



This is a joint *KPA* and Greenfield Resrach workshop



Statistical Aspects of Clinical Trials

A special hands on workshop with computer simulations designed and lead by

Tony Greenfield (Greenfield Research, UK) and

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

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

Participants who bring their own laptops are requested to upload the Gen simulation software from:

http://www.kpa.co.il/english/about_us/documents/GenAsthmaTrial.zip

Tony Greenfield was chair of medical statistics at Queen's University, Belfast where he managed and presented courses in statistics and computing for medical undergraduates and courses in statistical approaches to diagnosis for post-graduates. He was consulted widely in the medical faculty to assist with research projects leading to publications and to assist post-graduates with their research for MDs. He developed the MetaGen computing package for the modelling and simulation of clinical trials. Several pharmaceutical companies use this package as an aid to planning clinical trials and it is used for training about clinical trials.

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.