

The LINC logo features a stylized graphic of three curved lines in red, orange, and yellow, resembling a flame or a dynamic shape, positioned above the letters 'LINC' in a white, sans-serif font.

LINC

The TU/e logo consists of the letters 'TU' in a dark blue, bold, sans-serif font, followed by a red diagonal slash and the letter 'e' in a dark blue, sans-serif font.

TU/e

The Catharina ziekenhuis logo is a dark grey/black rectangle with the text 'catharina ziekenhuis' in a white, lowercase, sans-serif font.

catharina
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Event adjudication in clinical trials: How does it work? The CEC and DSMB

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Disclosure

Speaker name:

Marc van Sambeek

I have the following potential conflicts of interest to report:

Consulting and speakersfee

WL Gore & Associates

Medtronic

Unrestricted research grants

Medtronic

W.L Gore & Associates

Philips Medical Systems

Disclosure II

I have participated in the following DET trials as a member of the
Clinical Event Committee and/or Data Safety Monitoring Board

- * Levant 1 Trial (Lutonix)
- * IN.PACT DEEP Trial (Medtronic)
- * Biolux PIII Benelux (Biotronik)
- * Eminent Trial (Boston Scientific)
- * Regal Trial (Boston Scientific)

Trial Safety



You may ask yourself, "Why should I try something that researchers are not sure will work?"

Being part of a clinical trial may have risks, but it may also have benefits.

By law, researchers are required to follow strict rules to make sure that trial participants are safe.

Research abuses like the Tuskegee Syphilis Experiment, which began in 1932, before safeguards were in place, will NOT happen again.

Clinical event committee

For certain trials, sponsors may choose a CEC to review important endpoints reported by the investigators to determine if they meet protocol-specific criteria.

Clinical trials are often driven by clinical events, which may lack standard definitions and are subject to interpretations. Sponsors need a method to reduce the impact of this potential variability on conclusions drawn from outcomes data.



Clinical event committee

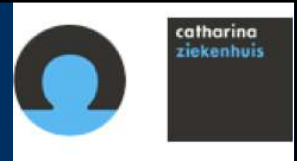
The mission of a **CEC** is a consistent and unbiased adjudication of all pre-specified potential endpoint events (AE, SAE, MAE). The objective of the CEC is to ensure that the endpoint events are judged uniformly, using the same criteria, by one independent group.

Responsibilities:

1. Periodically review, evaluate and adjudicate pre-specified potential endpoint events, according to the protocol-specific criteria.
2. Make recommendations to the investigators to the minimum amount of data that is required to adequately review and adjudicate events (source data).



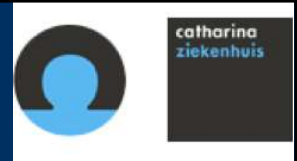
Data Safety Monitoring Board



The Data Safety Monitoring Board (DSMB) is a group of independent individuals, external to the trial, who are experts in relevant areas. They review the accumulated data from the ongoing clinical trial on a regular basis and advise the sponsor about:

- The continued safety of the trial participants.
- The continued validity of the trial.
- The continued scientific merit of the trial.

Data Safety Monitoring Board



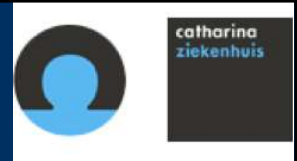
How do Data Safety Monitoring Boards work?

The DSMB convenes when pre-determined analysis points are met – for instance, when 50% of the participants of the trial have reached six months of treatment.

At this time, the sponsor submits a report to the DSMB to consider in light of specific questions.

The DSMB then carefully and rigorously analyses the data and arrives at a recommendation, preferably after reaching a consensus.

Data Safety Monitoring Board



What is a safety signal?

If any concern arises from the data then a safety signal occurs. A safety signal suggests a causal relationship between the intervention and an adverse event or set of related events which is judged to be strong enough to justify further action.

When evidence arises that the original assessment of benefit-risk is no longer favourable, or when the beneficial effect is so evident that it is unethical not to give the treatment to all the participants, then the trial may be prematurely terminated.

CEC and DSMB



Although DSMBs and CECs are similar in that they provide clinical oversight and monitoring of a trial, their function is slightly different as delegated by the sponsor.

CEC: adjudicates all pre-specified potential endpoint events (AE, SAE, MAE).

DSMB: reviews the accumulated data from the ongoing clinical trial on a regular basis and advise the sponsor.

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