# Designs for Clinical Trials with Practical Applications

*Alessandro Baldi Antognini, Marco Novelli and Maroussa Zagoraiou (University of Bologna)*

This course addresses the issue of designing randomized clinical trials for comparing two or more treatments. Particular attention will be placed on adaptive experiments, i.e. sequential trials where the experimenter wishes to make use of the information accrued along the way. Multipurpose optimal allocations of the treatments that achieve a good trade-off between different experimental goals - such as ethics and inferential demands – will be also discussed. Finally, practical implementation of the suggested methodologies will be carried out using R software.

**Main topics of the course:**

* Introduction to the design of experiments for clinical trials
* Local optimality and sequential designs
* Ethics vs Inference: multipurpose designs and their implementation.

**Software:**

Participants are encouraged to bring their own laptops for the applications. It is recommended to install the free software R and its interface [RStudio](http://www.rstudio.com/).

**References:**

Baldi Antognini A., Novelli M. and Zagoraiou M. (2018) Optimal designs for testing hypothesis in multiarm clinical trials. Statistical Methods in Medical Research, available online (doi: [10.1177/0962280218797960](https://doi.org/10.1177/0962280218797960))

Baldi Antognini A, Giovagnoli A. (2015) Adaptive Designs for Sequential Treatment Allocation. Chapman & Hall/CRC Biostatistics.

Rosenberger W.F. and Lachin J.L. (2015) Randomization in Clinical Trials: Theory and Practice, Second Edition. John Wiley & Sons.

**Further reading:**

Baldi Antognini A., Vagheggini A., Zagoraiou M. and Novelli M. (2018) A new design strategy for hypothesis testing under response adaptive randomization. Electronic Journal of Statistics 12: 2454-2481.

Network TDRCR (2015) Aflibercept, bevacizumab, or ranibizumab for diabetic macular edema. The New England Journal of Medicine 372: 1193–1203.

Dworkin R.H., Corbin A.E., Young J.P. et al. (2003) Pregabalin for the treatment of postherpetic neuralgia. a randomized, placebo-controlled trial. Neurology 60: 1274–1283.