



INTRODUCTION TO WORKSHOP 'FINE-TUNING THE STUDY PROTOCOL' & 'THE MEDICAL ETHICAL COMMITTEE'

Eric van Roon – September 29 2017 – EAHP Academy Seminar

mcl
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CONFLICT OF INTEREST

THERE ARE NO CONFLICTS OF INTEREST TO DECLARE

Workshop 'Fine-tuning the research protocol'

Saturday 13.30-15.00

THE GOAL OF THE WORKSHOP

- Define the primary end point
- Define secondary end points (if relevant)
- Translate the study end points to measurable entities
 - E.g. %, HR, RR, OS,...
- Draw Table 2 and/or Figure 1
 - Based on virtual study data
- Discuss ethical aspects of the proposed study
 - Adapt the study proposal if necessary
- Discuss failure potential of the study proposal
 - Adapt the study proposal if necessary

THE CONCRETE END RESULT

- A coherent study protocol
 - Clear research question
 - A defined set of variables to be collected
 - A proposal for data analysis

- That can be explained to another workshop group

- That can be discussed with another workshop group

Workshop 'The medical ethical committee'

Part 2 15.30-16.30

SET-UP OF THE WORKSHOP

- 15.30 - 15.40 Group 1 (3) explains its protocol to group 2 (4)
- 15.40 - 15.50 Group 2 (4) explains its protocol to group 1 (3)

- 15.50 - 16.00 Discussion within groups on the study proposal of the other group

- 16.00 - 16.15 Group 1 (3) is the MEC for the study proposal of group 2 (4)
- 16.15 - 16.30 Group 2 (4) is the MEC for the study proposal of group 1 (3)

ANY QUESTIONS?

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