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The Long and Winding Road:
(Some) EU and FDA Issues to Consider with Clinical Trials and Clinical Trial Agreements

20 September 2023 | Dr. Manja Epping, Alan G. Minsk & Irina Rebin

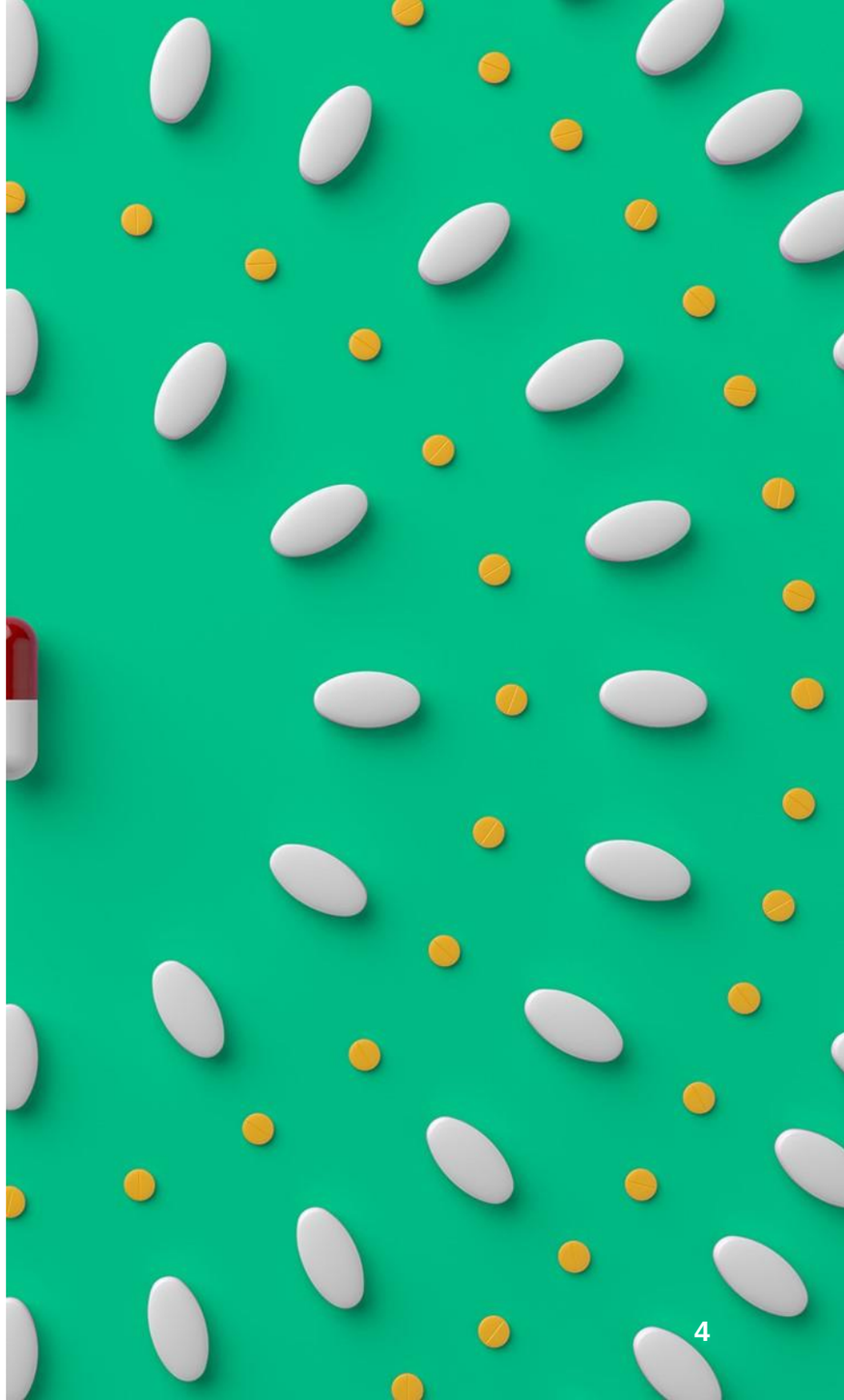
Content

1 FDA Defined Terms

Creativity Is One Thing, Stupidity Is Another

Where FDA has defined terms, use them

- While it is not divinely inspired, FDA's terminology should be considered sacred
  - Not the time to be Lennon/McCartney
- It is advised to use the defined terms in an agreement when applicable
- Companies make mistakes when they try to be too creative and summarize these terms rather than merely incorporating them verbatim
- Not only should such defined terms be included in the contract in the event that FDA inquires, but having a common vocabulary and one language reduces the risk of ambiguity and different interpretations



2 Signature Authority

Signature Authority

- Can the investigator sign for the institution?
- What if the investigator leaves the institution?
  - Who has regulatory obligations?
  - Do you want to stay with the investigator or institution?

3 Roles and Responsibilities

Roles and Responsibilities

Need clear delineation of roles and responsibilities

– Departments of both the sponsor and site should be involved

If chart or a matrix is attached, make sure it is reviewed by the appropriate internal people

Have complete contact information for expedited notices and responses

4 Entering Into an Agreement

Shall We Dance?

Before you enter into an agreement, conduct due diligence of your potential site to ensure FDA compliance, financial stability, and ability to perform the job

While much of the compliance information is publicly available (e.g., Establishment Inspection Reports, FD-483s, Warning Letters), it can take months, if not years, to obtain these materials from FDA, so it is advisable and easier to ask for the information directly from your potential site at the outset

Presumably, the site will comply with this request to expedite the transaction

Shall We Dance?

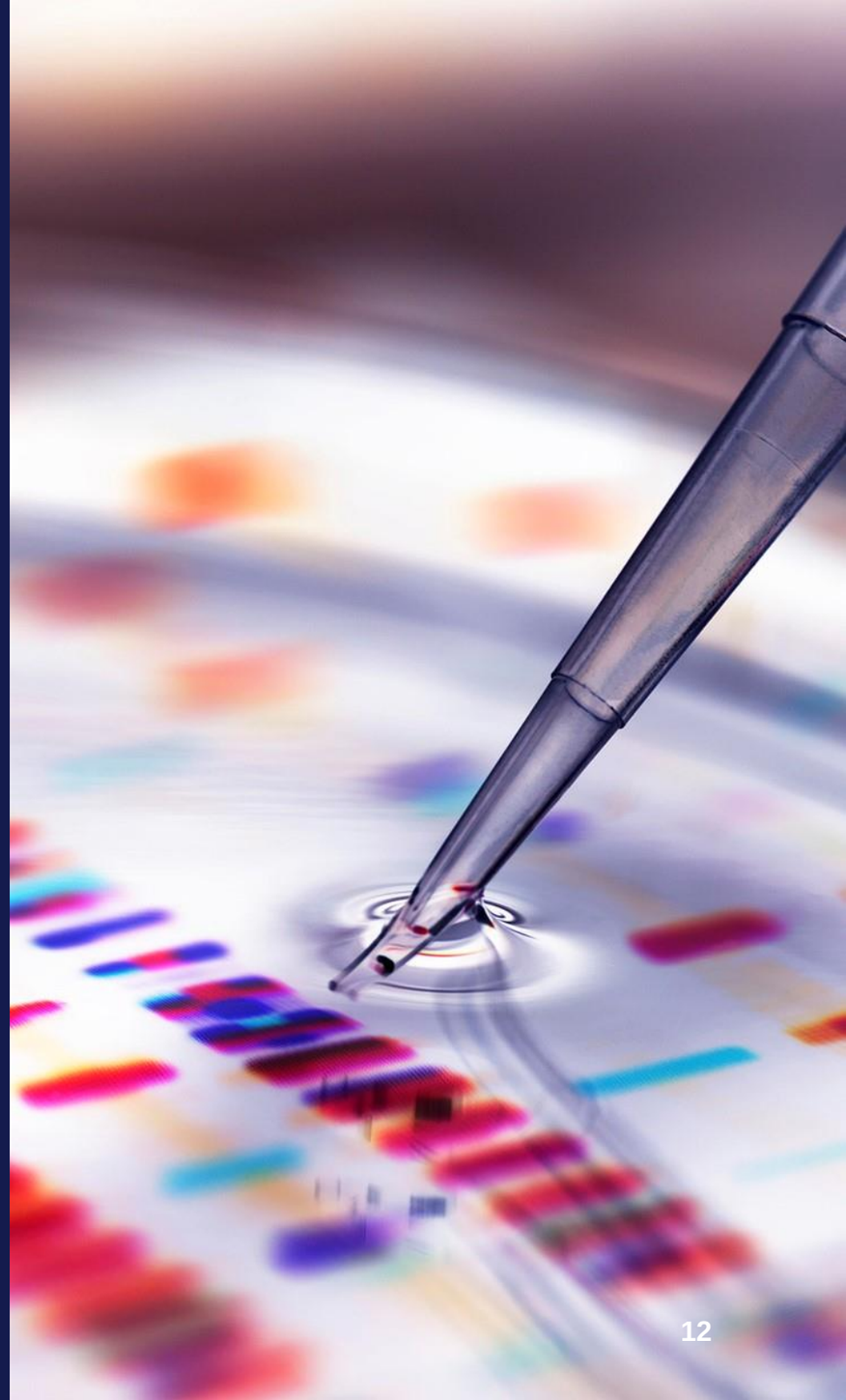
However, it is also possible that a party may be hesitant to show potentially confidential information or that could relate to another company

In such a case, you may wish to consider entering into a confidentiality agreement with the party or you may allow the party to redact the confidential information or summarize the issues

Shall We Dance?

At the end of the day, verifiable trust of the other party will make or break a relationship, so it’s better to know as much as you can in the beginning

If the potential partner is not willing to share a little bit of itself without a good reason, consider moving on to the next potential partner



Show Me Yours, and I'll Show You Mine

- Include a provision in an agreement that, if you are the application holder, you should be made aware ASAP (tied to a specific period of time) if the site is inspected or under investigation by FDA
  - If your product is at issue, you should be involved in the resolution of the FDA issue
  - Even if your product is not at issue, you still want to know, because of potential delays and disruptions in the study recruitment or performance until the FDA inspection or inquiry is over
- Include a provision that you can audit the site to ensure compliance

5 FDA Considerations to Include in Agreements

Tag, You’re It!

- Clearly define who is responsible for handling FDA-related issues (e.g., GMP regulations, informed consent, complaint handling, corrective action)
- Ensure that the agreement specifically defines what functions the site will perform and what is expected
- The application holder should not allow the site to subcontract out responsibilities without giving and obtaining prior written consent from the application holder

Don’t Be Shy – Get Involved

Be involved in the review of any agreement involving FDA-related issues

– Not everyone in your company is aware of, or knowledgeable about, FDA compliance

If one party says “it’s so” or “they spoke to FDA and everything is OK,” ask for the opinion in writing or have them send you the applicable law

– If they can’t provide support, be cautious

Did Simon Say?

- Define what changes, if any, a site can make and where the sponsor must provide prior written approval before the change is made
- Certain changes might trigger regulatory considerations for the applicant
  - Changes could have potential adverse effects on patients, exposing the manufacturer to regulatory and liability risks

6 FDA Inspections

Inspections

FDA may conduct bioresearch inspections, which cover clinical trials, preclinical trials, and other activities that are used to support a marketing application

Be aware of FDA guidances

– e.g., Informed Consent – Guidance for IRBs, Clinical Investigators, and Sponsors (August 2023)

Refusal to permit an inspection is a violation of the Federal Food, Drug, and Cosmetic Act (“FDC Act”)

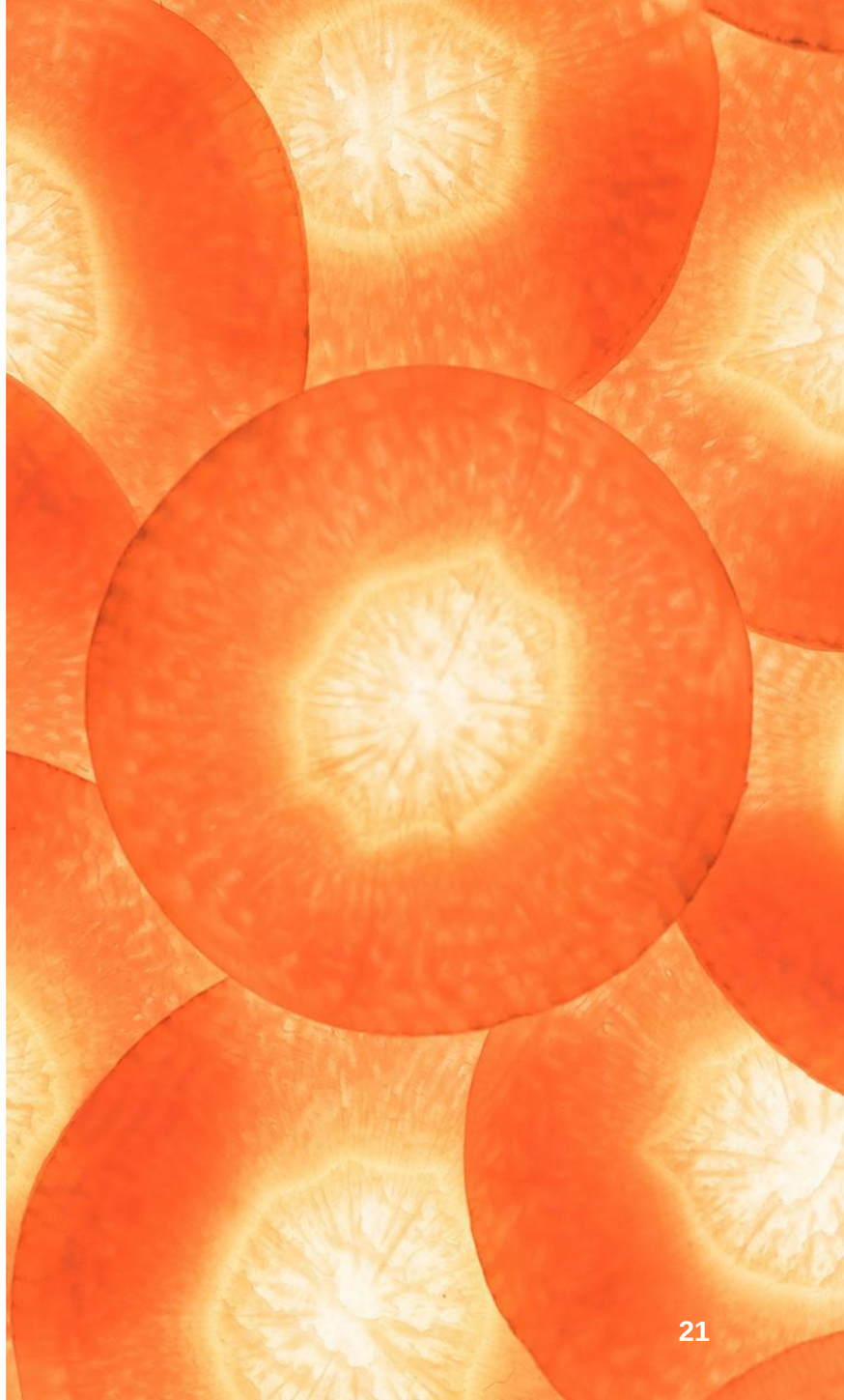
FDA may allege that a refusal to give access to documents to which it believes it is entitled is violative

FDA may detain and refuse admission to imported products where it “appears” that the products fail to comply with good manufacturing practices or are otherwise non-compliant with U.S. law

7 Compliance With FDA and Non-FDA Issues

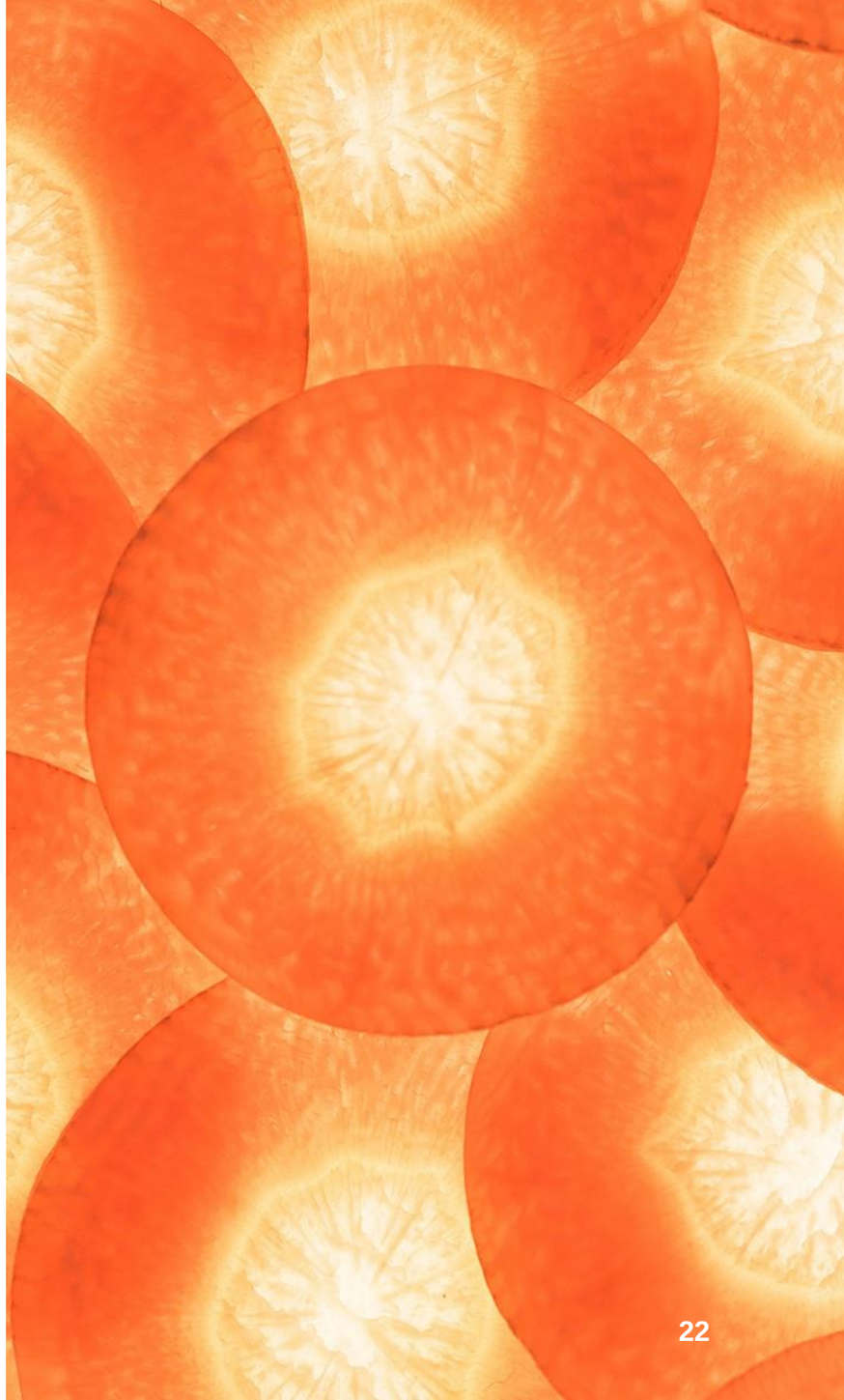
Compliance Issues

- Significant number of deficiencies include problems with protocol deviations, records, and IRB communications
- The agency also typically scrutinizes investigators who are doing a large number of trials, as well as so-called “outliers” — trials whose data deviate too far from the data from other trial sites in the study or that have reported many more or far fewer adverse events
- Other flags for FDA are sites that enroll more subjects than allowed and sites that have received FDA Form 483s previously



Compliance Issues

- Don’t forget compliance with non-FDA issues, such as HIPAA, cybersecurity laws, the Anti-Kickback Statute, and Sunshine Act/state reporting
- Key concerns for FDA inspectors include data integrity, subject protection, and the proper conduct of studies
- Reviewers do not like trials with:
  - Study imbalances
  - Lots of dropouts
  - Study changes
  - Protocol violations
  - Hidden problems
- Changes in clinical studies should be made through protocol amendments and not without authorization



8 Who Owns What

Who Owns What

- State/public investigators/sites often do not agree to liability caps or indemnification due to state law
- Publication of study and intellectual property rights to inventions
  - Who owns what
  - The ownership of samples/biological material/data

9 Confidentiality and Management of Clinical Data

Confidentiality and Management of Clinical Data

Trade Secrets, PHI, Confidentiality, and Informed Consent

- **Trade Secret Materials**
  - Drug manufacture specifics
  - Analytical materials
  - Underlying data (e.g., stability, raw material sources, data requested by FDA)
- **Trade Secret Protection**
  - Control access to confidential information (investigator staff, limited access by sponsor personnel)
  - Provide physical barriers to access of the information
  - Provide technological barriers to access of the information
  - Understand your risk of breach or misappropriation
  - Train employees and explain the risks
  - Create a recovery and incident response plain

Confidentiality and Management of Clinical Data

- **Use of data from trials**
  - What type of disclosure is allowed – anonymized?
  - Incorporation into drug master files and patent applications
- **Confidentiality**
  - Explanation of trial parameters, ingredients, obligations
- **Informed consent**
  - FDA guidance issued on August 15, 2023 (link provided previously)
- **Explanation to subjects of the uses of data**
  - A covered entity may continue to use and disclose PHI obtained prior to the time of revocation “as necessary to maintain the integrity of the research study”
  - Ask subject if their withdrawal is limited to the administration of investigational interventions or willingness to provide clinical data going forward

Non-Compliance Can Affect Status of Clinical Studies

Non-compliance can lead to FDA action

- Clinical hold
- Refusal to accept data to support marketing applications
- Loss of credibility
- Enforcement actions, such as a warning letter
- Disqualification of principal investigator(s)
- Other delays and more questions

10 | AGG Observations

AGG Observations

- Companies should audit and monitor sites for compliance
- Keep an eye on privacy requirements/obligations
- An agreement, without follow up and proper execution, is merely a piece of paper
- To paraphrase the classic Seinfeld line, “Anyone can enter into an agreement; it’s the “hold” (or execution) that’s most important.”
- Proactive planning is needed
- Conduct periodic reviews of the agreements to make sure current and relevant

11 Clinical Investigation with Medical Devices in the EU

Old and new legal framework for clinical investigations

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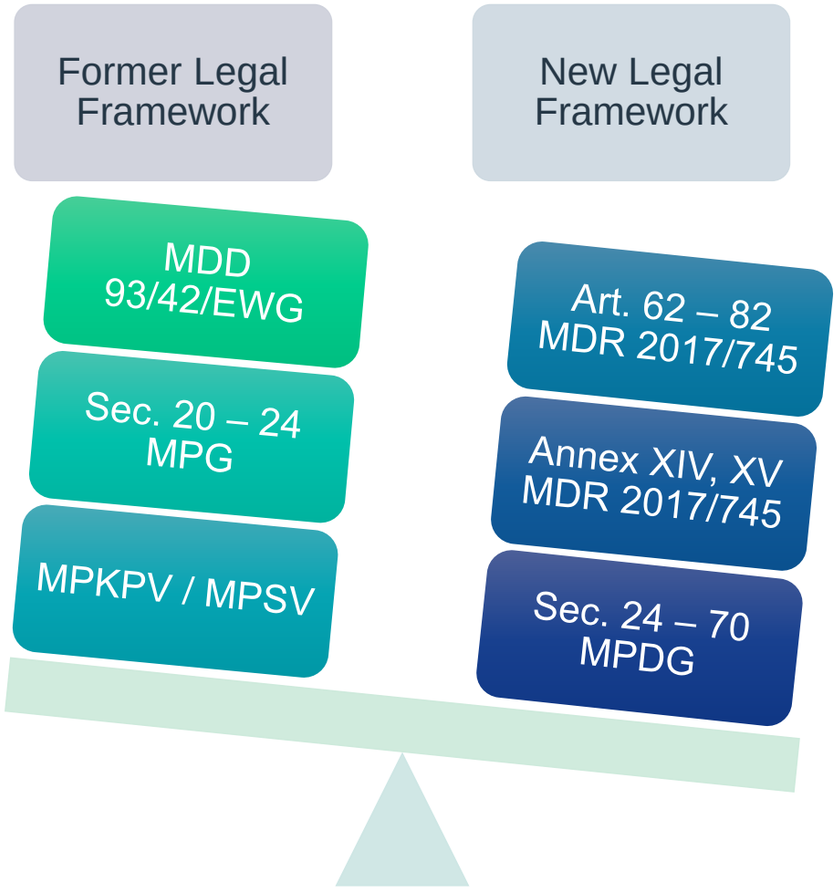
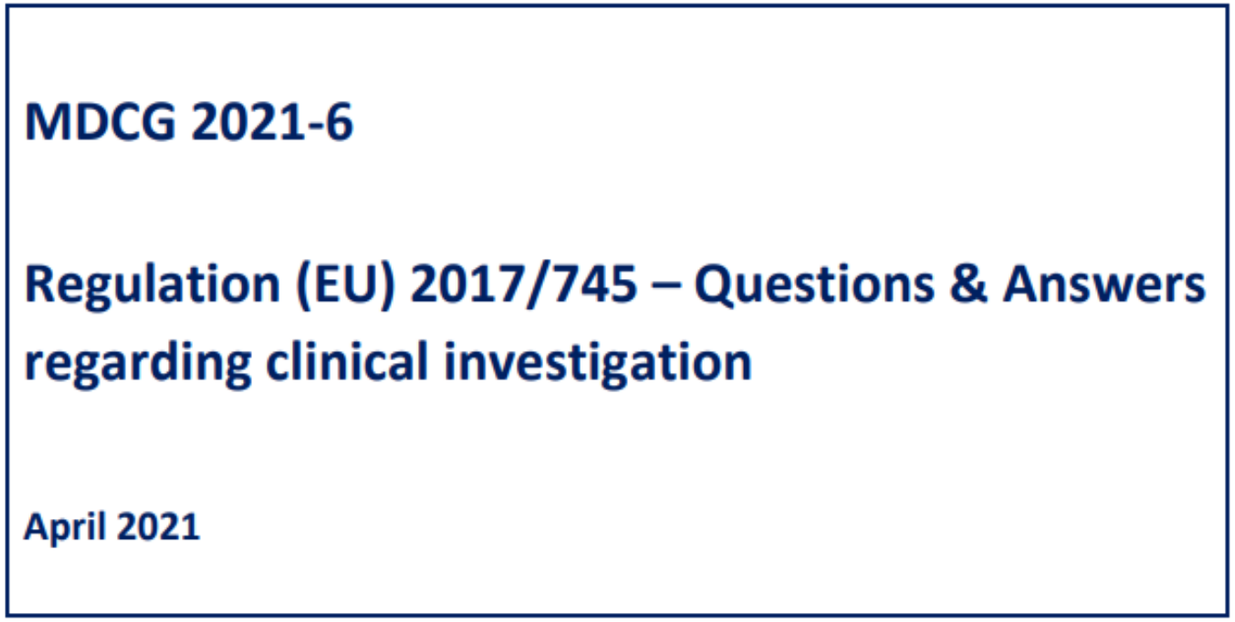
Clinical investigations with medical devices– old and new legal framework at a glance



New vs. former legal framework at a glance

- Regulation instead of directive
- Standardization of clinical investigations in the EU through new approval procedure
- Transparency of clinical investigations
- Detailed catalogue of definitions
- Protection of trial subjects: special requirements for informed consent, special requirements for certain trial subjects (e.g. minors)

MDCG Guidelines



MDCG: Medical Devices Coordination Group

Consisting of representatives of all EU Member States of the EU, chaired by a representative of the EU Commission

Not binding, but of particular importance in practice for the uniform application of the MDR

Guidance- and **Q&A-Documents** online:

https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en

Transitional Provisions

Art. 120 (11) MDR

- Clinical investigations which **have started to be conducted** in accordance with Article 10 of Directive 90/385/EEC or Article 15 of Directive 93/42/EEC prior to 26 May 2021 may continue to be conducted.
- As of 26 May 2021, however, the reporting of serious adverse events and device deficiencies shall be carried out in accordance with this Regulation.

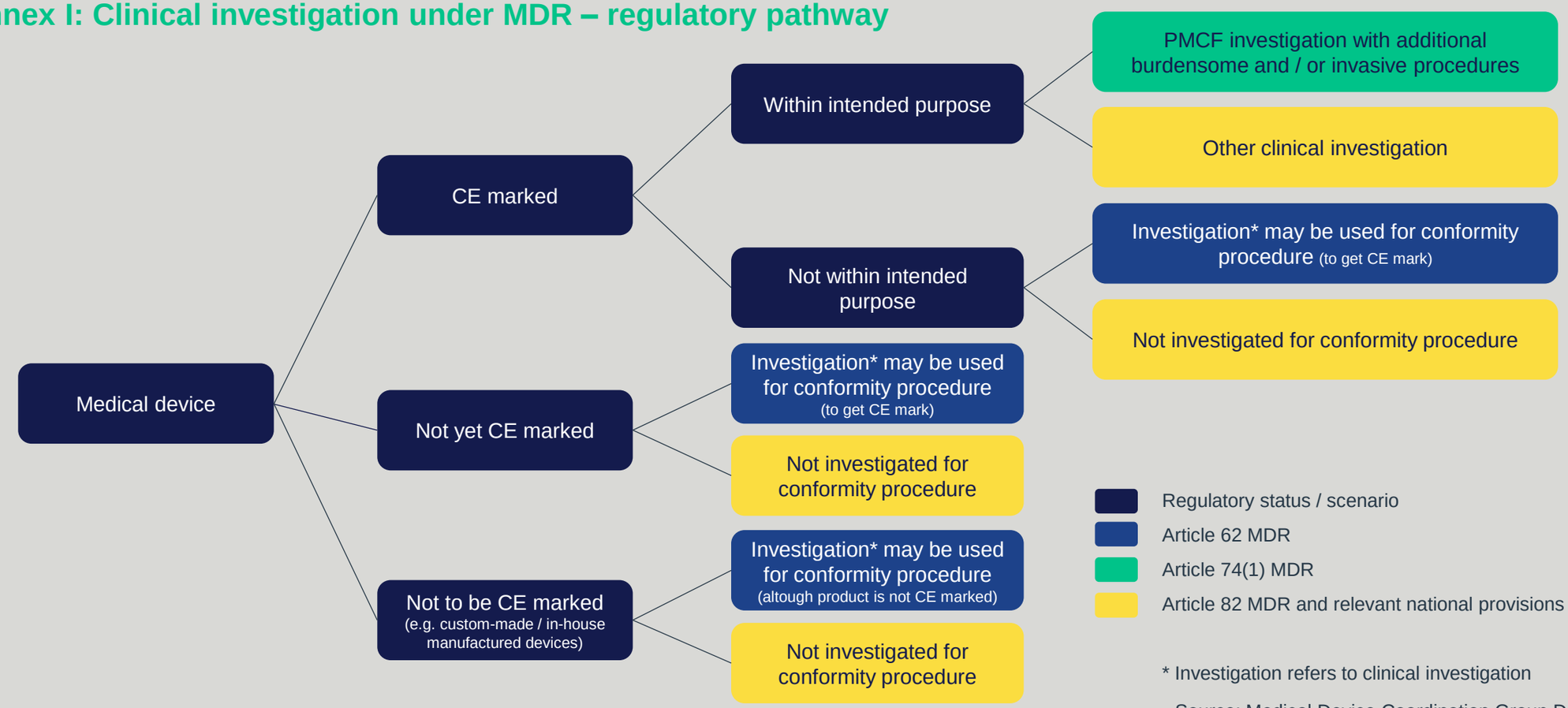
Sec. 99 (3) et. seq. MPDG

In Germany, clinical investigations **have started to be conducted**

1. Clinical investigations,
   - that have received approval from the relevant EC by May 25, 2021
   - and have been approved/ exempted from approval by the relevant higher federal authority.
   - ➢ If one of the two conditions is not fulfilled, a new application according to MDR-MPDG requirements is necessary!
2. Clinical investigations not subject to approval by the competent higher federal authority (e.g. with a purely scientific question)
   - for which the first subject **has consented to participate** by May 25, 2021.

Clinical Investigation under MDR (1)

Annex I: Clinical investigation under MDR – regulatory pathway



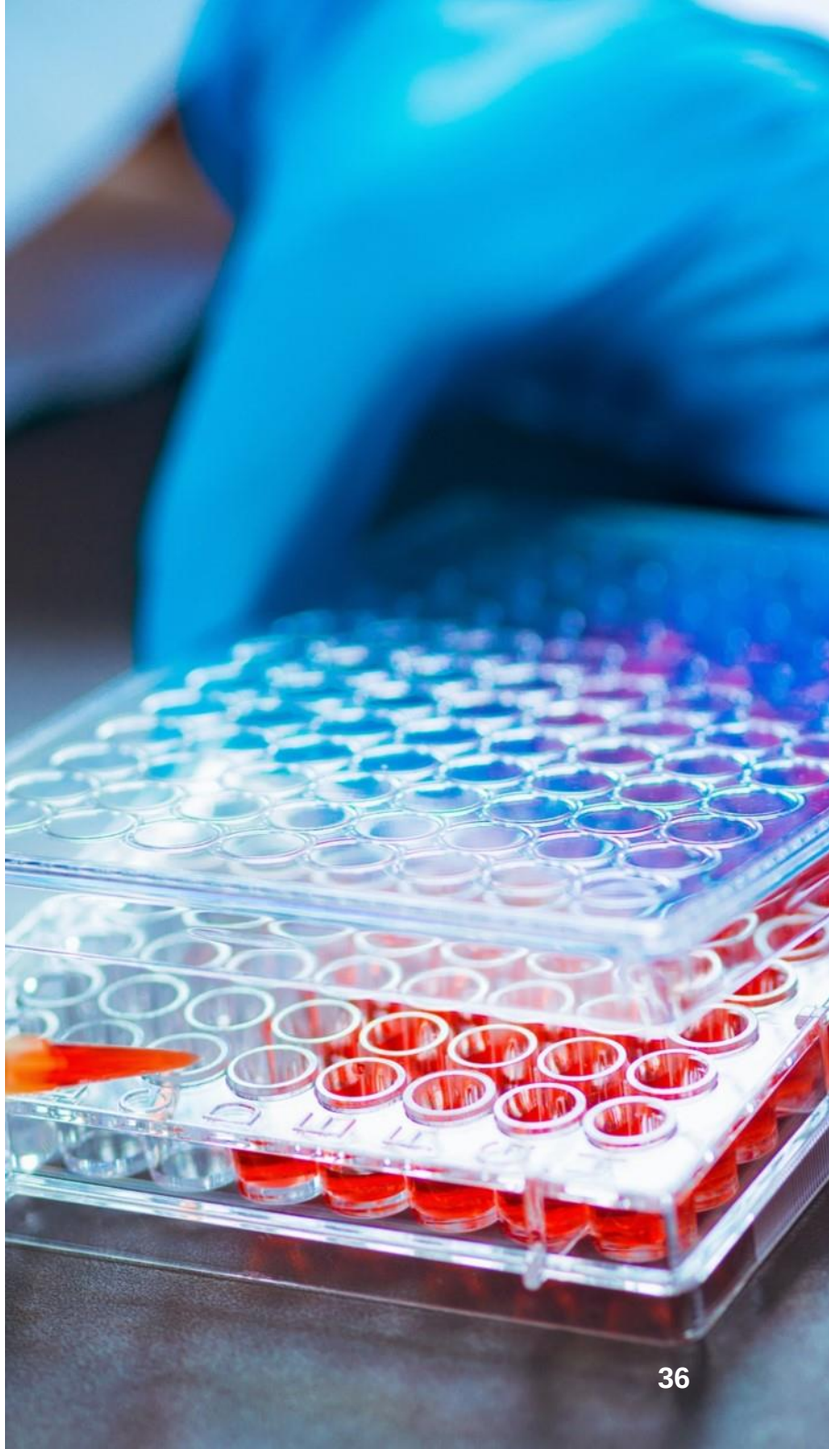
* Investigation refers to clinical investigation

Source: Medical Device Coordination Group Document / MDCG 2021-6

Clinical Investigation under MDR (2)

What is meant by "invasive" or "burdensome" procedures within the meaning of Article 74 (1) MDR?

- MDCG 2021-6 – Regulation (EU) 2017/745 – Questions & Answers regarding clinical investigations
  - Medical Device Coordination Group (Art. 103 MDR)
  - Guidance documents and Q&A on MDR and IVDR available at: https://ec.europa.eu/health/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_de
- Sec. 9 of MDCG 2021-6:
  - burdensome: (…) wide variety of different interventions, may include procedures which may cause pain, discomfort, fear, potential risks or complications(…), disturbances of lives/ personal activities, or otherwise unpleasant experiences. (…) determined from the perspective of the person bearing the burden
  - invasive: (…) (but are not limited to) penetration inside the body through the surface of the body, including through mucous membranes of body orifices (…).



“Other Clinical Investigations” under MDR and MPDG

Requirements of Art. 82 (1) MDR

Clinical investigations, not performed pursuant to any of the purposes listed in Article 62 (1) MDR:

- to establish and verify that, under normal conditions of use, a device is designed, manufactured and packaged in such a way that it is suitable for one or more of the specific purposes listed in point (1) of Article 2 MDR, and achieves the performance intended as specified by its manufacturer (lit. a);
- to establish and verify the clinical benefits of a device as specified by its manufacturer (lit. b);
- to establish and verify the clinical safety of the device and to determine any undesirable side-effects, under normal conditions of use of the device, and assess whether they constitute acceptable risks when weighed against the benefits to be achieved by the device (lit. c).

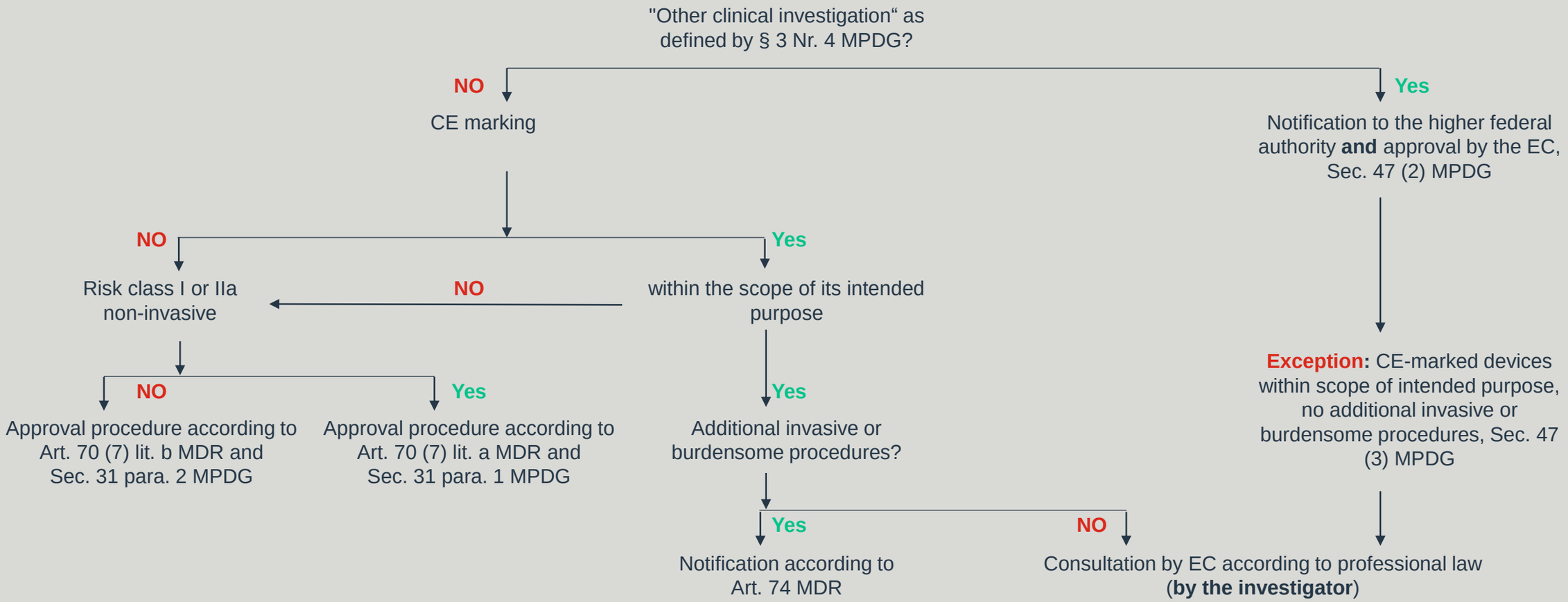
Other Clinical Investigations

Definition in Sec. 3 no. 4 MPDG

A clinical investigation that

- is not part of a systematic and planned process for product development or product monitoring of a current or future manufacturer (lit. a),
- is not carried out with the aim of demonstrating the conformity of a product with the requirements of the MDR (lit. b);
- serves to answer scientific or other questions (lit. c) **and**
- takes place outside of a clinical development plan in accordance with Annex XIV, Part A, point 1(a) of the MDR (lit. d).

Application and Approval Procedures for Clinical Investigations



Case Study: Issues of Delimitation

Pilot studies/feasibility studies

e.g.: Prototypes, “first in human” studies, “feasibility studies”

- Crucial for determining regulatory requirements: purpose of the clinical investigation

MDCG 2021-6, Sec. 6:

“In general, as pilot stage clinical investigations are conducted to gather preliminary safety and/or performance data, the use of Article 62 of the MDR should be foreseen. In cases of doubt, it is recommended to apply under Article 62 of the MDR.”

Other clinical investigations (Art. 82 MDR)

Explanatory Memorandum to the German MPDG:

“In the synopsis of Article 62(1) and Article 82(1), and using recital 71 of the MDR, it can be deduced that Article 82 only covers a clinical investigation that is not conducted with the aim of providing clinical evidence demonstrating the conformity of the product with the regulatory requirements.”

12 | Overview – Clinical Trials with Medicinal Products under new Regulation 536/2014

Clinical Trials Regulation 536/2014

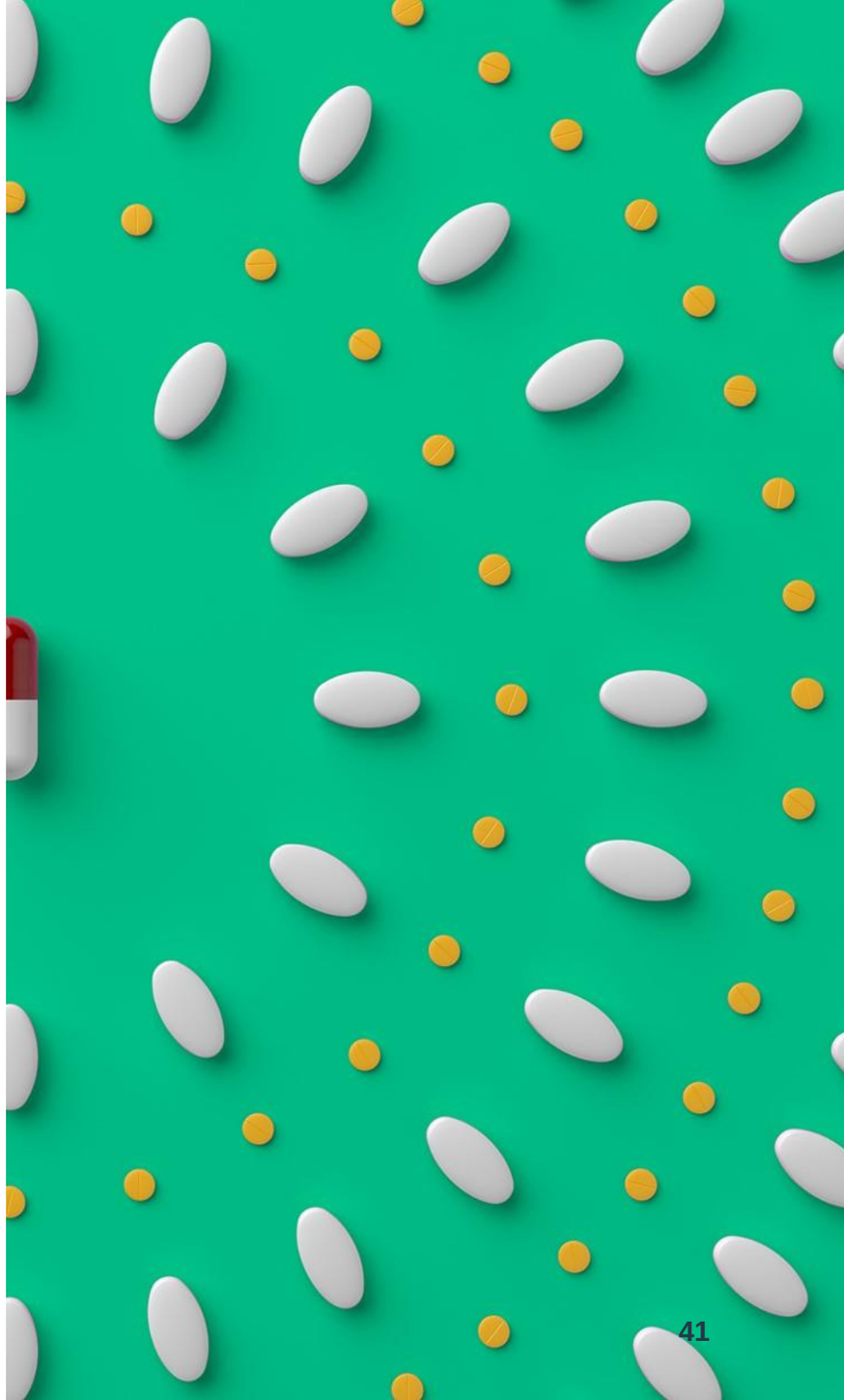
Effective Date: January 31, 2022 (January 31, 2023)

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

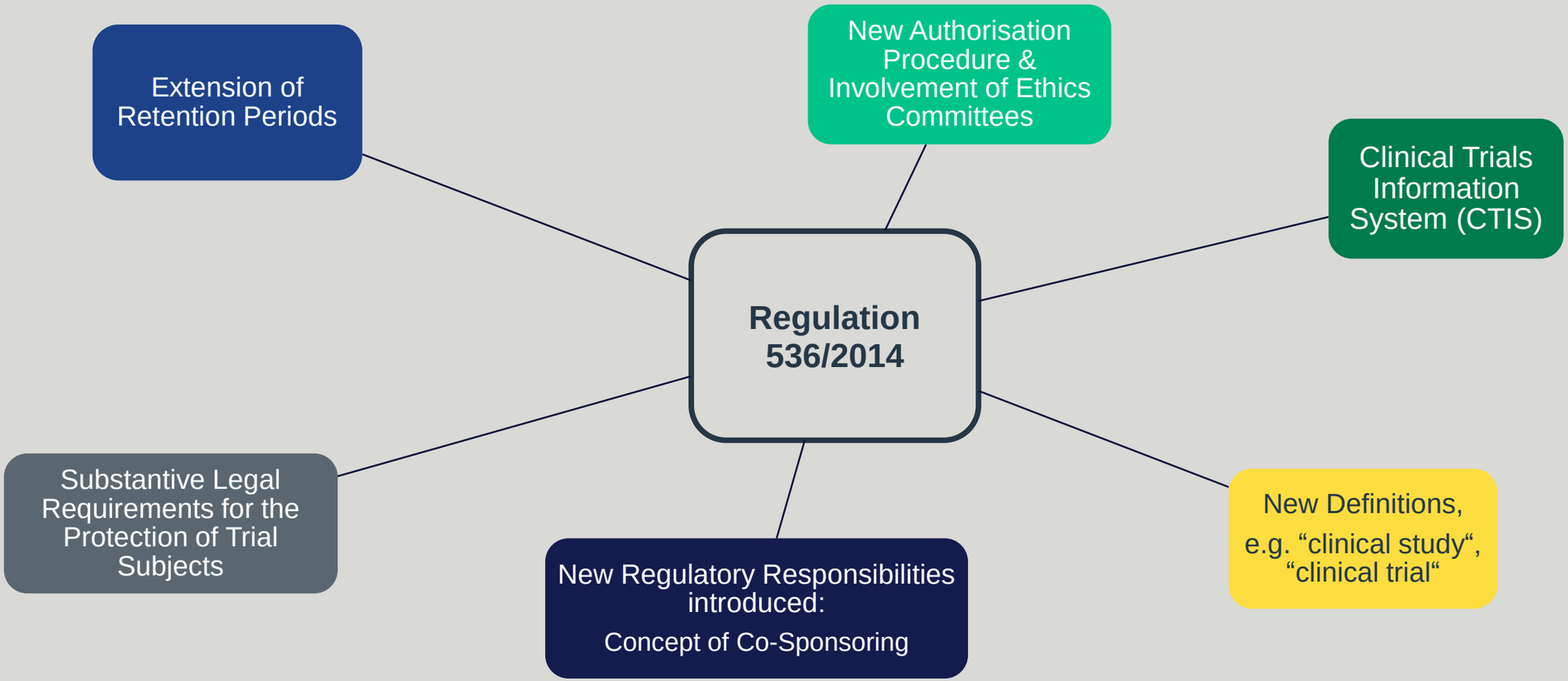
"*Directive 2001/20/EC aims to simplify and harmonize the administrative provisions governing clinical trials in the Union. However, experience shows that a harmonized approach to the regulation of clinical trials has only been partly achieved.*" (reason for consideration (4))

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**).



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

13 Medical Devices used in Clinical Trials with Medicinal Products

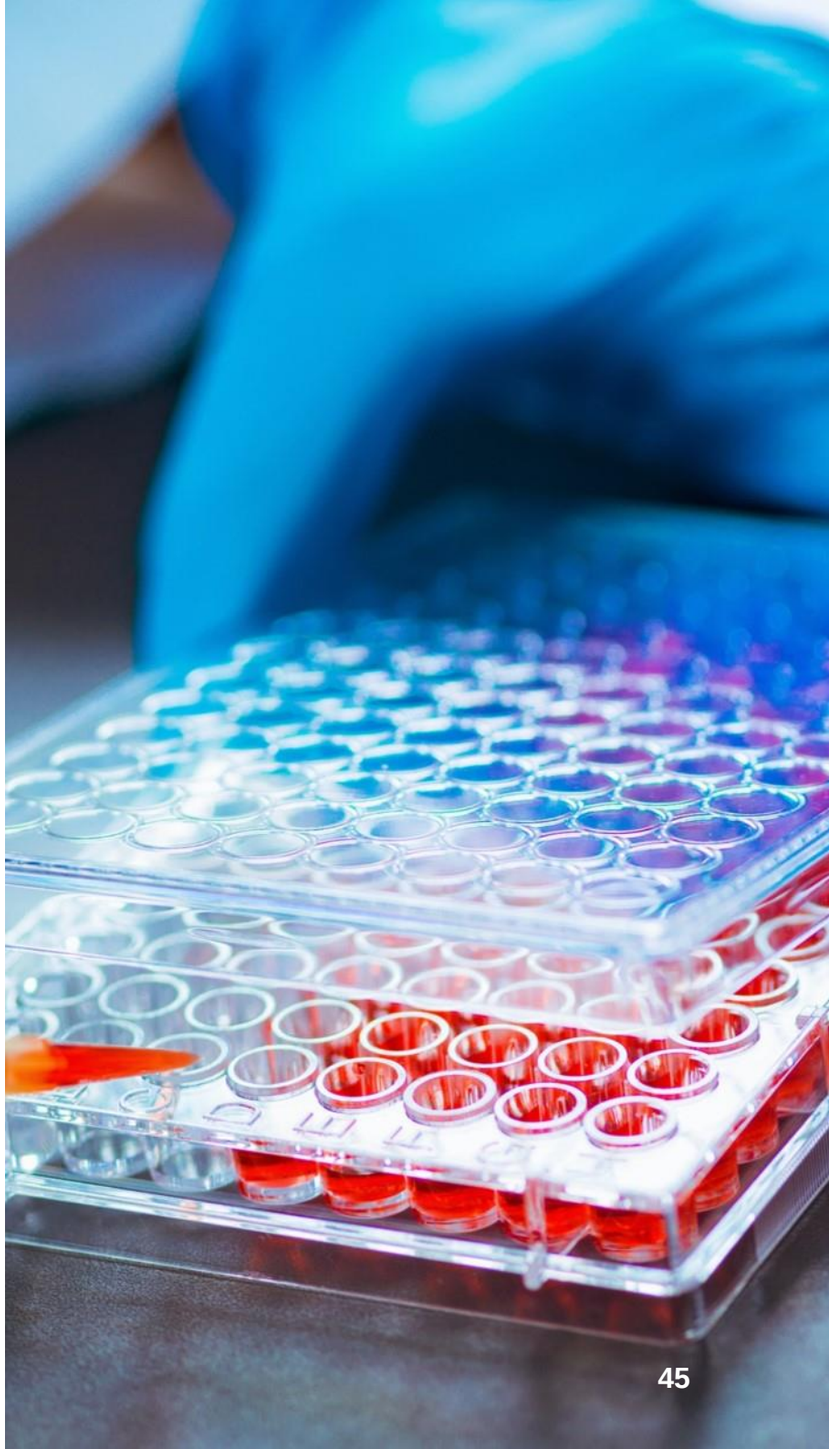
IVD/CDx in clinical trials with drugs (1)

Use of IVD in the context of clinical drug trials only if

- IVD with CE marking according to IVD Regulation 2017/746 ("**IVDR**")
- (and use within CE marking)
- Use of LDT (laboratory developed tests)
- Device used in parallel to clinical trial for performance studies within the meaning of **Art. 2 (45) IVDR**:

"***'device for performance study'*** *means a device intended by the manufacturer to be used in a performance study.*

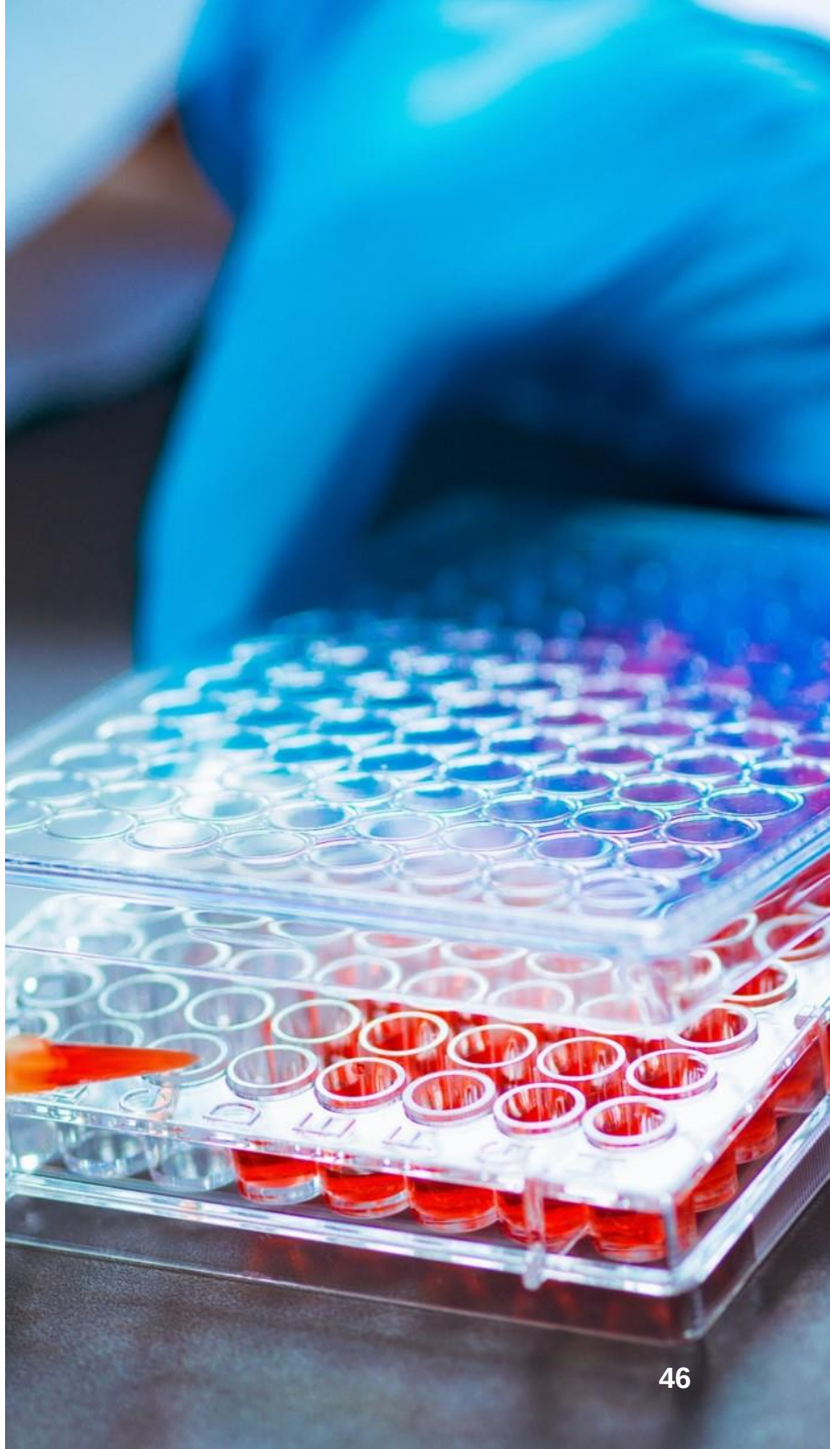
A device intended to be used for research purposes, without any medical objective, shall not be deemed to be a device for performance study."



IVD/CDx in clinical trials with drugs (2)

Do all assays used in a clinical drug trial have to comply with the requirements of the IVDR?

- No, only those assays that qualify as IVDs.
- The scope of application of the IVDR is only opened if the assay is an IVD in the sense of Art. 2 No. 2 IVDR.
- (+), if the assay has a medical purpose within the clinical trial (e.g., if the assay serves as the basis for decisions about the medical treatment of the subjects or their follow-up care).
- Medical purpose is assigned by
  - **Manufacturer** of the assay specifying a purpose of use that meets the IVD definition
  - **Sponsor** of the clinical drug trial itself, if it assigns a medical purpose to the assay as part of the clinical trial **(Consequence: Sponsor itself becomes the manufacturer of the IVD with all associated obligations!)**



IVD/CDx in clinical trials with drugs (3)

Example of assays used in clinical trials and qualifying as IVDs (according to MDCG 2022-10, Q&A No. 6)

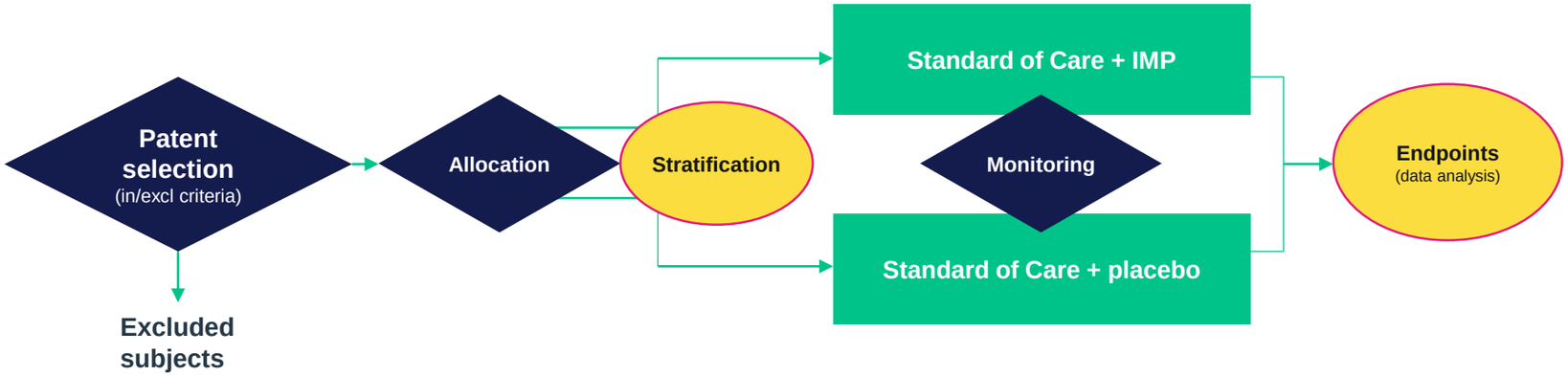
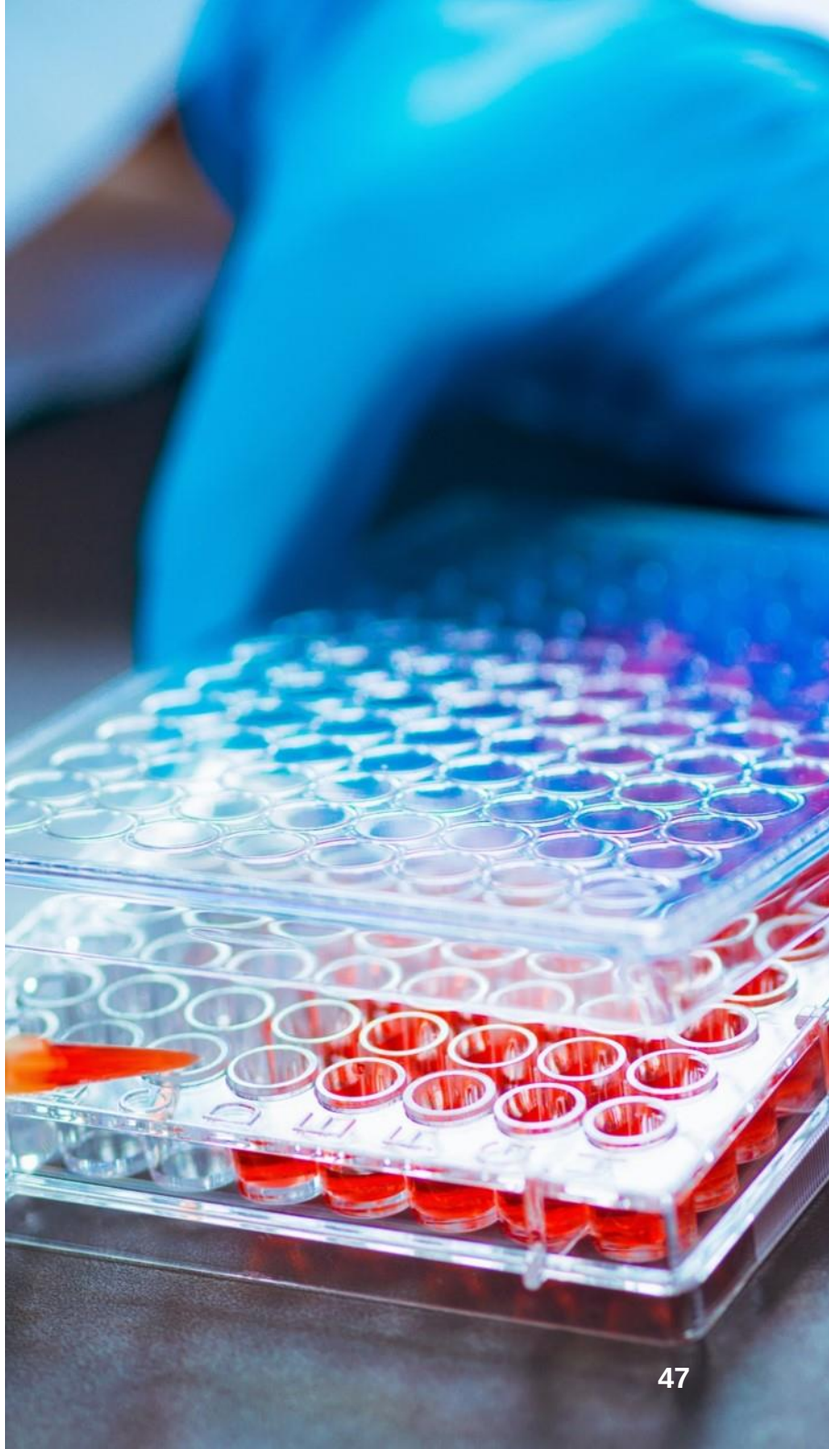


Fig. 1 Simplified examples of use of assays on human samples in a clinical trial. Assays marked in blue (diamonds) are considered to be assays which will likely be considered IVDs as they are used for medical management decisions of trial subjects within the trial. The processes in yellow pink (ellipses) are considered to likely not to impact the medical management of the trial subjects and therefore would not have a medical purpose in the trial.



14 Clinical Trial Agreements – Aspects to consider in negotiations

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)

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, MDR and IVDR** clearly state 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, MDR and IVDR 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 oblige the sponsor to provide comprehensive information to trial subjects, also from a data protection point of view!
- In addition to the **CTR, MDR and IVDR**, 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.*

Impact of General Data Protection Regulation on clinical trials regulation in the EU (3)

Re. clinical trials with medical devices and IVD: Sec. 29 of the German Medical Devices Implementation Act (MPDG)

He/she must be informed of the purpose and scope of the processing of these data, in particular that

1. *The data collected, to the extent necessary,*

a) *will be kept available at the trial site for the duration of the clinical trial, performance study or other clinical investigation for inspection by the supervisory authority or authorized representatives of the sponsor in order to verify the proper conduct of the clinical trial, performance study or other clinical investigation,*

b) *pseudonymously forwarded to the sponsor or a body appointed by the sponsor for the purpose of scientific evaluation,*

c) *in the case of use of the test or study results for conformity assessment, be passed on in pseudonymized form to the manufacturer and to the notified body involved in carrying out a conformity assessment procedure, to the European Commission and, where applicable, to expert bodies in accordance with Article 106 MDR,*

d) *in the case of adverse events, serious adverse events and device deficiencies, be shared in pseudonymous form by the investigator with the sponsor for recording in accordance with Article 80(1)(a) to (c) MDR or Article 76(1)(a) to (c) IVDR,*

e) *in the case of a serious adverse event that has a causal relationship with the investigational device, a comparator, or the investigational procedure, or where a causal relationship is reasonably possible, pseudonymized by the sponsor to the authorities of the other Member States of the European Union via the electronic system referred to in Article 73 MDR or Article 69 IVDR, in accordance with Article 80(2) MDR or Article 76(2) IVDR*

2. *in the event of withdrawal of consent to participate in the clinical trial, performance study or other clinical investigation, the stored data may, alone or together with the withdrawal of consent pursuant to the first sentence, continue to be used in accordance with Article 62(5) MDR or Article 58(6) IVDR, to the extent necessary in order to*

a) *achieve or not seriously compromise the objectives of the clinical trial, performance study or other clinical investigation; or*

b) *ensure that interests of the trial subjects that are worthy of protection are not compromised,*

3. *The data are stored in accordance with the requirements of Annex XV, Chapter III, Section 3 of the MDR or Annex XIV, Chapter II, Section 3 of the IVDR for the periods specified therein.*

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).

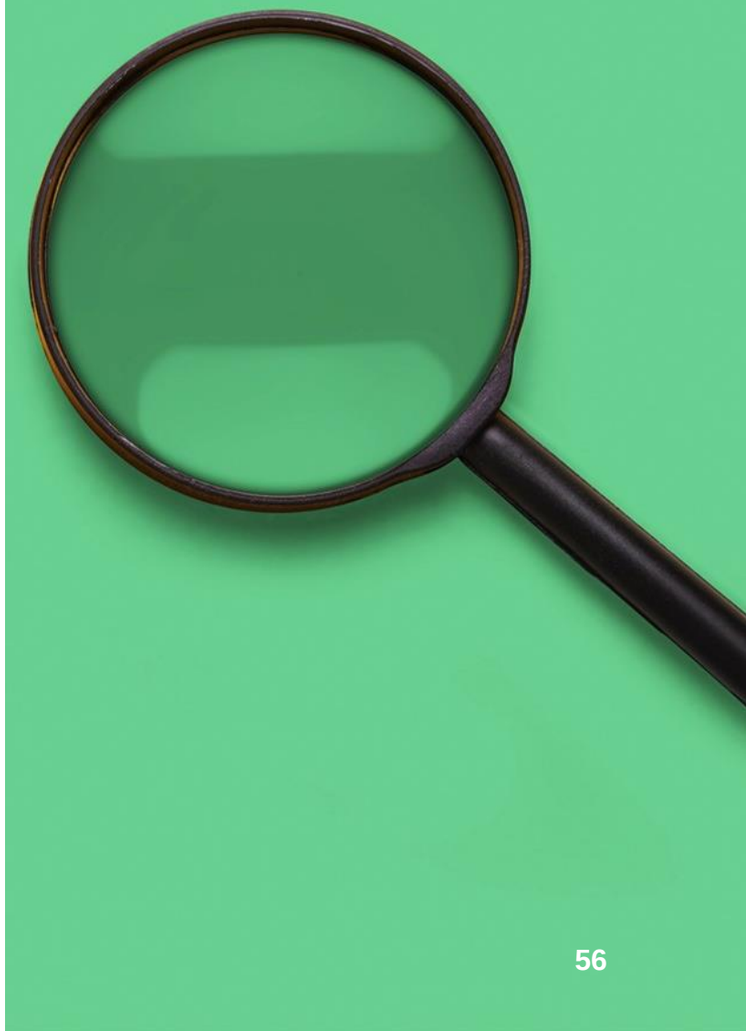
Can’t be waived/limited by agreement between employee and institution

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.

Thank you very much for your attention!

Questions?

Your AGG Team

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Alan is recognized by *Chambers USA America's Leading Lawyers* for Life Sciences, Regulatory/Compliance and has been selected for inclusion in the International *Who's Who of Life Sciences Lawyers* from 2013-2020. Nominees are selected based upon comprehensive, independent survey work with both general counsel and private practice lawyers worldwide. He serves as general counsel of The Sharing Alliance Inc., a pharmaceutical trade organization focused on compliance with the Prescription Drug Marketing Act and sample accountability.

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Best Lawyers in America®, Biotechnology and Life Sciences Practice, FDA Law, 2018-24

Chambers Global, Life Sciences Regulatory and Compliance – USA, 2020-23

Chambers USA: America's Leading Lawyers, Life Sciences: Regulatory/Compliance, 2015-23

JD Supra Readers' Choice Top Author in Life Sciences, 2018, 2020-21

Who's Who Legal, Life Sciences: Regulatory, "Global Leader," 2013-23

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Manja advises pharmaceutical and biotechnology companies, medical device manufacturers, and food producers on all matters relating to intellectual property and regulatory questions for many years. A focus of her practice involves advising clients on contractual projects of a complex and cross-border nature, in particular, research and development cooperations, manufacturing agreements, distribution agreements, licencing agreements, as well as providing advice on all matters relating to transactions.

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Highlighted as Lawyer of the Year for Pharmaceuticals Law, Best Lawyers in Germany, Handelsblatt 2022, 2023

Highlighted as Best Lawyer for Intellectual Property and Pharmaceutical Law, Best Lawyers in Germany, Handelsblatt 2018-2023

Highlighted as Best Lawyer for Biotechnology Law and Life Sciences Practice, Best Lawyers in Germany, Handelsblatt 2022, 2023

Highlighted as Best Lawyer for Information Technology Law, Best Lawyers in Germany, Handelsblatt 2022, 2023

Frequently recommended for Pharmaceuticals and Medical Products, JUVE 2016/17, 2017/18, 2018/19, 2019/20, 2020/21, 2021/22, 2022/23

“The Munich team around Epping is renowned for its regulatory advice on pharmaceutical law.”, JUVE Legal Directory 2019/2020

“‘Excellent lawyer’, Manja Epping ascends the rankings on the back of numerous positive comments.”, Chambers 2017

Frequently recommended for Life Sciences, Who‘sWhoLegal 2016

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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.

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