EDUCATION PLATFORM

Seminar Series:

Facts and pitfalls of observational studies - How to plan and conduct HRO projects

Q&A from the session

"Research according to HRO Chapter 4 and 5"

November 19, 2025

- Thank you in advance for providing different situations, specifying whether general consent is required or not, who should sign it, and whether Article 34 is acceptable or not
  - Fully answered by the speaker of part I of the presentation:
    - Please consult the Pdf or video recording of the presentation part I (especially the table comparing requirements for different types of HRO research)
    - Article 34 HRA as well as General consent cannot be applied for research projects according to HRO Chapter 4 and 5
    - Research may be carried out in deceased persons if, before their death, the persons concerned consented specifically to the use of their body for research purposes.
    - If no documented consent or refusal of the deceased person is available, the body or parts thereof may be used for research purposes if specific consent is given by the next of kin or by a trusted person designated during the lifetime of the deceased person.
      - The consent of the next of kin or the trusted person is governed by Article 8 of the Transplantation Act of 8 October 2004.

- Even if the person said "NO" to general consent during his/her life?
  - Question refers to a statement during presentation part I, that consent for participation can still be obtained for a potential study participant, if he/she has not given consent during lifetime, but relatives/ persons of trust designated during lifetime get asked to provide the consent instead
    - Yes, even if the person concerned said "NO" to general consent during his/ her life, specific consent for participation in a HRO chapter 4 project can still be given by the next of kin or by a trusted person designated during the lifetime of the deceased person.
    - The General Consent does not apply to research according to Chapter 4 and 5.

- Why do we need approval for anonymized body parts? I thought that research on anonymized data/biological material is completely out of scope of the HRA and does not need approval at all.
- How about if you declare in writing how anonymisation is performed with your body parts?
  - Actually, fully answered by the speaker of part I of the session:
    - One does not need EC approval in case of anonymously collected health-related data or research with anonymized health-related data or biological material, but a deceased person or parts of it does not account as "biological material", since by definition biological material always arises from living persons.

- Do you have to justify the sample size of your studies to the Ethics committee?

- Do you have to justify the sample size of your studies to the Ethics committee?
    - Actually, fully answered by the speaker of part II of the presentation:
        - Sample size = number of specimen needs to be reported and justified by the Sponsor-Investigator of a study
        - Change in the number of specimen even counts as substantial amendment, which always have to be notified to the EC and which have to be approved again before implementation