TaylorWessing

Session #8

Webinar

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COFFEE BREAK Life Sciences Start-ups

Clinical Trials in the Medical Devices Area

Tips and Tricks for CTA Negotiations

21 August 2024 | Sarah Aschenbrenner

Agenda

1. What is the Key Regulatory Framework?
2. What is a Clinical Evaluation and why is it required?
3. What is a Clinical Investigation and when is it required?
4. What are essential Terms for CTAs?

1 What is the Key Regulatory Framework?

What is the Key Regulatory Framework for Clinical Trials with Medical Devices?

Regulation 2017/745 – Medical Device Regulation “MDR“

- Definition of roles and responsibilites of economic operators.
- Requirements for medical devices, such as general safety and performance requirements or requirements for placing the medical device on the market.

German Medical Device Operator Regulation (MPBetreibV)

- National particularities, such as specific requirements for clinical trials.

2 | What is a Clinical Evaluation and why is it required?

What is a Clinical Evaluation?

Art. 2 No. 44 MDR "*clinical evaluation" means a systematic and planned process to continuously generate, collect, analyse and assess the clinical data pertaining to a device in order to verify the safety and performance, including clinical benefits, of the device when used as intended by the manufacturer*.

- Manufacturers are obligated to conduct a clinical evaluation for the medical device to demonstrate conformity with general safety and performance requirements, evaluate undesirable side-effects and the acceptability of the benefit-risk- ratio.
- Clinical evaluation is an ongoing process and must be conducted throughout the entire life cycle of a medical device and for different purposes, e.g. to obtain the CE-marking.
- Clinical evaluation is a theoretical assessment of already existing data.

3 | What is a Clinical Investigation and when is it required?

What is a Clinical Investigation?

Art. 2 No. 45 MDR "*any systematic investigation involving one or more human subjects, undertaken to assess the safety or performance of a device*".

- Clinical Investigations are (with exceptions) mandatory for implantable medical devices and Class III medical devices (Art. 61 para. 4 and 6 MDR).
- Clinical Investigations shall be performed for products without an intended medical purpose listed in Annex XVI, unless reliance on existing clinical data from an analogous medical device is duly justified Art. 61 para. 9 MDR).
- Manufacturers must undertake a strategic regulatory assessment to determine the necessity and extent of clinical evaluations, minimising unnecessary investigational burdens.

When are Clinical Investigations Not Required?

Clinical evaluation shows adequate existing clinical data:

- Not applicable to implantable devices and Class III devices.

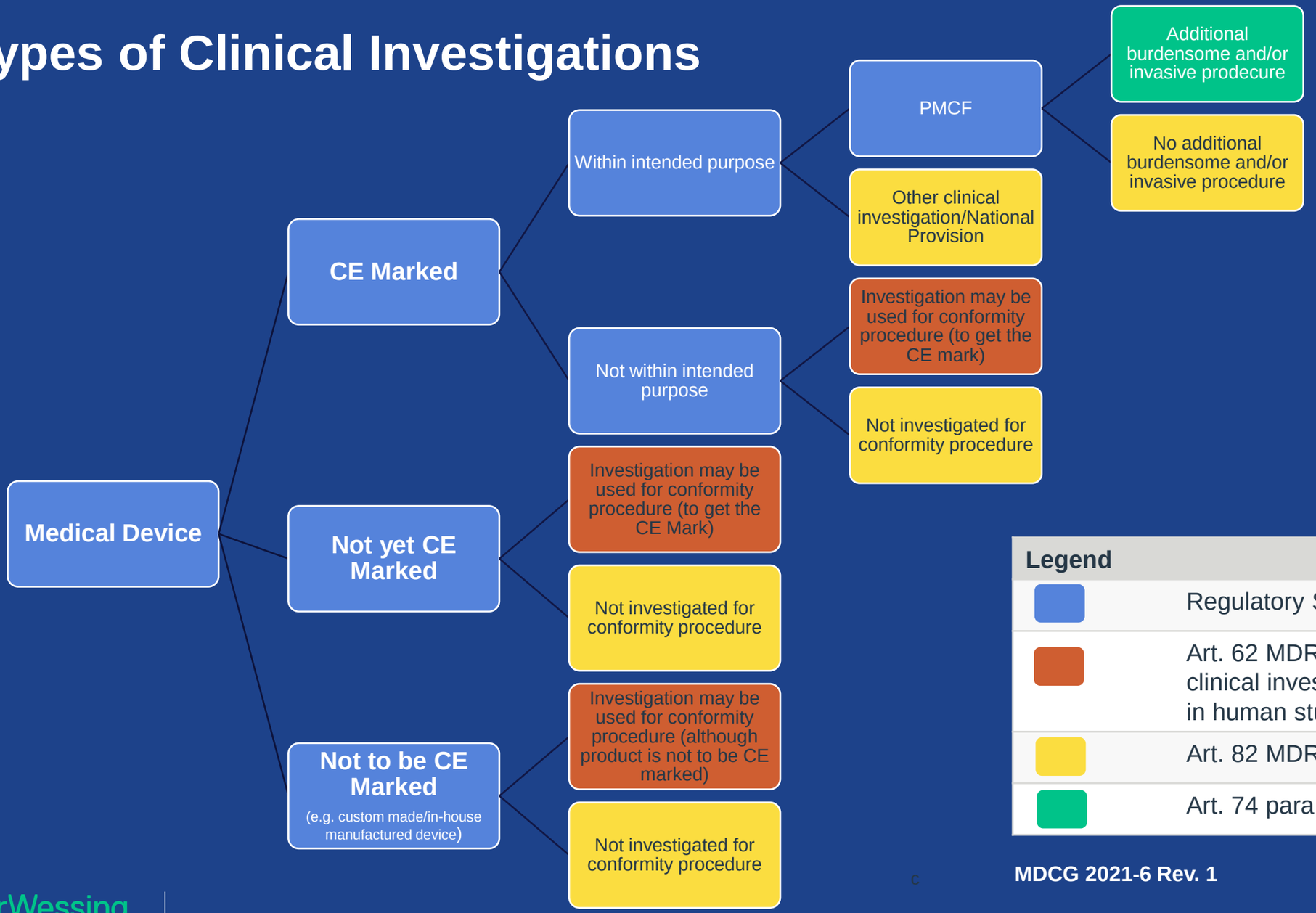
Equivalence Assessment:

- Comparative analysis with an equivalent device may suffice under specified conditions.

Regulatory Note:

- Manufacturers must undertake a strategic regulatory assessment to determine the necessity and extent of clinical evaluations, minimising unnecessary investigational burdens.

Types of Clinical Investigations



Legend	
	Regulatory Status/Scenario
	Art. 62 MDR (Investigation refers to clinical investigation, pilot studies or first in human studies)
	Art. 82 MDR/National provisions, if any
	Art. 74 para. 1 MDR

MDCG 2021-6 Rev. 1

4 | What are essential Terms for CTAs?

Clinical Trial Agreement

- Clinical investigations should always be subject to a written agreement between the parties involved.
- The CTA provides the roles and responsibilities of the parties involved and particularly ensures that
  - the sponsor complies with regulatory framework;
  - the sponsor can use the results without restrictions.

Essential Contract Terms – Contract Template

Use of contract templates

- Mandatory use of official standard contract templates in some member states of the EU, such as France and Italy.
- In Germany standard contractual clauses are to be implemented for clinical trials with medicinal products under the new German Medical Research Act.
- Decision on whether to use the sponsor’s own contract template or the institution’s.

Essential Contract Terms – Regulatory Aspects

- Be aware that regulatory obligations (e.g. recordkeeping or monitoring) are addressed to the sponsor of a clinical trial and do not automatically apply to the institution.

- Include contractual obligations of the institution to either comply with the regulatory obligations or support the sponsor in fulfilling such obligations.

Essential Contract Terms – Regulatory Aspects

Compliance

- Obligating the institution to comply with applicable law and the study protocol.

Data protection

- Obligating the institution to interview the patient and only include patients that have signed an authorized ICF.

Reporting

- Obligating the institution to report all necessary events (SAE, device deficiency) in due time.

Termination

- Conditions under which the agreement may be prematurely terminated, detailing the consequences and handling of ongoing or pending trials.

Inspections and Monitoring

- Access rights for the sponsor/CRO and regulatory authorities to conduct audits and monitoring.

Essential Contract Terms – Compliance Aspects

Be aware that your contracting party is a health care organization which requires adherence with specific compliance aspects (e.g. criminal law).

Terms for loaning the medical device to the institution

- Define terms for loaning medical devices to the institution, including duration of the loan and specific usage conditions.

Payment terms

- Payments should only be made to the institution – not individual personnel of the institution.
- Include a concrete budget per patient that represents fair market value.

Essential Contract Terms – ‘Commercial’ Aspects

Ensure the protection and use of results and inventions made in relation to the medical device during the clinical trial.

Confidential information

- Include confidentiality provisions to protect proprietary information related to the medical device and clinical trial.

Rights to results and inventions

- Clear allocation of all rights to results and inventions to the sponsor.
- Obligate the institution to only use personnel which has waived its negative publication right.

Questions and discussion

Your Taylor Wessing Team

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Sarah absolved her first state examination at the Ludwig-Maximilians-University Munich. After her legal clerkship at the Higher Regional Court of Munich and the second state examination in 2021, she was admitted to the bar in 2022. Sarah previously worked at Fieldfisher before joining Taylor Wessing as an associate in 2023.

Languages

- German, English

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Key areas of expertise

- Patents, Technology & Life Sciences

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