TaylorWessing

Session #7

Webinar

17 July 2024

TaylorWessing

COFFEE BREAK
Life Sciences Start-ups

Clinical trials in the pharmaceutical area

Tips and tricks for CTA negotiations

17 July 2024 | Irina Rebin

Agenda

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5	Contracting parties to the CTA
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Clinical Trials Regulation 536/2014

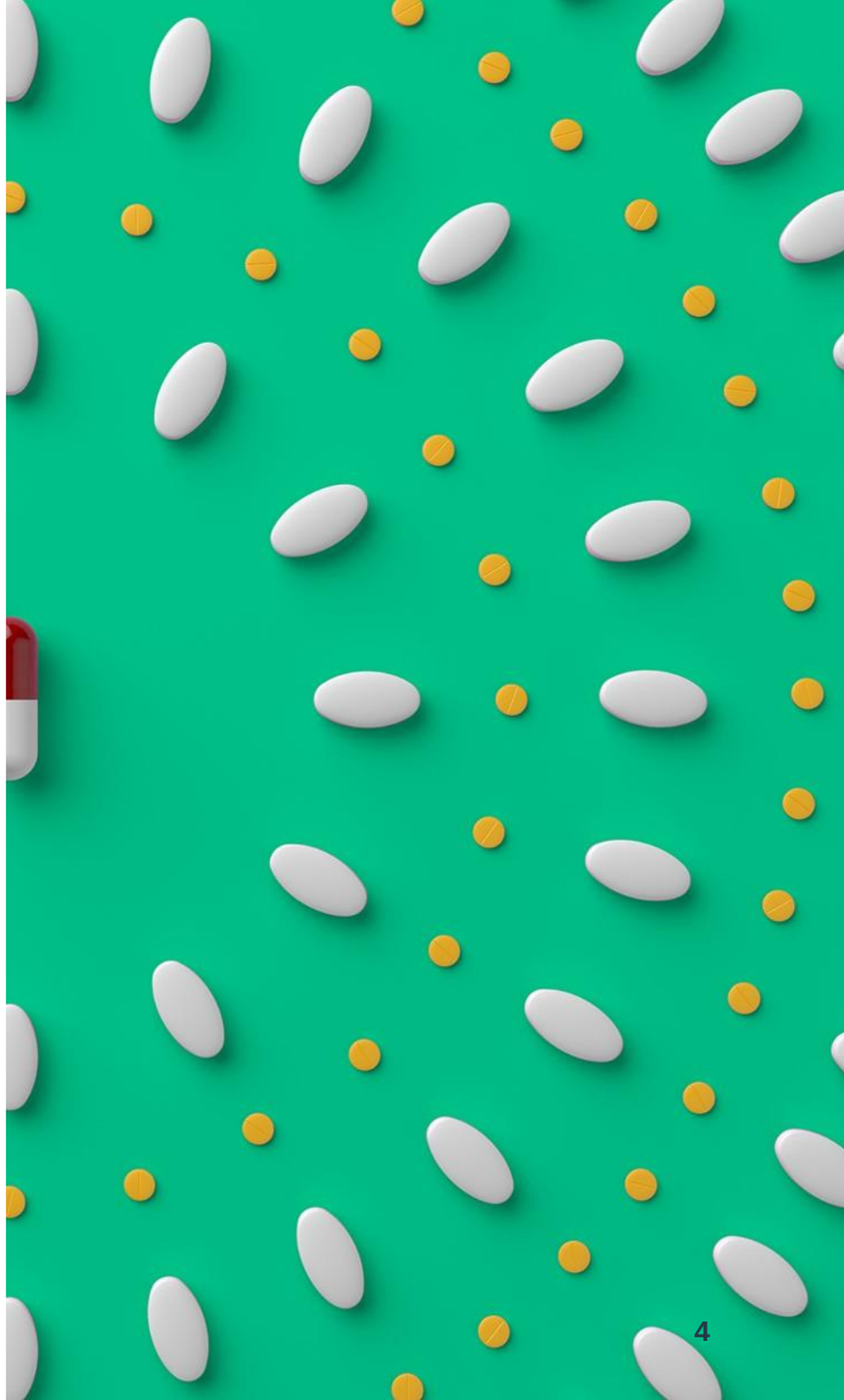
Effective Date: January 31, 2022 (January 31, 2023)

Replaces the former Good Clinical Practice Directive 2001/20/EC (GCP Directive)

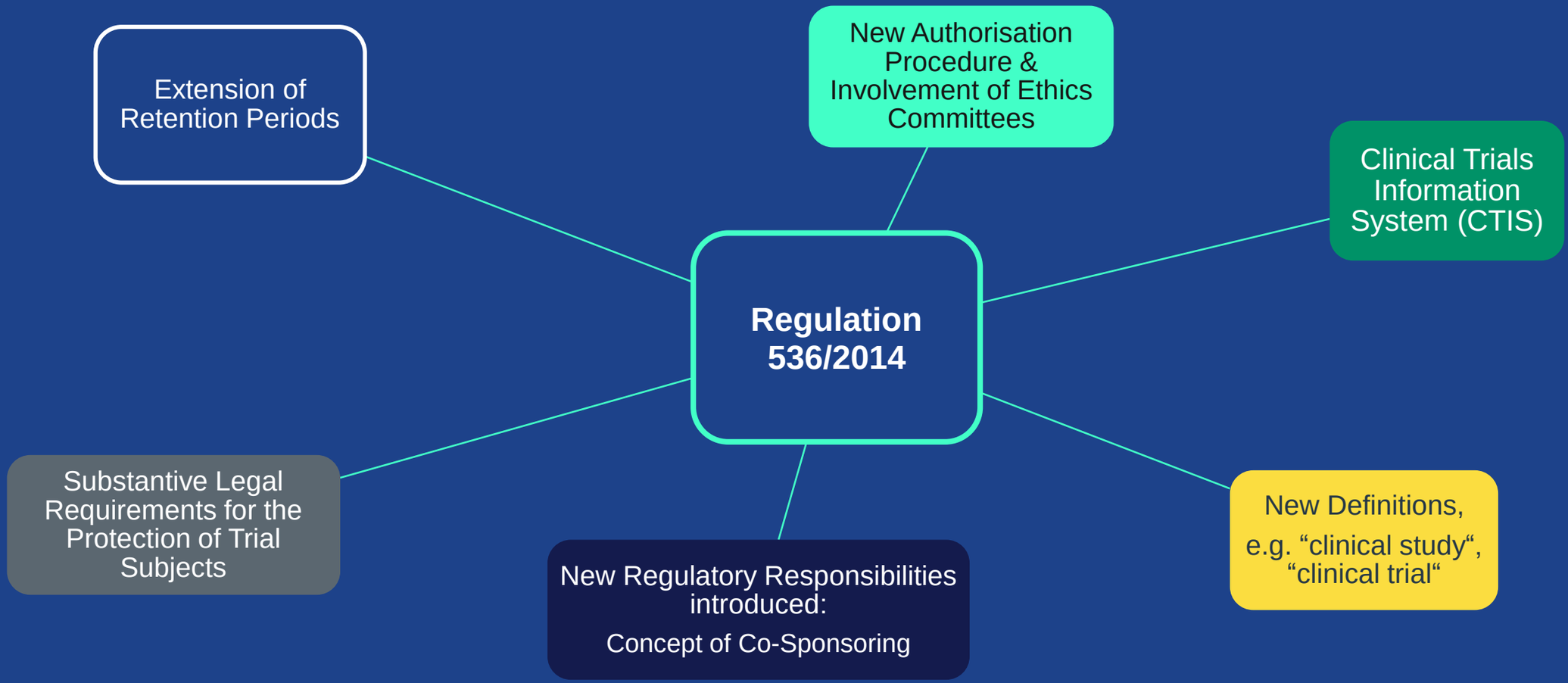
"*Directive 2001/20/EC aims to simplify and harmonize the administrative provisions governing clinical trials in the Union. However, experience shows that a harmonized approach to the regulation of clinical trials has only been partly achieved.*" (reason for consideration (4))

Through its unrestricted applicability in all Member States of the European Union, it leads to a **harmonisation** of the application procedure, authorisation and supervision of clinical trials in the EU.

The **transition period** for the trials ongoing at the moment of applicability is a **maximum of 3 years** from the date of application of the Regulation (= **January 30, 2025**); cf. EMA – Q&A on "CTIS – how to get started and how to transition a trial".



Main changes under the new Regulation



Initial Authorisation Procedure under CTR

Submission

6 days

rMS proposal by sponsor or selected by agreement

10 days validation

+10 days for the sponsor to respond to questions

+5 days for rMS and cMS to assess and discuss responses

Assessment

Part I Assessment: Scientific Part

45 days

rMS/cMS assessment Part I
+50 calendar days for ATMPs

In case of a **multinational trial**:

26 days	**12 days**	**7 days**
Initial assess-ment	Coordinated review	Consolidation phase

Part II Assessment: Ethical Part

45 days

rMS/cMS assessment Part II
+ 50 calendar days for ATMPs

Clock Stop

31 days

- 12 days for the sponsor to respond the question
- 19 days for rMS and cMS to assess and discuss responses

Clock Stop

31 days

- 12 days for the sponsor to respond the question
- 19 days for rMS and cMS to assess and discuss responses

One Decision

Use of CTA templates published by local competent authorities

- Competent authorities or competent ethics committees of certain EU Member States require the use of their own CTA-template(s) for clinical trials with medicinal products and/or medical devices to be concluded between sponsor and trial sites, e.g.:

  France: La convention unique - Ministère de la Santé et de la Prévention (sante.gouv.fr)

  Italy: Ethics Committees Coordination Centre | Italian Medicines Agency (aifa.gov.it)

  Further: Hungary, Greece

- Scope of “allowed” changed/amendments depends on the respective Member State (highly likely with regard to commercial aspects between sponsor and trial site)

- **Germany:** Standard Contractual Clauses to be published as announced by the Federal Ministry of Health with view to the new German Medical Research Act

Contracting Parties to a CTA

- Choice of contracting party – trial site, investigator or both – also depends on the Member State where the clinical trial is to be conducted; e.g.:

  Germany: German institution usually object to enter in tripartite contracts (with the investigator being a contracting party besides the institution itself) and usually insist on entering into the CTA with the sponsor

  Poland: Polish law deems it mandatory that the PI becomes a contracting party to the CTA (solely or beside the trial site in a then tripartite agreement)

Impact on CTA if investigator does not become a contracting party to the CTA:

- Investigator should sign a “read and acknowledged” passage on the signature page
- general obligation of trial site to ensure that investigator fulfils its obligations assigned to him/her in the CTA or by applicable laws

Impact of General Data Protection Regulation on clinical trials regulation in the EU (1)

- **CTR** clearly states that the provisions of the EU General Data Protection Regulation 2016/679 ("**GDPR**") need to be observed in addition to the provisions of the CTR with regard to clinical trials.
- **GDPR** requires a legal basis for the process of personal data (e.g. provision in local laws, informed consent etc).
- Up to **EU Member States** to further develop such a legal basis.
- German local ECs oblige the sponsor to provide comprehensive information to trial subjects, also from a data protection point of view!
- In addition to the **CTR,** Germany, for example, requires minimum content of trial subjects' information to be implemented in the ICF template (cf. following slides in detail).
- **Impact on CTA negotiations:**
  - In practice, sponsors often request the trial sites to draft and provide the ICF template to be used for the intended clinical trial.
  - Regulatory obligation of the sponsor itself to ensure that all trial subjects have also been effectively informed in terms of data protection law and have given their consent to the processing of their personal data.
  - Therefore, it is essential that the ICF template provided by the trial site is checked by the sponsor itself to ensure that it also complies with the GDPR and local data protection laws applicable to clinical trials.

Impact of General Data Protection Regulation on clinical trials regulation in the EU (2)

Re. clinical trials with medicinal products: Sec. 40b para. 6 of the German Medicinal Products Act (AMG)

The person concerned or, if this person is incapable of giving informed consent, his/her legal representative must consent explicitly and in writing to the collection, processing and use of personal data, in particular health data. He/she is to be informed of the purpose and scope of the collection and use of these data. The person concerned is to be informed especially of the fact that:

1. *where necessary, the recorded data:*

a) *will be kept available for inspection by the supervisory authority or the sponsor's representative in order to verify the proper conduct of the clinical trial,*

b) *will be passed on in a pseudonymised form to the sponsor or to an agency commissioned by the latter for the purpose of scientific evaluation,*

c) *will be passed on, in a pseudonymised form, to the applicant and the competent authority for the marketing authorisation if an application for a marketing authorisation is filed,*

d) *will be passed on, in a pseudonymised form, by the investigator to the sponsor in the event of adverse events or serious adverse events pursuant to Article 41(1), (2) and (4) of Regulation (EU) No 536/2014,*

e) *will be passed on, in a pseudonymised form, by the sponsor to the database pursuant to Article 40 (1) of Regulation (EU) No 536/2014 in the event of suspected unexpected serious adverse reactions pursuant to Article 42 of Regulation (EU) No 536/2014,*

f) *will be passed on, in a pseudonymised form, by the sponsor to the EU portal in the event of unexpected events pursuant to Article 53 (1) of Regulation (EU) No 536/2014,*

2. *in the case of a revocation of a declaration of consent pursuant to sentence 1 and subsection (1) , it is permissible for the stored data to be continued to be used where necessary, in order to:*

a) *determine the effects of the investigational medicinal product,*

b) *to ensure that those interests of the person concerned, which are worthy of special protection, are not prejudiced,*

c) *satisfy the obligation to provide complete marketing authorisation documents,*

3. *The data are archived by the investigator and the sponsor for the period specified pursuant to Article 58 first subparagraph of Regulation (EU) No 536/2014.*

Remuneration for so-called “employee inventions” in Germany (1)

German trial sites often insist on a separate remuneration for the transfer of so-called employee inventions.

Background: statutory provisions of the German Employee Inventions Act (“*Arbeitnehmererfindungsgesetz*” – “ArbnErfG”)

Employee invention (“*Diensterfindung*”) defined in Sec. 4 para. 2 ArbnErfG:

“*Tied inventions (service inventions) are inventions made during the term of employment which either*

1. arose from the employee‘s task in the enterprise or in the public administration, or

2. are substantially based on experience or work of the enterprise or the public administration.“

Sec. 5 ArbnErfG: German employees are obliged to immediately notify the respective employee invention to their employer/the Institution in writing.

Remuneration for so-called “employee inventions” in Germany (2)

Sec. 6 ArbnErfG: German employers/Institution have the right to claim such employee inventions.

Moreover: An employee invention is **deemed claimed by the employer/Institution**, if the Institution does **not** release the employee invention to the employee by declaration in text form **within four months** after receipt of the proper notification.

Sec. 9 ArbnErfG: Employee is entitled to appropriate remuneration as soon as the employer has made use of the employee invention.

Please note:

- Sec. 9 ArbnErfG is a statutory provision, which **can’t be waived/excluded** between Institution and its employees.
- Obligation to compensate its employees lies with employer/Institution but not between the employee inventor and any third party (i.e. sponsor). But since the Institution is – on the one hand – usually obliged through the CTA-provisions to transfer its rights to any inventions (thus, also employee inventions) to the sponsor and – on the other hand – obliged by law to compensate its employees for any employee inventions claimed, German Institution often insist on being remunerated **separately for the transfer** of each employee invention to sponsor.

Waiver of so-called “negative right of publication” by German University members (1)

Under Sec. 42 No. 2 of the German ArbnErfG, **university** employees (investigator, other study team members) have the **right not to disclose a service invention to their employer** (Institution).

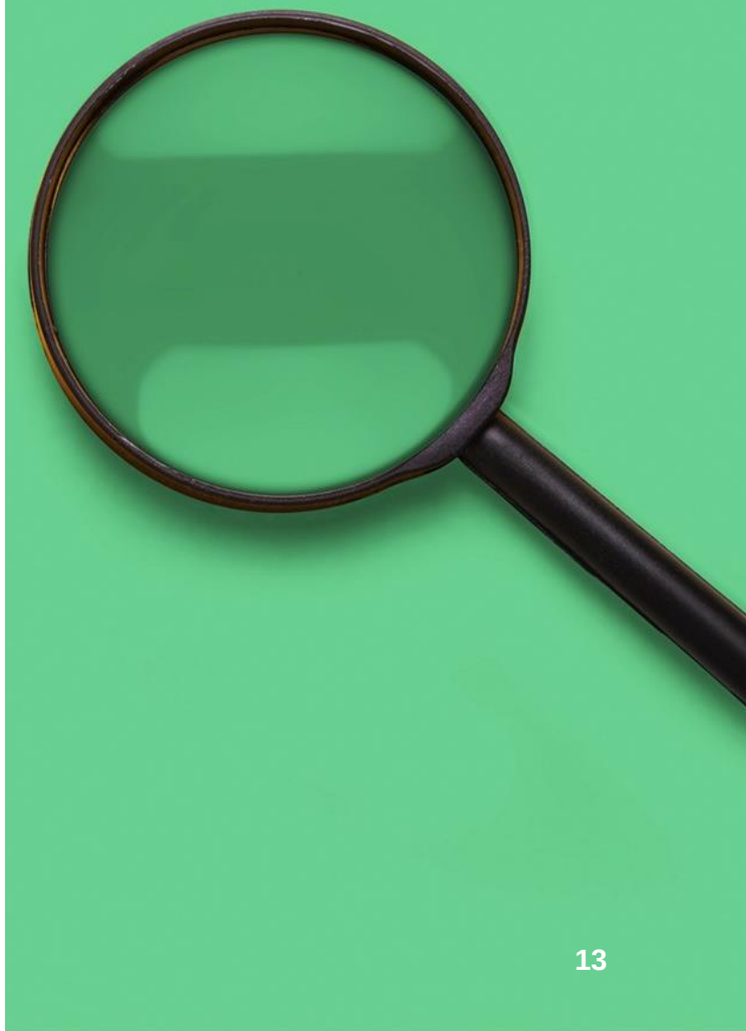
Can’t be waived/limited by agreement between employee and institution

Can be waived/limited by agreement between employee and a third party (e.g. Sponsor)

➡ there has to be a **separate agreement** (German Employee Invention Agreement) between the each of Institution’s employees and the Sponsor, mandating that the employees disclose their employee invention(s) to Institution, which then discloses such inventions to Sponsor and the Institution is able to assign such employee invention to Sponsor.

Impact on CTA negotiations:

German Institutions often ask for a template for such “German Employee Invention Agreement”.



Waiver of so-called “negative right of publication” by German University members (2)

Recommendations

1.

Template to be attached to the CTA

2.

Obligation of Institution to only involve those employees in the conduct of the clinical trial who have **previously** signed such a waiver vis-à-vis the sponsor.

Any questions?

Your Taylor Wessing Team

Irina is member of the Practice Area Patents Technology and Life Sciences and the Life Science & Healthcare Industry Group. She advises national and international pharmaceutical and medical device companies on regulatory aspects and industry-specific agreements.

Irina passed her state law examinations in Goettingen in 2013 and in Munich in 2019. During her doctoral studies in the field of clinical trials of medicinals products, she worked as research and teaching assistant at a chair for medical law at the Ludwig Maximilians University in Munich. Since September 2020, she is supporting Taylor Wessing as an attorney in the Munich office regarding all issues of medicinal products and medical device law, in particular clinical trial agreements.

Languages

- German, English

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