Session 2:Public-private collaboration in the area of clinical research

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My background

- Physician
- Specialized in clinical oncology and in clinical pharmacology
- Head of Precision Oncology Treatment Group in The Department of Molecular Medicine, AUH
- Have worked for the pharmaceutical industry in an early, preclinical drug development program
- Have included and treated patients in clinical studies (marketing studies)
- Teach medical students drug development and the clinical implementation of precision medicine
- Advisor for a pharmaceutical company
- Been a member of a RADS /Rådet for Anvendelse af Dyr Sygehusmedicin) working group
- Been a pre-assessor of applications for KRIS (Koordineringsrådet for Ibrugtagning af Sygehusmedicin)

Possibilities/advantages when working with the industry

- Financing
- Important partner when moving basic research into the clinic by way of developing .e.g. devices
- Early access to new drugs/contribution to drug development

Disadvantages when working with the industry

- Disqualification rules with regard to working with public institutions (Medicinrådet e.g.)
- Running clinical trials is administratively very extensive
  - KFE (Clinical Research Units), GCP (Good Clinical Practice), VEK (Ethical Commitee), The National Medicine Board (Lægemiddelstyrelsen)…..
- The scientific value?
  - Study design (inclusion/exclusion criteria, comparator, end points…)
  - Access to data (who ”owns” data?)
  - Co-authorship

Main questions (from my point of view)

- How can we (physicans) work with the industry and still maintain our integrity with respect to working for public institutions?
- How do we secure the scientific value of a study for the participating physician?