Note: these remarks are made by a data steward focused on scientific research in a non-academic hospitals. They reflect my personal input, not that of the entire hospital.

Remarks based on guidelines GDPR Scientific Research

- So, we have collected data for research pre-GDPR. If we want to re-use this data for medical research, does that mean that we can re-use it now without explicitly asking again for the consent of re-use of this research data?
- Broad consent in the context of the EHDS: once there is a system in place for consent for secundary use, is that the mechanism we will use as hosiptals for broad consent?
- How will legitimate interest for scientific interest be defined? Will this mean that the balancing test will always fall towards making scientific research possible when in doubt?
- As a clarification: in hospitals we have the discussion when in something scientific research and when is it a quality control, as a quality control in the medical setting can also provide new scientific insights. Based on this, do we explicitely have to state when something is scientific research and when something is quality control, based on the key-indicative factors?
- Does article 22 mean that if I have gained consent for my prospective medical research as a primary purpose and 5 years later I want to revisit this data to compare it to another database, I can use this data without having to obtain consent again, as it is the same legal basis?
- So, in line with the EHDS, does 3.1.2. mean that for old research, if data is asked for by another party and we are obligated to provide it because of a permit, we can do that without asking people again for their consent?
- How does article 44 work in the medical context, as due to the EHDS we all have to switch to electronic patient files, where we use the data for both healthcare and scientific research?
- Article 48 can be quite difficult as we use CTcue to get the psuedonymised data from the electronic patient files and due to privacy concerns do not link active research to patients. How do we have to do this?
- Regional hospitals also commit to research. We have heard that in the EHDS it will be an opt-out for secondary use, but if I read article 50, it seems like an opt-in. How do these work between one another, because you can't have both systems at the same time.