

FIRST ANNOUNCEMENT – SAVE THE DATE



Basel Biometric Society course on Data Monitoring Committees (DMCs)

Dear all,

We are pleased to announce an upcoming F2F course on **Data Monitoring Committees (DMCs)** for clinical trials and clinical development programs that will take place over two consecutive days in October 2026 (25th-26th). The target audience are statisticians and clinicians working on clinical trials in industry, academia and regulatory authorities.

Dates: October 25th, 13:00-18:00 and October 26th, 8:00-12:00

Location: ETH building D-BSSE E48 Meeting/seminar Room, Basel, Switzerland

Presenters: Tim Friede (University Medical Center Göttingen), David Lawrence (Novartis Pharma AG), Tobias Mütze (Novartis Pharma AG), Olympia Papachristofi (Novartis Pharma AG), Marisa Bacchi (AlfaSigma).

This course will provide a comprehensive overview of the purpose, structure, and operations of DMCs in clinical trials and clinical development programs. Topics include:

- Historical context and evolution of DMCs
- Basic principles and requirements (e.g., independence, confidentiality) with a focus on the confirmatory trial setting
- Operational considerations (e.g., how to write a DMC charter, contents of the DMC report, how to structure a DMC meeting) and their implementation in practice
- Overview of regulatory guidance (e.g., from EMA and FDA) on DMCs
- Role of DMCs in more complex settings (e.g., adaptive designs, accelerated approval, open-label studies, single arm studies, program level DMCs)

The course will be facilitated by speakers from the pharmaceutical industry and academia with experience in the field.

We encourage all interested colleagues to attend. For colleagues with no or little exposure to the topic so far, this could serve as an introduction. For more experienced colleagues the course could help to deepen their understanding of this critical aspect of clinical trials, in particular with regard to more complex settings.

Capacity is limited to 40 attendees. Registration is mandatory. A nominal registration fee of CHF50 will be levied.

For questions for the course itself, please contact Marisa Bacchi (marisabacchi@gmail.com) or, if any questions with regards to the registration, Fred Sorenson (fred.sorenson@cencora.com).

Following registration, please make your payment to:

CHF account IBAN: CH56 0077 0042 0177 8181 3
Bank institute: Basler Kantonalbank
Swift: BKBBCHBB
Owner: Basler Biometrische Sektion

EUR account (if preferred) IBAN: CH60 0077 0250 6852 9200 3