Notes Break-out Session Group C – Harmonized ethical requirements

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- **Fields of interests and motivation of participants for Digitalization in healthcare:**

  - Integrated Care – Treatment and how to interact with patients
  - Sensoric and diagnostic data in robotics
  - Initiative "Medical data space" (Fraunhofer FIT) – integration of intersectoral data
  - Management of medical image data and image data processing
  - Matching of patients and clinical trials
  - Digitalization in biopharmaceutical industries – selection of patients for clinical trials

- **Which challenges do you have in current projects and how do you proceed with them?**

  - High uncertainty of companies with the problem of national and international regulations for the implementation of digital solutions – how can we assure that?
  - Problems with the classification of data security and ethical requirements. What is the difference? There is an awareness that ethical requirements exist, but it is difficult to separate it from data security and privacy.
  - Difficulty that in Germany homogenous and transparent requirements don't exist.

- **Examples for ethical questions:**

  - When do I have the duty to report e.g. side effects while processing "dirty" real world data? What is admissible to know, what can be ignored and at which point do I have to report? - Within projects distinct go/no go decisions have to be incorporated.
  - What is with the "right of ignorance"? What is reasonable for patients to know about their diseases? Is it right to simply hand on patient data and indications which can contain severe information (i.e. cancer)? – There is a new guideline with recommendations for the handling ofhealth data also for delivering indications.
  - Personalized medicine i.e. genome-based biomarker medicine – Problem of identifiability of patients
  - What is with the assurance that real data in the cloud comes from reliable sources e.g. compliance of ethical requirements in clinical trials? Pharma companies buy data from different countries. Problem of different ethical aspects and data privacy in other countries. Should data from countries with less data privacy regulations should be used?
  - Ethical question in handling with literature about clinical trials. There is a significant problem that about 60% of the pre-clinical trials are unfeasible (e.g. problem of reproducibility, low numbers of test persons). How can they be used? How credible are the data? Which conclusion can be drawn from such poor data?
  - There should be an ethical instance also for pre-clinical trials. Pharma companies should not be obliged to proof the accuracy of clinical data to generate new ideas.
  - Introduction of minimum requirements before starting a project or trial and regulations for the harmonization of clinical trials, which are globally conducted.
  - Who is the owner of the data? Are there public good, if they are publicly available and cannot be assigned to a specific patient?

- **Summary:**

  - Ethical requirements are not always harmonized, but there are global ethical guidelines, which aim at harmonization. What should be done: Creation of Transparency and enhancement of quality and traceability of the data.
  - Differentiation of data from research and data from patient care.
  - RWD is an example for a new technology - guidelines need to be adapted for the transition from regulated trials to RWD.

- **Summary on Flipchart:**

How to harmonize---global international guidelines

Purpose: allow international collaboration, increase transparency—quality of generated data

Ideally: translate into legislation/standard procedure

Feasibility

Challenge:

1) Guidelines applied differently for research and non-research,

2) RWD = example for new technology—guidelines to be adapted