Clinical Evaluation Assessment Report (CEAR) Template (MDCG 2020-13)

Slides released on 16OCT2020 are for general educational use. Please share if helpful!

About Frestedt Incorporated

Since 2008, Frestedt (www.frestedt.com) and Alimentix (www.alimentix.com) have been delivering customized products and services to address specific clinical, regulatory, quality and engineering (CRQE) needs.

- ✓ We are a small, dynamic, woman-owned business and we work as an integrated extension of your team while ***providing exactly the right solution*** within specific timelines and budgets.
- ✓ We support ***details*** from creating a clinical trial to developing and troubleshooting clinical data reports
- ✓ We deliver ***solutions*** from creating regulatory documents to negotiating with regulatory authorities about drug, device and food products.
- ✓ We build ***quality*** systems and deliver engineering services designed to secure the success of our client's products in US and global markets.

For more info, please call: +1-952-426-1747
or email: info@frestedt.com

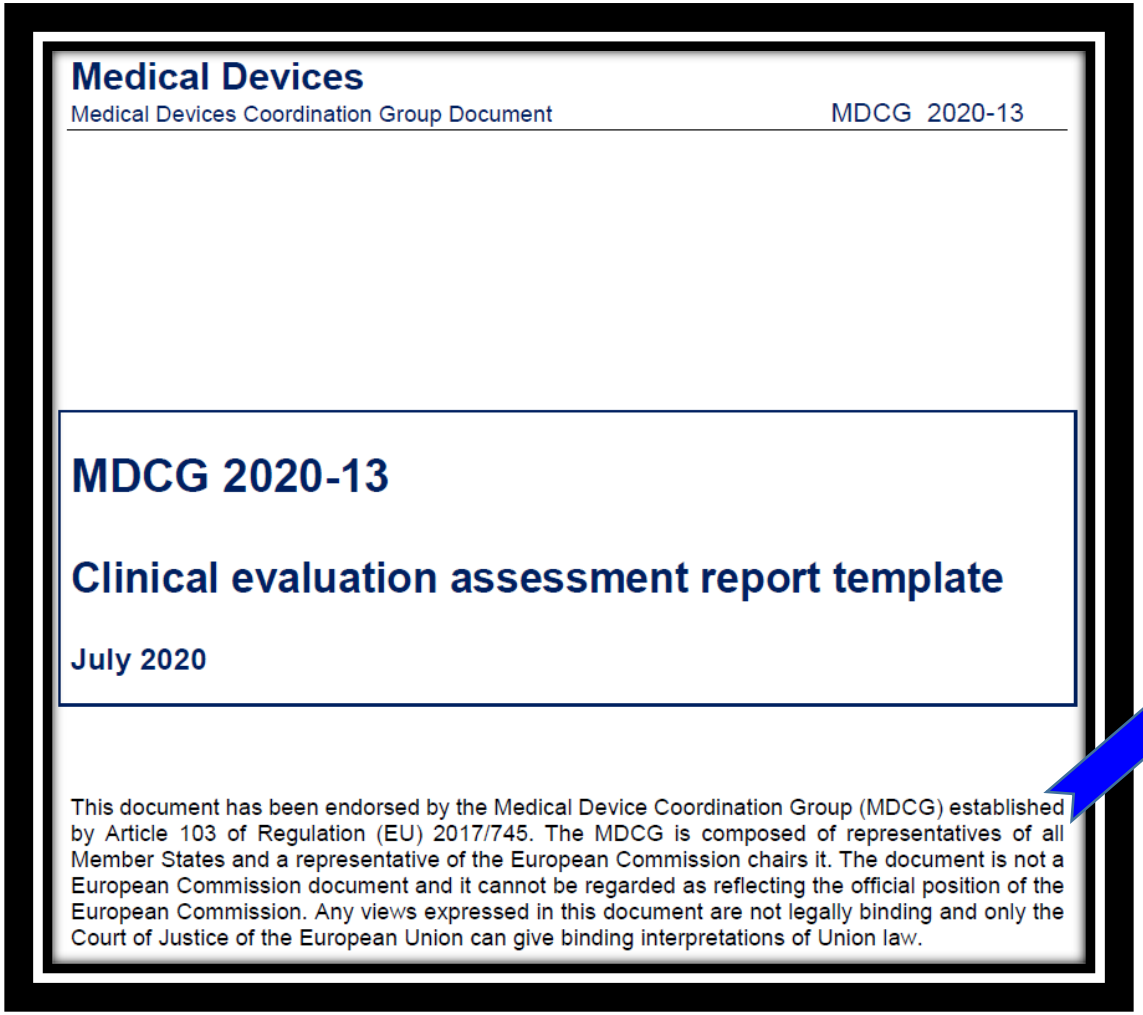
Introduction and Purpose

This slide deck provides a summary of the Medical Device Coordination Group template

“MDCG 2020-13 Clinical evaluation assessment report template July 2020”

NOTE: These slides provide notified body (NB) template training to support learning about Clinical Evaluation Reports (CERs)

Template Cover Page



Medical Devices

Medical Devices Coordination Group Document MDCG 2020-13

MDCG 2020-13

Clinical evaluation assessment report template

July 2020

This document has been endorsed by the Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/745. The MDCG is composed of representatives of all Member States and a representative of the European Commission chairs it. The document is not a European Commission document and it cannot be regarded as reflecting the official position of the European Commission. Any views expressed in this document are not legally binding and only the Court of Justice of the European Union can give binding interpretations of Union law.

NOTES: MDCG includes "representatives of all Member States" and "European Commission chairs" – they oversee NBs

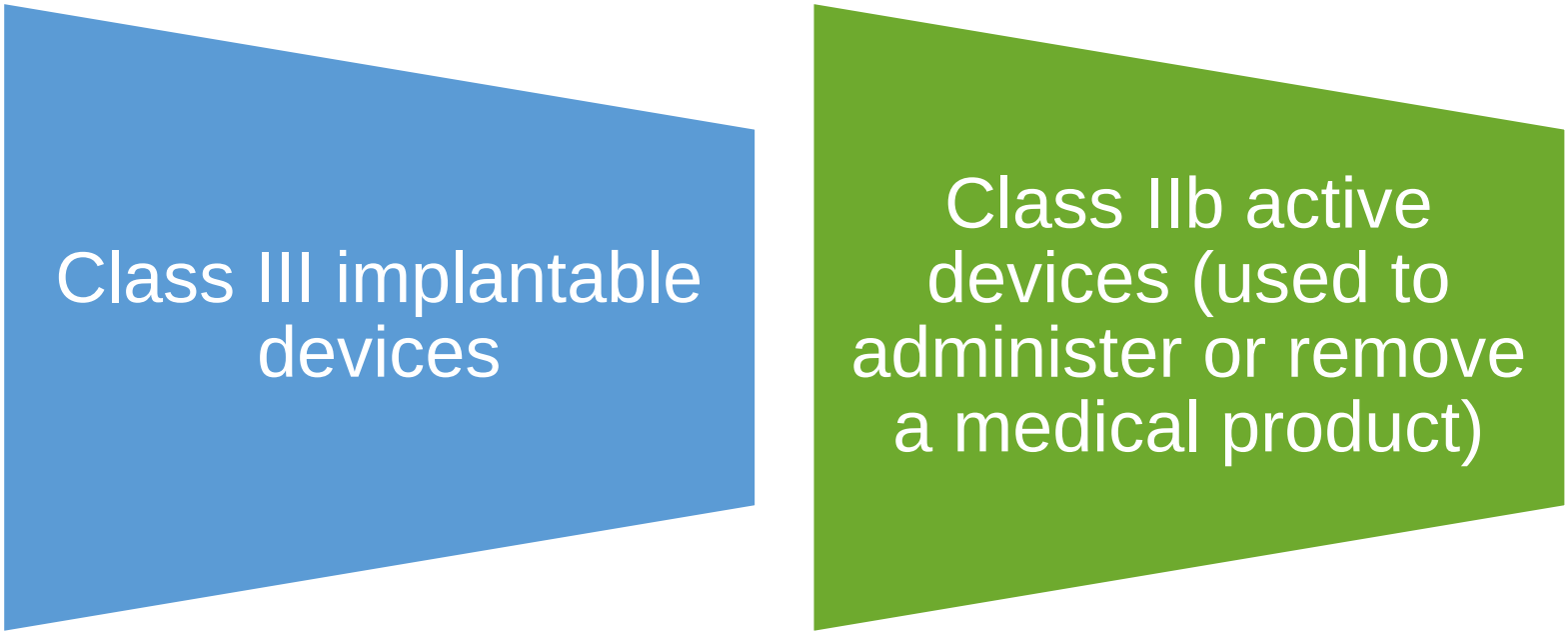
History: Notified Body CER Review

Notified body (NB) assesses **Clinical Evaluation Report (CER)** in **Clinical Evaluation Assessment Report (CEAR)** by:

- Checking REQUIRED CER alignment with benefit-risk management, non-clinical data, instructions for use and conformity with general safety and performance requirements (GSPRs)
- Assessing suitability of data from "claimed" equivalent devices
- Reviewing supporting information and state of the art (SOTA) data
- Verifying conclusions are adequate and supported by clinical evidence
- Determining further required NB review at clinical evidence milestones based on post-market surveillance (PMS) and post-market clinical follow-up (PMCF) data
- Sending CER for Expert Panel review, if required

Required Expert Panels

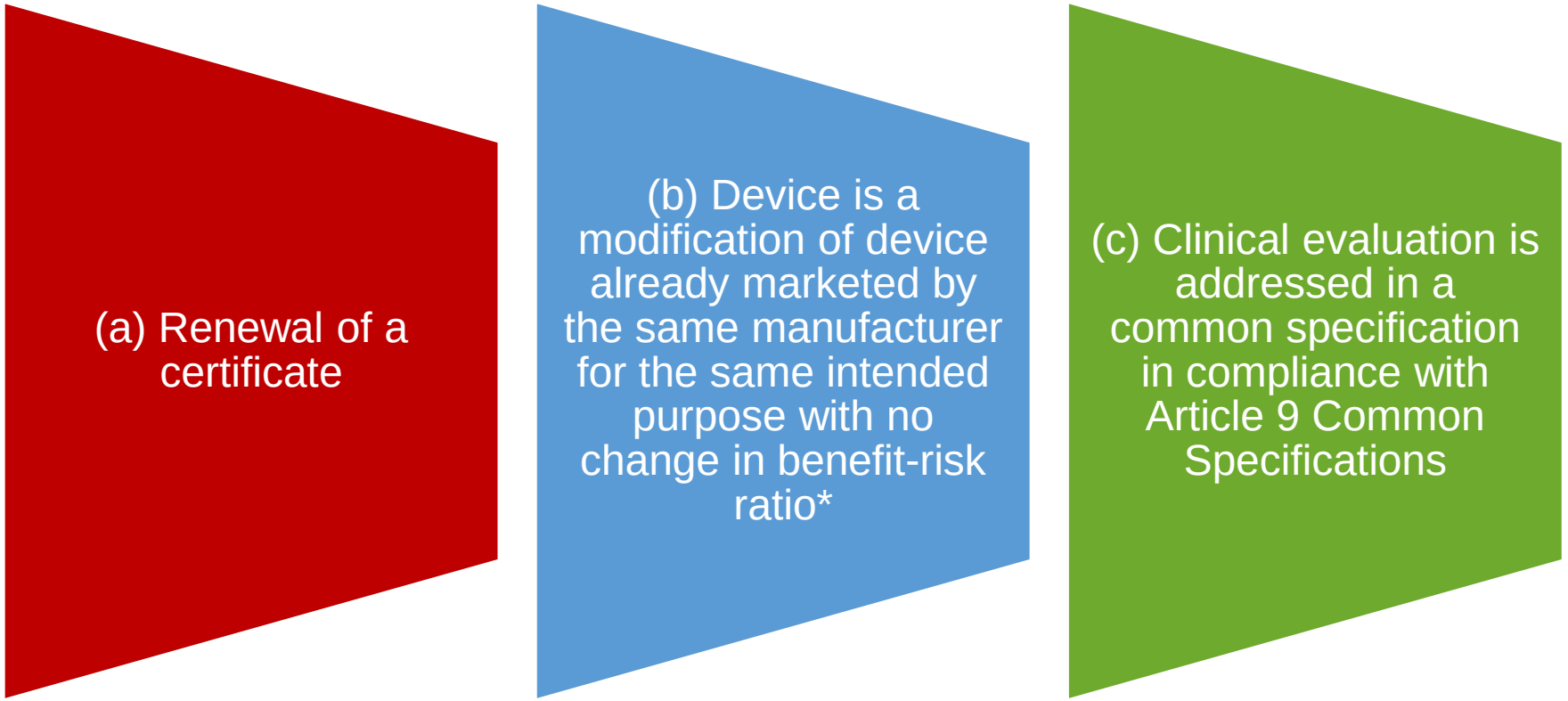
Expert panel assessment is required for:



Per article 54(1)

Expert Panel Exceptions

Three exceptions to required expert panels [Article 54(2)]



*See “MDGC 2019-3 Rev. 1 Interpretation of Article 54(2)b”

Expert Panel Assessment

During the **clinical evaluation consultation procedure (CECP)**, the expert panel needs the CEAR to provide sufficient information about the manufacturer's clinical evidence, in particular:

- "the benefit-risk determination, the consistency of that evidence with the intended purpose, including the medical indication or indications and the PMCF plan."
- "Expert panels may also request the notified body to present its conclusions regarding the clinical evaluation assessment report."

CEAR Template

The **CEAR** template represents **minimum content** for NB review process – each NB needs **standard operating procedures (SOP)** for their CEAR work!

- NB documents non-compliances, deficiencies and follow-up actions required to resolve non-compliances
- NB must provide access to complete "audit trail" of NB's CEAR actions if requested by designating authority
- NB responds to Expert Panel requests, if required
- NB grants positive assessment only after all findings are closed

CEAR Template Sections

A. Administrative Particulars
B. NB Reviewers
C. Device Description
D. Clinical Literature Review
E. Clinical Investigations
F. PMS, PMCF and update plans
G. IFU, SSCP, Labeling
H. Conclusions
I. **Article 54** Consultations for certain Class III and IIb
J. **Article 61(10)** Clinical Data Deemed "Not Appropriate"
K. **Article 61(2)** Clinical Development Strategy

Section A: Administrative Particulars

Device Information	Name, model, unique device identifier (UDI), certificate number, risk class, intended purpose
Manufacturer Information	Name, Single Registration Number (SRN) and authorized representative (if applicable)
Notified Body	Name, number, contact information (must check which parts of template were used)
Assessment Type	Initial, update, re-certification, technical documentation for Class IIa/b on sampling basis
CER Authors	Signed and dated, CVs, CER required expertise

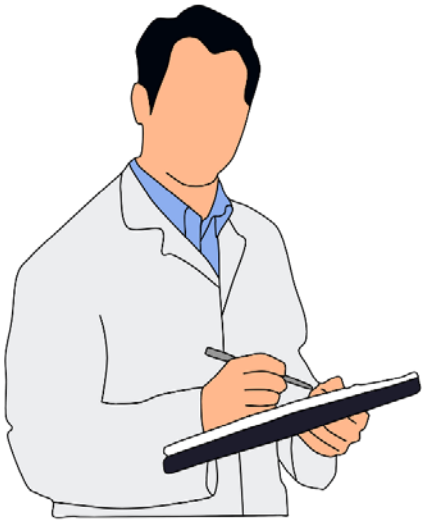
Section A: List References

- **If appropriate**, NB will list:
  - Technical file identification number, if available
  - Technical documentation assessment report (TDAR) reference, if available
  - Documents assessed (e.g., CER, clinical investigation plan/report, publications, etc.)

Section B: Justify NB Reviewers

NB reviewers involved in CER Assessment

- Identify NB reviewer with relevant clinical expertise
- State relevant NB reviewer experience
- Justify additional reviewers (names, specific aspects assessed, relevant competence/experience)



Section C: Device Description

Device Description	Device, intended purpose/population, functions, components, operation, novel features
Classification	Applicable classification rules
Configurations/ Variants	Sizes, design features, device images, history and changes, reasons for design variations
Accessories	Compatible devices/components, packs, images/diagrams, clinical safety impact
Prior/Similar Devices	Previous generations, similar devices, sales volumes, time on market (in EU, elsewhere)
BRIEF Clinical Evaluation Plan	GSPRs, intended purpose, indications, contraindications, benefits, outcomes, methods, future plans

Section C: Performance & Safety

Clinical Performance – NB must summarize in the CEAR how the clinical data provided in the CER demonstrate the device **achieves the claimed "intended purpose**… leading to a **clinical benefit** for patients, when **used as intended**…"

Clinical Safety – NB must answer several questions: Does CER "adequately" address safety including **"residual risks and undesirable side effects"**? Does CER specify the **"qualitative and quantitative" methods** used to evaluate safety? Does CER accurately describe the **impact of complaints, trends, vigilance issues**?

Section C: Device Information

Specifications	Common specifications, harmonized standards, other solutions - deviations/data integrity impact?
Equivalence	Clinical, biological, technical assessments by clinical trial or literature? Exclude not relevant devices. Describe non-compliance!
Access to Data	Technical documentation contract for equivalent class III device “by another manufacturer”
State of the Art (SOTA)	Benchmark devices, alternative treatments, same indication, performance and safety endpoints; are adequate parameters specified for benefit/risk?
Novelty	Possible clinical or health impacts on benefit/risk

Section D: Clinical Literature Data

NB must briefly summarize

- **Search Criteria addressing**
  - All sizes, variants, models, accessories
  - Same clinical condition
- **Selection Criteria related to**
  - Device under evaluation and equivalent device
  - SOTA and alternative therapy

Section D: Literature Search Protocol

NB must summarize literature search strategy

- Are search terms broad enough to determine SOTA, “establish benchmarks”, adverse events (AEs), undesirable side effects?
  - **NOT RESTRICTED to device under evaluation alone!**
- Does CER include:
  - Use of multiple databases (e.g., EMBASE, PubMed)
  - Appropriate inclusion and exclusion (I&E) criteria
  - Favorable and unfavorable data
  - Methods to avoid duplication of data and bias
  - Assessment of deviations and adequacy of search methods

Section D: Literature Appraisal (I&E)

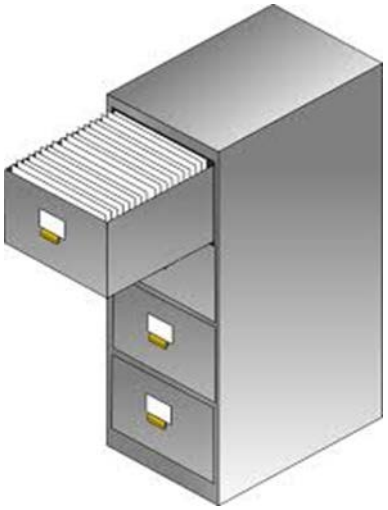
NB must justify appraisal acceptability

Are data from a given article of **sufficient quality and relevance** to be included in the CER?

- ✓ study design
- ✓ bias
- ✓ peer reviewed
- ✓ scientific validity
- ✓ contribution
- ✓ weight (scientific quality and relevance)

Section E: Clinical Investigation Data

NB will assess clinical investigations conducted by manufacturer



- Pre or post market?
- Public registration? EUDAMED?
- Publication of results?
- Are conclusions valid, based on trial data?
- Rationale for lack of sponsored trials if NO clinical investigations performed by manufacturer?
- Competent/Regulatory Authority correspondence?

Section E: Clinical Investigation Plan

NB will assess adequacy of clinical investigation plan (CIP) to demonstrate "safety, performance and benefit risk of subject devices"

- Scope
- Study design
- Devices identified
- Patient population
- Patient numbers
- Objectives and endpoints
- Length of follow up and intervals
- Study locations

Section F: PMS, PMCF, update plan

- Report appropriateness of **PMS and PMCF plans and reports** and **periodic safety update report (PSUR)**, where relevant and available
- Describe PMS/PMCF verification of no difference between device under evaluation and equivalent devices
- Is PMCF planned (esp. to demonstrate implantable or class III device safety and performance)?
- State if acceptable justification provided for not performing a PMCF
- Describe when CER updates will be assessed

Section G: Information Materials

Are **information materials** compliant with MDR?

Instructions for Use (IFU), Summary of Safety and Clinical Performance (SSCP), labelling and other information supplied with device

Frestedt incorporated

Section G: Device Info. questions

Does clinical evidence support:

- ✓ Intended purpose?
- ✓ Intended patient population?
- ✓ Intended users and needed training for users?
- ✓ Device safety and performance?
- ✓ **Quantitative** AND qualitative risk estimation?

Are warnings adequately described?

Does device require limitations?

Are further contraindications needed?

Is information clear, understandable, aligned with technical documentation?

Section H: Summary

The NB will provide a summary of:

- **clinical investigations** (with reliability assessment of monitoring, standards application)
- **equivalence**, compliance with Annex I
- **compliance with relevant GSPRs**

  (HINT: Review GSPRs 1, 6, 8)

- **safety and performance data**

Sufficient clinical evidence?

- Unanswered questions for PMS / PMCF

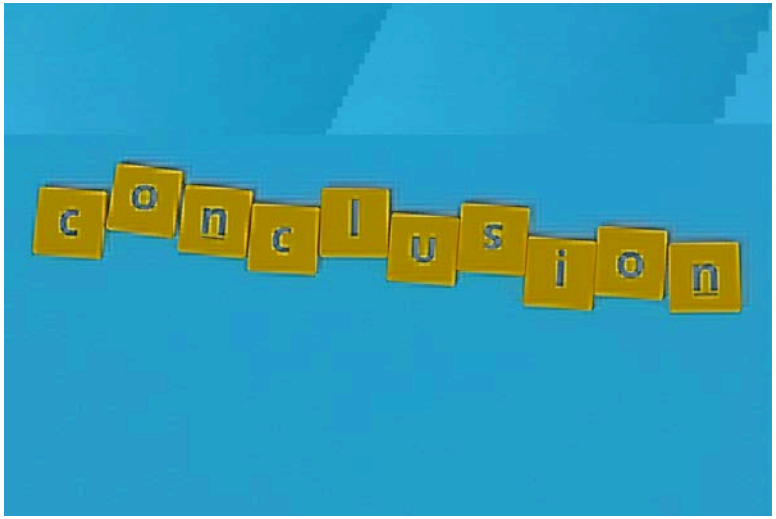
https://commons.wikimedia.org/wiki/File:Question_book_compressed_.svg

Frestedt incorporated

Overall CEAR Conclusions

NB will summarize:

- Clinically-relevant benefits
- Clinically-relevant risks
- How benefits outweigh risks
- Alignment between clinical evaluation and risk management
- Resolution of outstanding deficiencies and non-compliances
- **Recommendation regarding CEAR conclusions for granting certification**



- ✓ *Are PMS/PMCF plans adequate?*
- ✓ *Any milestones for further review?*
- ✓ *How often is review and why?*

Section I: Consultation Procedure

Specific Considerations: Clinical evaluation consultation for class III and class IIb devices

- Justify if consultation procedure not required
- Recommend relevant scientific panel
- Conclusions for expert panel to consider
  - Novel aspects
  - Benefit-risk determination
  - Consistency of clinical evidence with intended purpose/indication for use and PMCF plan

Section J: Clinical data not required?

- Is manufacturers claimed conformity with GSPR and performance requirements deemed **NOT** appropriate per Article 61(10)?
- If so, evaluate manufacturer's **evidence-based justification (JUS)** and describe:
  - Performance evaluation
  - Bench testing
  - Pre-clinical evaluation
- Consider clinical data from literature including similar devices, risk management support of non-clinical tests, interaction between device and body from non-clinical data, intended performance, claims needing support

Section K: Expert Panel Consultation

Manufacturer may choose “voluntary consultation” with an expert panel prior to clinical evaluation for class IIb and III devices

- NB will assess whether expert panel “clinical development strategy” recommendations were taken by manufacturer or justified if not taken

Conclusion

Template details CER qualities enforced by NBs

- CEARS should describe NB evaluation of…
  - ✓ Administrative details (device, NB, data)
  - ✓ Competence of NB reviewers
  - ✓ Safety and performance, device details
  - ✓ Clinical literature, investigations, PMS, PMCF plans
  - ✓ Information provided with device
  - ✓ Sufficient clinical evidence and CER conclusions
  - ✓ Benefit / risk profile and compliance with GSPRs

References

1. MDCG 2020-13 “Clinical evaluation assessment report template” accessed on 30AUG2020 at https://ec.europa.eu/health/sites/health/files/md_sector/docs/mdcg_clinical_evaluationtemplate_en.pdf
2. MDCG 2019-3 “Interpretation of Article 54(2)b” accessed on 15OCT2020 https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_2019_3_rev1_cecp_en.pdf

MDCG=Medical Device Coordination Group

Thank you for reading!

If these slides were helpful or if Frestedt or Alimentix can help in any other way, please let us know!

You can call us at: +1-952-426-1747

or send us an email: info@frestedt.com