (Costing template; factor method for cost rates)	n.n.
Ireland	2022	✓ (National)	✓ (see UK)	(↗) (Low sample size)
France	2014	✓ (National)	✓ (Costing template; national coordinating site)	↗ (>40% significantly reduced cycle time)
Italy	2019	✓ (NATIONAL)	No (Harmonized cost categories only)	(↗) (~16% non-significantly reduced cycle time)
Spain	N/A (Regional/local)	✓ (Regional/Local)	No (Single trial budget or site-based budgets)	N/A (Regional/local)
Belgium	2019	Optional	No	(→) (Positive differentiation when template applied)
The Netherlands	n.n.	Optional	No	(→) (Positive differentiation when template applied)
Denmark	2021	Optional	No	n.n. (Overlap with Covid period)
Germany	2025[1]	✓[1] (National standard contract clauses, regulatory decree expected)	No (Harmonized cost categories only)	N/A (Too new to evaluate)

Source: IQVIA analyses (Strategic site solutions, local country site activation)

[1]Expected enforcement of mandatory standard contract clauses in summer 2025 — following prior optional model contract clauses.

In 2003, the UK was not only an early adopter of a national model CTA (clinical trial agreement), but it has also established one of the most far-reaching standardizations with a 'de facto' mandatory CTA template with multiple standardized appendices and a centralized budgeting approach. Next to the two-party model CTA template between institution and sponsor, it has also developed a CRO-specific model CTA which addresses all three parties. However, this introduction is too far removed in time to allow for reliable analysis of its impact and the government response to the Lord O'Shaughnessy report reiterates the UK's commitment to further standardize contracting and costing.[7] More recently, Ireland has introduced a comparable contracting approach. Based on IQVIA data, median contracting cycle times in Ireland have decreased significantly in the year after the introduction of the standardized contracting and budgeting approach but should be interpreted carefully due to a small sample size.

Similarly, France has introduced a mandatory CTA template in 2014 which is being applied by all public and private hospitals. Also, the CTA template is accompanied by a costing template. Study budgets are being negotiated for each study by a national coordinating site. Based on IQVIA data, median contracting cycle times have decreased directly by over 40% in the year after the introduction of the standardized contracting and budgeting approach.

Italy and Spain do also have mandatory CTA templates at national, regional, or site level. Italy has introduced a mandatory CTA template in 2019 which functions as

minimum agreement. In contrast to the UK and France, only budget categories, i.e., budget types which should be reflected in trial site budgets, are harmonized, but there is no costing template. IQVIA data indicates a small, non-significant decrease in median contracting cycle times by 16% in the year after the template introduction. However, the impact on cycle times does not persist and cycle times are bouncing back with a record high in 2023. Spain is a special case. While there is no national template, there is a mandatory site template at each site. Some regions have their own template applicable to all sites in the region.

In contrast to the countries studied so far, Belgium, the Netherlands, and Denmark have introduced non-mandatory CTA templates only. The Belgian CTA template has been introduced in 2019 and updated in 2022. The usage has seen a continuous ramp-up curve with an estimated 80-90% adoption rate in 2024. No significant decline of overall contracting cycle times across all study sites is observed. An analysis of the sub-set of the top 80% quantile indicates a drop in median contracting cycle times for three years from 2019-2021, but an increase again afterwards. A manual analysis of contracting cycle times for IQVIA's Belgian Prime Site Alliance — IQVIA's most important research sites in the country — indicates that contracts based on the national template are being negotiated significantly faster than those agreements which do not make use of the national template. Similarly, an optional CTA template was introduced in the Netherlands a few years ago. Usage rates strongly depend on individual sponsors. Finally, Denmark has seen the launch of a national optional contract template in November 2021 with an estimated adoption rate of 50% by now. No reduction of cycle times can be observed in 2022 which, however, overlaps with the Covid-19 period and a sharp decrease in new study agreements.

To sum up, IQVIA data indicate that countries like France with a mandatory CTA template and harmonized budgeting approach tend to see a short-term reduction in contracting cycle times, while evidence for countries with optional CTA templates and lack of harmonized budgeting is more mixed and/or limited to those agreements which make use of

the national template. Results should be interpreted carefully due to the limitations of the analysis. It should also be noted that the introduction of national templates in several countries overlaps with the Covid-19 period which has negatively impacted cycle times and therefore the analysis remains inconclusive. However, there is some evidence that consistent use of standard contract templates has a positive impact on start-up times.

When comparing the performance of contracting cycle times with number of trials per country, both tend to correlate. Between 2008 and 2014, the UK has significantly gained in relative importance as trial location although it has seen a drop-off in relative importance in recent years. More recently, France has closed the gap in number of trials initiated per year to countries like Germany with a lack of widely used CTA templates until 2023. Most prominently, Spain has increased its relative relevance as study location. The introduction of mandatory (regional/local) CTA templates is only one of a whole range of concerted measures and as a result the country has even overtaken countries like the UK and France as attractive trial location.

Case Study: Introduction of standard contract clauses in Germany

Finally, we take a closer look at Germany as clinical trial location. This market is an interesting case study, because it had fallen behind in its attractiveness as clinical trial location in recent years and is currently reviewing and taking measures to restore that attractiveness.

In December 2023, the government adopted the National Pharmaceutical Strategy with the goal of strengthening Germany's attractiveness as research and production location for the pharmaceutical industry. The proposed measures include speeding up clinical studies, among other things by introducing model contract clauses, streamlined approval processes for clinical trials, incentives for pharma production, and incentives for innovation and research projects. The Medicine Research Act, which has been passed by the Federal Council (Bundesrat) in September 2024, is part of this strategy and is intended to simplify clinical studies. With the Medicine Research Act, the Federal Government is authorized, after consultation with the associations and organizations concerned, to adopt standard contract clauses on the rights and obligations of the sponsor and the trial site in the conduct of a clinical trial by statutory order with the consent of the Bundesrat.* This is following the alignment and publication of model contract clauses in a joint effort by the German sponsor, site, and CRO associations (vfa, BPI, German University Medicine — VUD/MFT, KKS Network, and BVMA). The latest version was published in October 2023. In other words, Germany has optional standardized contract clauses already available, and the government is building on this work in their effort to release mandatory clauses in the coming months. This is addressing the recommendations and concerns by the national sponsor, research site and CRO associations (e.g., Ruppert et al., 2024)[8] and clinical scientists (e.g., Bauer et al., 2022;[9] Grünwald et al., 2022).[10] In the short run, contracting parties need to decide to which degree they intend to adopt the model contract clauses. In the mid-term, German policy makers are going to implement mandatory standard contract clauses which may only be lifted on a study-by-study basis if the contracting parties jointly agree to do so.

In preparation of the launch of the model contract clauses version 2.0, the German industry associations vfa (representing the interests of 46 of the world's leading research-based pharmaceutical companies and its affiliates) and KKS Network (representing the interests of the central coordination centers for clinical studies within university medical centers) had conducted surveys with their members in 2023.

The KKS Network showed an average contract cycle time of 120 days on behalf of the German university medicine (n=12).[11] Average contract cycle times of individual university hospitals ranged from 82 to 240 days. This site survey also showed that contract drafts are usually provided by the industry, and the model contract clauses would only be beneficial for study sites when implemented with a more binding nature. Similarly, the vfa survey revealed a medium contracting cycle time on the sponsor side of 156 days with a range from 15 to 629 days (n=7 sponsors with 705 contracts). These are by far the highest values when compared to the European peers in Netherlands (96-151 days), Italy (91-173 days), UK (78-134 days), Belgium (79-125 days), Spain (61-111 days) and France (24-76 days).[12]

From October 2023 to January 2024, IQVIA initiated a strategic site survey which has been completed by the strategic initiative leads of 13 key research sites, representing about half of IQVIA's Strategic Sites which in turn account for >60% of total patient recruitment. The survey revealed that the model contract clauses had already been fully or partially accepted by over 75% of IQVIA's strategic sites

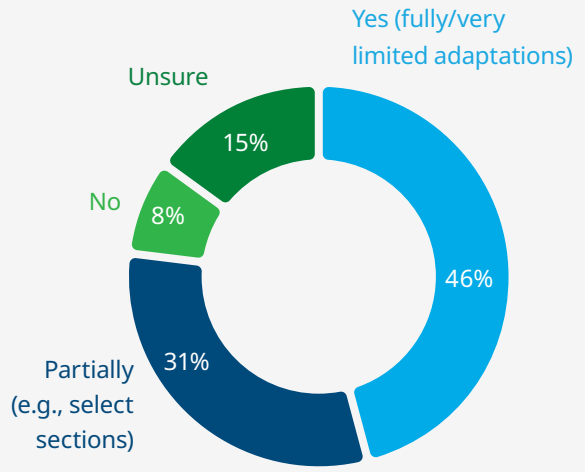
(see Figure 4). Among all respondents, 46% of sites accept the model contract clauses fully or with very limited adaptations such as site-specific adjustments to the contracting parties. Further, 31% of sites accept the model contract clauses partially which usually refers to select sections of the model contract clauses. Only one respondent declared that they don't accept the model contract clauses at the time of the survey.

*Standard contract clauses" is the term used in the Medicine Research Act, while "model contract clauses" is the term initially utilized by the national associations.

Figure 4: Willingness to adopt German model contract clauses by sites at time of survey (10/2023-01/2024)

Question

If proposed by a sponsor or CRO, are you willing to accept the model contract clauses today?

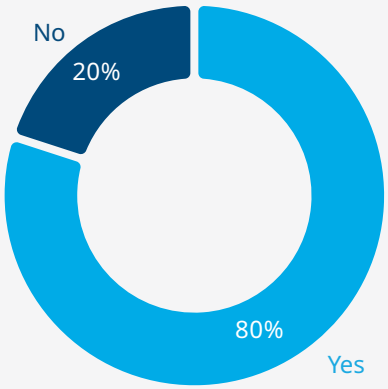


Source: IQVIA strategic site survey, Jan 2024

Figure 5: Planned adoption of German model contract clauses by sites

Question

[If the model contract clauses are not yet fully accepted:] Do you plan to re-consider an adoption of the model contract clauses again in the next six months [...]?



Source: IQVIA strategic site survey, Jan 2024

Among those sites which do not fully accept the model contract clauses yet, nearly all planned to re-consider an adoption of the Model Contract Clauses again in the next six months (see Figure 5). 4 of 5 respondents of this sub-group replied that they plan to re-consider their adoption, referring either to the anticipated publication of Version 2.0 of the Model Contract Clauses (n=3) and/or an anticipated broader adoption by sponsors and CROs (n=2). Only 1 site had neither adopted nor planned to reconsider an adoption in the following six months.

Notably, in addition to the accelerated cycle times, sites also expect that standardization of agreements could contribute to a reduction in the number of review hours of relevant agreements between 20 and 80%. Effectively, the impact will depend on the degree of standardization, the requirement for additional functional service agreements, and other need for negotiation and alignment.

Conclusions and recommendations

- **Global competition**: Countries compete to attract clinical trials and shorter start-up times can be a critical differentiator, especially in Europe under the standardized Clinical Trials Regulation.
- **Impact of contract templates**: Nationally enforced contract templates have contributed to significantly reduced cycle times, especially in conjunction with a standardized costing approach. For example, France saw a 40% reduction after introducing a national template in 2014. Where optional contract templates exist, agreements using these templates are shown to have shorter negotiating times than those which do not. Contract templates are also expected to free up resource time in the participating trial sites.
- **Germany's strategy**: As part of the national Pharma Strategy and in order to strengthen Germany's attractiveness for clinical research, Germany is moving towards mandatory standard contract clauses. This development is strongly supported by clinical trial sites and other stakeholders. National sponsors also contribute to the use of national templates and recognize their advantages. International sponsors, perhaps due to less familiarity with local law and regulations, tend to stick to their own clauses yet but may be well advised to reconsider the benefits of standardized templates.

Acknowledgements

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About the authors

DR. KAI HÄNEL,
Associate Director,
Global Site Activation

Kai has nearly a decade of experience in the clinical research industry. Currently, he serves as the Head of the Country Site Activation Team for the DACH region, where he is instrumental in optimizing and expediting clinical trials. His primary focus is on reducing the startup timelines and contract cycle times within these countries. Kai holds a PhD in Biochemistry and Molecular Biology from RWTH Aachen University.

MEIKE MADELUNG,
Engagement Manager,
EMEA Thought Leadership

Meike has over 15 years of experience in life sciences and develops, publishes, and speaks on insights and analyses of strategic relevance on a range of key topics and latest industry trends. She takes a special interest in topics relating to health system viability, therapeutic innovation, and patient engagement and has published a number of articles and white papers in this area. Meike holds an MBA in International Management from the University of London and an MA from the University of Bonn, Germany.

DR. MARC ROHDE,
Director, Strategic Site Solutions

Marc is responsible for IQVIA's strategic site and network relationships as well as strategic projects in Germany. He joined IQVIA in 2018 and has more than 15 years of experience in healthcare science, consulting and strategy. Prior to joining IQVIA Marc was a project lead at Monitor Deloitte's healthcare practice and led the Innovative Care division at Fresenius Medical Care. His experience includes the design of research strategies and programs, and he has published multiple papers in peer-reviewed journals. Further, he coordinates the model contract clauses working group at the BVMA, the national association representing the German contract research organisations, as well as the sub-working group on the representation of the CROs in the model contract clauses within the cross-association working group of the German sponsor, site, and CRO associations. Marc received his PhD from German Sport University Cologne and holds a Master of Science in Management from London Business School. He has also completed a certified executive education program in cancer genetics at Harvard Medical School.

CONTACT US

iqvia.com