

Missing data in clinical trials - a practical guide

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Abstract

This workshop will focus on the analysis of clinical trials with missing data, while making links to other applications.

The morning session will start with the ICH E9 guideline, and outline a principled, systematic approach to the issues raised by missing data. We will discuss why a different approach to the analysis often needs to be taken to address the 'Per-Protocol' and 'Intention To Treat' questions. We will then give a brief critique of ad-hoc methods which are often used when missing data are an issue. Lastly, we will review the Committee of Proprietary Medicinal Products (CPMP) guideline on missing data.

We will then go on to discuss the analysis of trials with missing data under the so called 'missing at random' assumption, considering continuous and discrete outcomes, and monotone and non-monotone missing data patterns.

After lunch, we will consider sensitivity analysis to the 'missing at random' assumption, outline three practical approaches and give their pros and cons.

Throughout, the methods will be illustrated with examples, and SAS code to fit these will be provided.