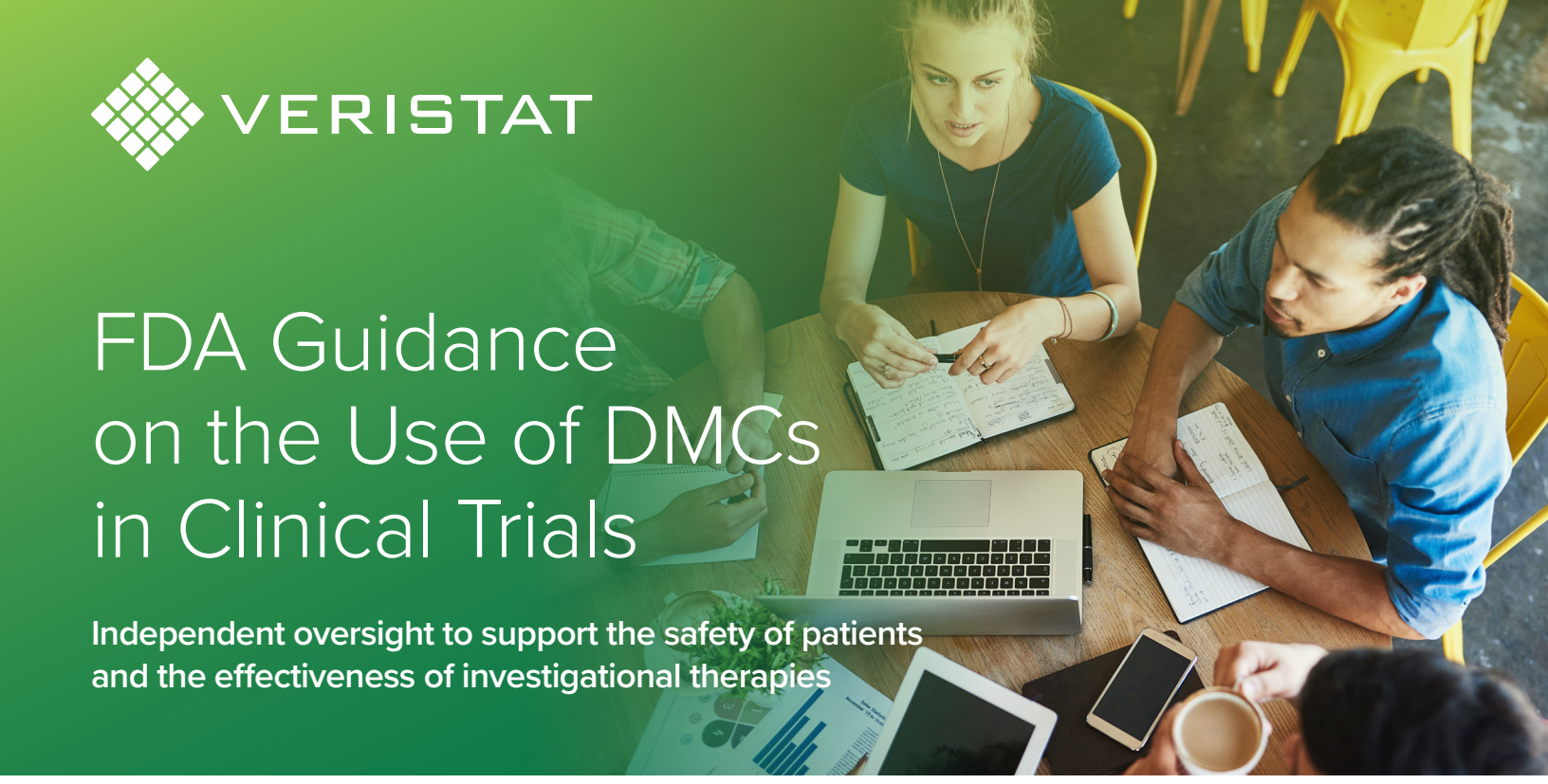
VERISTAT

FDA Guidance on the Use of DMCs in Clinical Trials



Independent oversight to support the safety of patients and the effectiveness of investigational therapies

What Are Data Monitoring Committees?

Data Monitoring Committees (DMCs), which can also be referred to as Data and Safety Monitoring Boards (DSMBs), Data and Safety Monitoring Committees (DSMCs), or Independent Data Monitoring Committees (IDMCs), are established by study sponsors but are independent of the sponsor to ensure decision-making is conducted without bias.

DMCs are put in place to:

- Make recommendations to protect trial patients
- Monitor trial conduct and safety
- Assess risks and benefits

DMCs review unblinded safety and efficacy clinical data as the trial progresses, and work independently from the clinical trial team.

When Should Sponsors Establish a DMC?

- **If patients are at risk of serious morbidity or mortality (e.g., heart attack, stroke, death)**
- **When investigational products may cause serious unexpected adverse events**
- **Where an assessment of causality can be made on the basis of a single event**

FDA Recommendations for DMCs

In its latest draft guidance, the FDA noted that DMCs are increasingly being utilized by sponsors to:

IMPLEMENT adaptive trial designs

REVIEW aggregate data for safety reporting

OVERSEE a whole clinical development program rather than a single trial

Sponsors should consider the risk to trial participants and whether a DMC is practical when determining whether to establish one for their study.

2006 longstanding examples of implementing a DMC include

- **Unusually high safety concerns, such as serious toxicity with the study treatment**
- **Studies involving a potentially fragile or high-risk population**
- **The study is large, of long duration or multi-center**

2024 examples of when a DMC is practical:

- There is limited experience in the therapeutic area
- Causation of adverse events may be difficult to assess without a review of unblinded data

The new draft guidance outlines the potential use of DMCs, emphasizing the value they may bring to certain studies.

Learn more about Veristat's DMC capabilities

Contact us to arrange an introductory call

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