WHEN TO ENLIST A DSMB OR CEC *For Your Clinical Trial*

DSMB

- Reviews cumulative study data
- Looks at safety indicators primarily, and may review effectiveness information, to decide whether a study should continue

CEC

- Reviews individual occurrences of specific endpoints or adverse events, such as a heart attack or a secondary intervention
- Determines whether events were possibly connected to the clinical trial and/or investigational product

CHECK ALL THAT APPLY TO DETERMINE YOUR NEEDS

DOES YOUR TRIAL...

- ☐ Have multiple sites participating?
- ☐ Include a complex protocol design (randomization, blinding, crossover arms, etc.)?
- ☐ Evaluate mortality or morbidity as primary endpoints?
- ☐ Carry the potential for unacceptable toxicity risks, based on prior data?
- ☐ Involve emergency research or vulnerable populations (ex., children or elderly)?
- ☐ Carry ethical concerns that may require termination before completion?
- ☐ Raise concerns from a regulatory body that advises independent oversight?

→ **DSMB**

DOES YOUR TRIAL...

- ☐ Have endpoints open to interpretation (ex., determining the severity of a reaction)?
- ☐ Have endpoints that could be misreported or underreported?
- ☐ Include risks that could result from preexisting conditions or exposure to the study/product?
- ☐ Require intervention that is not blinded, introducing potential bias?

→ **CEC**

If you checked items in both categories, you should consider enlisting both a DSMB and a CEC

→ **BOTH**

TAKING THE NEXT STEP TO ENSURE SAFETY

A clinical research organization (CRO) can manage relationships between sponsors and safety boards, assisting with:

- Recruiting, selecting, onboarding and training qualified members
- Obtaining agreements from members and managing payments
- Defining responsibilities and timelines in a project Charter
- Ensuring proper documentation at every step
- Conducting meetings and following up

TO LEARN MORE ABOUT SAFETY MONITORING AND HOW A CRO CAN HELP, DOWNLOAD OUR WHITEPAPER.

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NEED HELP MANAGING YOUR SAFETY MONITORING?

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WE'LL EARN YOUR APPROVAL.

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