15 - 20 June 2014

Advanced Clinical Epidemiology Summer School in Denmark

Initial Program

Updated 29 April 2014

Department of Clinical Epidemiology

Monday 16 June

Topic: Randomized Trials

Teacher: John Baron

Aims:
- To understand the structure of randomized clinical trials
- To understand the statistical and epidemiological rationale for randomization, blinding, intention-to-treat analyses, and stopping rules
- To understand the statistical basis for subgroup analyses
- To understand the uses of different types of clinical trials

8.00-12.00	**Introduction: Clinical trials in the context of observational studies** **Basic paradigm: Parallel group superiority trials** - Organization, hypotheses
	Break

13.00-16.00	**Parallel group superiority trials (continued)**
	
	   - Subjects, sample size , treatment allocation
	
	   - Blinding, Endpoints

* Exact times for coffee breaks and lunch TBA

Department of Clinical Epidemiology

Tuesday 17 June	
Topic: Randomized Trials (continued)	
Teacher: John Baron	
8.00-12.00	Parallel group superiority trials (continued) - Analysis - Subgroups, interactions - Monitoring, early stopping
Break	
13.00-16.00	Types of clinical trials - Cross-Over trials - Inferiority/equivalence trials - Factorial trials Summary: trials vs. epidemiology

Department of Clinical Epidemiology

Wednesday 18 June
Topic: Drug safety
Teacher: Tom MacDonald

8.00-16.00	**Outline**
	1. Spontaneous reporting
	2. Comparative effectiveness studies
	3. Pharmacoepidemiology
	4. Streamline trials methodology
	5. More novel ways of assessing drug safety

Department of Clinical Epidemiology

Thursday 19 June		
Topic: Systematic Review & Meta-Analysis		
Teacher: Olaf Dekkers		
8.00-9.00	Lecture	**Why & How meta-analysis?** - A short overview
9.15-10.30	Lecture	**Measures of association** - Ratio measures (risk ratio, hazard ratio, odds ratio) - Interpretation of ratio measures - When is it appropriate to combine different ratio measures in a meta-analysis? - Continuous measures, including standardized measures
11.00-12.00	Lecture	**Basic statistical methods** - Approach to study data - Fixed and random effect models - Binary and continuous outcomes
Break		
12.45-13.00	Practical	**Short introduction to STATA** (optional)
13.00-14.30	Practical	**Basic meta-analysis in STATA** - Fixed and random effect models - Forest plots - Binary and continuous outcomes
15.00-16.00	Lecture	**Heterogeneity and sources of bias** - Potential sources of heterogeneity - Study quality - Risk of bias and its assessment

Department of Clinical Epidemiology

Friday 20 June Topic: Systematic Review & Meta-Analysis (continued) *Teacher: Olaf Dekkers*		
8.00-9.00	Lecture	**How to deal with bias** - Restriction, sensitivity analysis - Meta-regression - Funnel plot asymmetry
9.15-10.30	Lecture	**Meta-analysis of observational studies** - Differences with meta-analysis of RCTs - Risk of bias - To pool or not to pool?
10.45-12.00	Practical	**Heterogeneity** - Meta-regression - Funnel plot asymmetry
	Break	
13.00-13.45	Lecture	**Problems with data-extraction** - Standard deviations, standard errors - P-values, confidence intervals
14.00-15.00	Lecture	**Network meta-analyses** - Basic principles of network meta-analyses
15.00-15.30	Lecture	**Q & A**

Department of Clinical Epidemiology