KPA
Insights through analytics

Clinical Trials at Work

A special hands on workshop with computer simulations

designed and lead by:

Ron Kenett (KPA Ltd. and University of Torino) and

David Steinberg (Tel Aviv University and KPA)

Clinical trials are the gold standard for assessing the value of new medical treatments and interventions. The key to a successful clinical trial is careful planning. What is the primary endpoint? What is the comparator for the new treatment? What rule(s) will be used to assign treatments? How many patients are needed? How many centers? What data will be collected? How many follow-up visits are essential? How will blinding be applied? The answers to these questions will dictate how the study data can be analyzed and interpreted. A common thread is that all the questions have statistical components and good statistical thinking can help direct you to effective answers. Our workshop will explore these issues in the context of a mock clinical trial, with actual simulated patient flow and data collection. We will see how good trial design provides the basis for clear conclusions from the trial.

The hands on workshop will allow participants to run a Simulation based Clinical trial, analyze its outcome using basic Statistical techniques, review its design and rerun it with modifications. The objective of the workshop is to provide a basic introduction to statistical aspects of trial design and statistical analysis.
Specifically the simulation exercise will discuss:

- responses to treatments
- influence of other factors such as age, gender or life style
- number of patients
- how patients are selected for the trial
- how patients are allocated to treatments
- type of trial: parallel or crossover
- compliance of patients to treatment
- show how data are recorded, analyzed and interpreted

The workshop will assume some basic prior knowledge of Statistics. Participants who bring their own laptops will be able to upload (and keep) METAGEN from www.kpa-group.com

Ron S. Kenett, is CEO and Senior Partner of *KPA Ltd*., an international management consulting firm with expertise in biostatistics and clinical trials design and Professor at the University of Torino, Torino, Italy. His 4 books and 130 papers cover topics such as Industrial Statistics, Experimental Design, Change Point Detection, Multivariate Quality Control, Survey Design, Quality Management and Biostatistics. Professor Kenett's Ph.D. is in Mathematics from the Weizmann Institute of Science. Ron is President of ENBIS, the European Network for Business and Industrial Statistics.

David M. Steinberg is Professor of Statistics at Tel Aviv University and a Senior Statistical Consultant at *KPA* Ltd. He has a Ph. D. in statistics from the University of Wisconsin-Madison. Professor Steinberg's primary research area is experimental design. He has served as statistical consultant for a large number of clinical research projects, including both study design and data analysis.