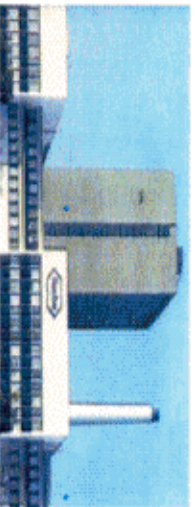


# Clinical Research in Oncology

New drugs

Standard of Care

New drugs



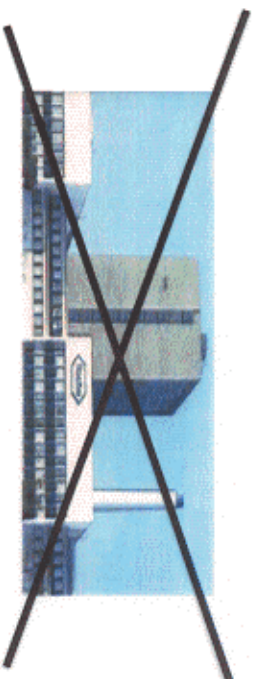
Regulatory authorities on country level or more global

- „Good Clinical Practice“ guidelines
- Registration of a safe effective product
- Oncology
  - Patients in life threatening situation
  - i.e. colorectal cancer: Survival correlates with the number of available drugs
- Costs of clinical development (actually around 1'000'000'000 \$ per new drug



## Standard of Care

- Which is the best drug / drug combination
- How long should we treat
- Multimodality approach
- Outcome research
  - Quality of life
  - Socio-economics
  - Late (side) effects
- Which therapy works in which tumor?



## „Quality Control“

- Why
  - Special insurance (studies of the Swiss Cancer Research Organisation (SAKK) all deadlocked at this timepoint!!)
  - even a patient informed consent

**Proposal**

## **Clinical Research in Oncology**

**New drugs**

GCP “..... Should be followed when generating clinical data that are intended to be submitted to regulatory authorities “

**Standard of Care**

“Only“ independent Ethics Committee approval for that type of studies

- Quality
- Feasibility
- Scientific question