[cite]med

PARTICIPANT WORKBOOK

WORKSHOP · EU MDR 2017/745

Learning From Mistakes: Common Pitfalls Of Clinical Evaluation Reports

From A Class III Medical Device

Notified Body Perspective

Anna Varlese
BSI Clinical Assessor

Ethan Drower
Co-Founder, CiteMed

citemed.com
Evidence Management Platform

TT LIFE SCIENCES CONFERENCE

[cite]med

YOUR FACILITATORS

Meet Your Hosts

Thisworkshop is ledby two practitioners with deep experience on both sides of the clinical evaluation process — from writing and reviewing CERs to assessing them as a Notified Body.

Anna Varlese

BSIClinicalAssessor

Anna is a Clinical Assessor at BSI, one of the world's largest Notified Bodies. She specializes in clinical evaluation for Class IIa, IIb, and III medical devices under EU MDR 2017/745 and UK MDR 2002, with deep expertise in software, diagnostics, and complex device systems.

Anna has completed over 900 CER and CEP reviews and counter-signs, and trains alongside BSI's internal clinical review team.

BSI Notified Body | EU MDR | Clinical Assessor | Software & AI Devices

Ethan Drower

Co-Founder, CiteMed

Ethan is a co-founder of CiteMed, an evidence management platform purpose-built for medical device manufacturers navigating EU MDR and FDA regulatory requirements. CiteMed is used by regulatory affairs teams to streamline systematic literature reviews, clinical evaluations, and post-market surveillance.

Ethan works closely with manufacturers and CER writers daily.

CiteMed | Evidence Management | CER Strategy | Regulatory Affairs

ONE QUESTION I WANT ANSWERED TODAY

Views shared during this workshop represent personal expert perspective and are not official statements from BSI or CiteMed. This distinction matters especially during the AI and PMCF discussions.

OVERVIEW

Today's Session At A Glance

DISCUSSION-DRIVEN
Interactive format — your questions and real-world challenges shape the session.

FLEXIBLE TIMING
Sections expand or contract based on where the conversation goes.

GROUP ENERGY
Pace adjusts to the room — no rigid schedule.

1	**Setting the Stage** Introductions · Audience pulse check · Common CER mistakes from the Notified Body view	Lecture
2	**Hands-On CEP Review** Read a real redacted Clinical Evaluation Plan · Form an opinion · Group debrief	Exercise
3	**Reading & Reviewing Complex Documents** How to read a CER you didn't write · Key review strategies · Skimming techniques	Discussion
4	**Working with Your Notified Body** How to respond to feedback · The anti-consulting rule · Making the most of clarifying calls	Discussion
5	**PMS, PMCF & Looking Ahead** The painful truth about PMCF plans · Execution gaps · AI in clinical evaluations	Discussion
6	**Open Q&A & Wrap-Up** Open questions · Key takeaways · Feedback	Q&A

KEEP THIS IN MIND ALL SESSION

A question from a Notified Body is not a question — it is a demand for a documentation update. Nothing communicated verbally can help, because the Notified Body is contracted to evaluate the QMS as written.

MY BIGGEST CHALLENGE WITH CLINICAL EVALUATION RIGHT NOW

MDR ANNEX XIV PART A

Clinical Evaluation Plan — Required Elements

Use this as your review checklist throughout the session.

Every item below is a legal requirement under MDR 2017/745.
Items marked N/A still require a documented rationale.

Intended Purpose & Target Groups

- [ ] Clear specification of intended purpose
- [ ] Target groups with clear indications
- [ ] Contraindications explicitly stated
- [ ] Intended users identified

Safety & Performance Methods

- [ ] Qualitative and quantitative safety methods defined
- [ ] Determination of clear reference to residual risks & side effects
- [ ] Acceptance criteria defined and SoTA-derived

Safety and performance acceptance criteria can be in the CER; only risk acceptability criteria must be in the CEP.

Benefit-Risk & State Of The Art

- [ ] Parameters for benefit-risk acceptability criteria listed
- [ ] Based on current state of the art in medicine
- [ ] Traceable from CEP all the way through the CER

GSPRs

- [ ] Clinically relevant GSPRs identified (1–8 and 23)
- [ ] Missing GSPRs have documented rationale

A GSPR checklist is not required in the CEP, but omissions may be challenged if not clearly justified.

Clinical Development & PMCF

- [ ] Progression from exploratory → confirmatory
- [ ] PMCF plan per Annex XIV Part B included
- [ ] Device lifetime defined and demonstrated

Not mandatory in the CEP — must appear somewhere in the clinical documentation.

Clinical Benefits & Outcomes

- [ ] Detailed description of intended clinical benefits
- [ ] Relevant clinical outcome parameters specified
- [ ] Benefits are measurable and patient-relevant
- [ ] Not just labelled — actually specific & measurable

CLINICAL BENEFIT (ART. 2.53)

Positive impact on health — meaningful, measurable, patient-relevant clinical outcome.

CLINICAL PERFORMANCE (ART. 2.52)

Ability of a device to achieve its intended purpose, leading to a clinical benefit.

SUFFICIENT CLINICAL EVIDENCE

Data of sufficient amount and quality to allow qualified assessment of safety and benefit.

PMCF (ANNEX XIV PART B)

A continuous, proactive process — complaints alone are passive and do not satisfy this.

WHICH OF THESE ELEMENTS DOES MY CURRENT CEP HANDLE LEAST WELL?

PART 2 — HANDS-ON EXERCISE

Clinical Evaluation Plan Review

Sample CEP — "Hijinx" Health Information System

Redacted real document · MDD → MDR transition device · Read time approx. 8 minutes

INSTRUCTIONS

Read the attached 5-page Clinical Evaluation Plan silently. Using the Annex XIV checklist on the right, identify what is present, what is missing, and what would trigger a question from a Notified Body. Note your reading experience — is the document clear? Does your attention drift? Record your observations in the spaces provided before the group discussion.

WHAT STANDS OUT (GOOD OR BAD)?

WHAT SEEMS TO BE MISSING?

Annex XIV Checklist

- [ ] Intended purpose clearly defined?
- [ ] Target groups specific — not "everyone everywhere"?
- [ ] Indications and contraindications stated?
- [ ] With contraindications present?
- [ ] Clinical benefit — measurable outcome parameters?
- [ ] GSPRs that need clinical support referenced and mapped?
- [ ] Acceptance criteria derived from SoTA?

  Safety and performance acceptance criteria canbe in theCER. Only risk acceptability criteria must be in the CEP.
- [ ] Safety assessment methods defined?
- [ ] Criteria for acceptability of the benefit-risk ratio detailed?
- [ ] Clinical development plan including: (1) development history, and (2) summary of PMCF plan?
- [ ] Pharmaceutical, human, and animal tissue handling addressed or N/A'd with rationale?

QUESTION I WOULD SEND THE MANUFACTURER

PART 2 — DEBRIEF

Group Debrief & Key Findings

Usethe spacesbelow to capture findings from thegroupdiscussion. Note where your observations aligned with others — and what you may have missed.

✓ DONE WELL	✕ FLAGGED ISSUES	ⓘ I MISSED THIS

COMMON PITFALLS IN CEPS — DID YOU SPOT THESE?

- [ ] Intended purpose too generic — device not described
- [ ] Target population is "everyone everywhere"
- [ ] Clinical benefit section missing or vague
- [ ] "Specific & measurable" label but not actually so
- [ ] No clinical outcome parameters defined
- [ ] Contraindications missing entirely
- [ ] GSPRs not referenced or misaligned
- [ ] Risk management section absent or circular
- [ ] No-clinical-data route not justified
- [ ] PMCF described in vague terms
- [ ] N/A items have no rationale
- [ ] "Various" appears repeatedly — always a red flag

THE INSIGHT FROM THIS EXERCISE I WILL APPLY TO MY OWN DOCUMENTS

PART 3 — READING A CER YOU DIDN'T WRITE

Clinical Evaluation Report — Key Sections

Afirstpassofa fullCER takes approximately3hours.A20-minuteCEPreadpredicts most of the issues that will appear. Priority #1 is always traceability.

Priority Scan Framework

Apply to the worked CER example distributed separately

Check These First

- [ ] Traceability: CEPobjectives traceable through CER?
- [ ] Clinical benefits with measurable outcome parameters?
- [ ] Acceptance criteria derived from SoTA?
- [ ] GSPR list complete and mapped to evidence?
- [ ] Device lifetime defined and demonstrated?
- [ ] Preclinical data fully analyzed — not just referenced?
- [ ] PMS / complaint / CAPA data comprehensively discussed?
- [ ] Risk profile clearly compared to state of the art?
- [ ] CER is standalone — no "see tech file"?

SECTION I REVIEWED FIRST — AND WHY

Language To Watch For

"Various sources will be consulted"

"See risk management file for details"

"Clinical benefit: to confirm safety and performance"

"Not applicable — no patient contact"

"An update report will address this"

"Clinical data are proactively collected" (no plan)

Solid Documentation Sounds Like

Numerical acceptance criteria tied to SoTA range

Risk probability + severity + literature reference

Named databases with date-stamped search results

"Device lifetime: X years, validated per [standard]"

SECTION I FOUND HARDEST TO EVALUATE

PARTS 4 & 5

Navigating Your Notified Body & Post-Market Obligations

✓ WHAT A NOTIFIED BODY CAN DO

- ☐ Explain the requirement
- ☐ Point to where it's located in regulation
- ☐ Share their interpretation of the requirement
- ☐ Answer "will this approach fly?" on a call
- ☐ Confirm your plan to address an issue

✕ WHAT A NOTIFIED BODY CANNOT DO

- ☐ Tell you how to comply
- ☐ Answer "how" questions
- ☐ Share what other manufacturers have done
- ☐ Use modal verbs in writing (must, shall, ought)
- ☐ Give advisory-sounding written feedback

ⓘ Tip: A clarifying phone call is worth the cost. Written questions are auditable — that's why they can seem harsh. On a call, you can narrow down solutions before wasting a full review round. *"My plan to address this is..."* is a strong opening.

⊕ Equivalence

Technical + biological + clinical equivalence required. Contract needed for competitor device data under MDR.

↑ Own Data Collection

Clinical investigations, PMCF, registries, PMS. Requires planning — gives you the cleanest evidence base.

◔ No Clinical Data

Only valid if no clinical benefit is claimed. Switching without checking first is one of the most common costly mistakes.

WHAT MAKES A PMCF PLAN ACTUALLY COMPLIANT? NOTES FROM DISCUSSION

THE BIGGEST EXECUTION GAP IN MY ORGANIZATION'S PMCF PROCESS

WRAP-UP

Key Takeaways

Captureyourtopinsights,memorable moments, and the concrete next steps you will actually take.

★ TOP 3 INSIGHTS FROM TODAY

★

★

★

KEY QUOTES FROM THE SESSION

> *"If you don't define specific and measurable objectives and clinical benefit in the CEP, there's no point in the other 700 pages."*

My Action Items

ACTION I WILL TAKE	BY WHEN	WHO ELSE IS INVOLVED

[cite]med

THANK YOU

It Was A Pleasure Having You Here.

We hope today's session gave you practical tools and frameworks to strengthen your clinical evaluation process. Please reach out with any follow-up questions.

WEBSITE

citemed.com

EvidenceManagement Platform
Built on Salesforce

GET IN TOUCH

Ethan Drower
Co-Founder, CiteMed
ethan@citemed.com

REQUEST A DEMO

See how CiteMed streamlines clinical evidence management for your team.

citemed.com/demo →

FOLLOW US

Stay current on MDR updates, clinical evidence best practices, and platform news.

linkedin.com/company/citemed →