



**8th-10th June 2021
(Virtual)**

A PSI Training Course:

Data Monitoring Committees

Presented by:

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Sponsored by Cytel

Data Monitoring Committees (DMCs) (also known as Data and Safety Monitoring Boards, DSMBs) are responsible for the review of accumulating data from ongoing clinical trials. The DMC will advise the trial sponsor regarding the continuing safety of trial subjects and those yet to be recruited to the trial, as well as the continuing validity and scientific merit of the trial (FDA Guidance for Clinical Trial Sponsor - Establishment and Operation of Clinical Trial Data Monitoring Committees). DMCs can also be used to analyse unblinded data for studies with group sequential design and other adaptive design elements to reduce potential operational bias.

This training course is suitable for statisticians working on clinical trials which require a DMC.

Topics covered include:

- Introduction to DMCs
 - Responsibilities within a DMC
 - DMC charter
 - Practical considerations
 - Statistical monitoring methods
- DMC case studies
- Interactive DMC workshop
- Perspectives from the Independent Statistician
- Importance and expectations of a DMC from a regulatory perspective
- The new role of DMCs in adaptive designs and platform studies
- Experiences of DMCs during the pandemic

Timings (BST):

Tuesday 8th June: 9am-1pm

Wednesday 9th June: 2.30-4.30pm

Thursday 10th June: 9am-1pm

Registration:

Please register online at www.psiweb.org and click on Events.

Registration costs

PSI Members on or before 7th May: £250 plus vat

PSI Member after 7th May: £290 plus vat

Non-Members on or before 7th May: £345 plus vat (includes PSI membership for 2021)

Non-Member after 7th May: £385 plus vat (includes PSI membership for 2021)

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