BBS training course on Data Monitoring Committees (DMCs)

October 14th, 13:00-17:30
October 15th, 8:30-12:00
In person only at Novartis Campus, Basel, Switzerland

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. The course will include case studies and interactive sessions.

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, for instance, the use of DMCs in adaptive designs.

Presenters: Marisa Bacchi (Independent Consultant), Lilla DiScala (Johnson & Johnson), Tim Friede (University Medical Center Göttingen), David Lawrence (Novartis Pharma AG), Tobias Mütze (Novartis Pharma AG), Olympia Papachristofi (Novartis Pharma AG)

Registration: Capacity is limited to 40 attendees. Registration is mandatory. A nominal registration fee of CHF50 will be charged. To register, please email Tobias Muetze (tobias.muetze@novartis.com). Payment details will be shared after registration.