

Industry-academic cooperation in
drug development and beyond.

What is realistic and feasible?
Examples and views from a dean`s
perspective

Thomas Krieg
University of Cologne

Academia-Industry Relationship

- General considerations
- Cooperation in basic research and target identification
- Preclinical research
- Investigator initiated clinical trials
- Participation in other clinical studies

Success stories

- Discovery of penicillin
(Nobel Prize 1945)
- Application of corticosteroids
(Nobel Prize 1950)
- Development of streptomycin
(Nobel Prize 1952)

Breakthroughs in Medicine

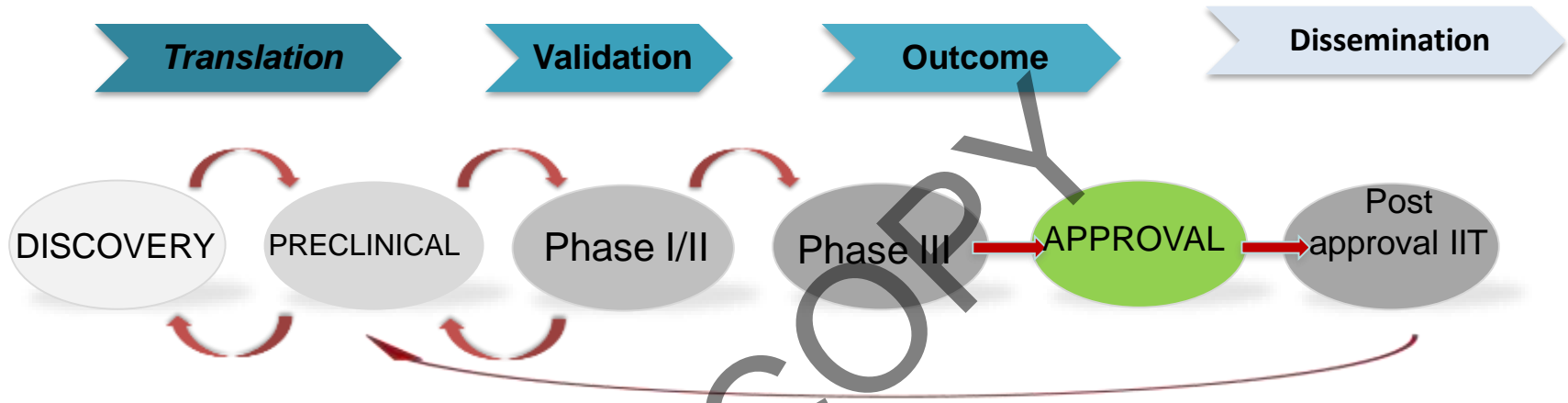
- Identification of molecular defects in inborn diseases (collagen VII in EBD)
- Discovery of cancer diversity based on molecular analysis (tyrosine kinase inhibitors in lung cancer)
- Immune checkpoint inhibition (melanoma therapy)
- Identification of gene variants in complex diseases (diabetes, autoimmune diseases)
- Novel targets in infectious diseases

Role of Academic Medical Centers

- Research
- Teaching and Education
- Patient care

- Independence
- Professional credibility and public confidence
- Patient trust

Goals of University Medical Centers Today



Today the final goal of university medical centers should be:

To understand the molecular mechanisms of diseases in individual patients.

To develop personalized therapies adapted to the individual genetic profile of the patient.

Translate these results into praxis-changing medicine

Primary Goal of Companies

Success in selling their product,
which not necessarily suits academic
interests or patient welfare

How can Academia support Industry?

- Broad education of the new generation of scientists and clinicians
- Guarantee a multidisciplinary approach
- Provide and exchange original ideas with a long term vision
- Identify future medical needs
- Identify new mechanisms and therapeutic targets
- Characterize patient cohorts for clinical studies

How can Industry support Academia?

- Provide funds for named professorships
- Establish graduate schools under the umbrella of the university
- Offer competitive grants
- Establish an independent scientific institute
- Offer access to screening facilities and other infrastructure
- Offer space for external scientists
- Create jointly owned companies with universities

Complex Balance

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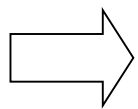
- Rapid progress
- Additional expertise
- Delegation of bureaucratic work
- Access to unpublished data

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- Partial loss of academic freedom
- Potential loss of credibility and trust of the society
- Shift of priority in research
- Potential disruption of physician-patient relationship

What is the current situation?

- Increasing influence of pharmaceutical companies on academic institutions
- Most clinical studies are financed by pharmaceutical companies
- Many conferences are sponsored by companies
- 50% of the biomedical research in the US is not governmentally funded
- Companies invest 20% in R&D, German government 3%



Does this influence the public trust in clinical research in Universities?

Conflict of interest for physicians treating patients and working with companies

- Physicians are invited from companies to conferences
- New drug information is provided by companies to the physicians
- Physicians receive honoraria for talks
- Companies are involved in writing manuscripts
- Physicians/scientists are founder of companies
- Physicians are stock holder

How can we guarantee academic independence and patients trust in drug development?

- Development of state-of-the art intellectual property management in the universities (technology transfer office)
- Long term governmental funding of patient registries and cohorts
- Independent drug information by the government/academia for physicians
- Strict regulation of sponsorship for conferences
- Establishment of clinical study centers at the universities
- National/international funding of investigator initiated trials

Basic Research and target identification

- Many successful examples (PDGF inhibitors, Il-10 functions, small molecules in lung cancer, breakthrough in melanoma therapy)
- Long term cooperation with industrial partners is required or...
- ...Founding of companies by the investigators themselves

Examples for long term Academia-Industry cooperation

- California Institute for Medical Research
 - Pfizer Centers for therapeutic Innovation
 - Gilead-Yale Cooperation
 - Sanofi-Stanford Cooperation
 - Astra Zeneka-Columbia Cooperation
 - The Milner Therapeutic Consortium
(3 academic centers, 7 companies)
- etc

University drug discovery centers

- Vanderbilt Center For Neuroscience Drug Discovery
- MRC Technology Center, London
- Drug Discovery Center, Dundee
- Center for Drug Design and Discovery, Leuven
- Broad Institute, Cambridge, USA
- Scripps Research Institute, Florida

Preclinical research

- Identification of mechanisms and potential other activities of compounds (Academia)
- Search for toxicity and long term side effects (Industry)
- Identification of the best delivery and dose finding (Industry)

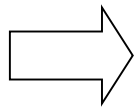
Investigator-initiated trials as important task for University Medical Centers

- Identification of the best patient cohort
- Identification of other international leading centers
- Development of protocols
- Ethical issues
- Organization of funding (preferentially governmental)
- University sponsorship

⇒ Requirement : Universities must have a clinical trial center with independent monitoring

Funding/cofunding of IIT´ s by industrial partners

- The intellectual property remains with the university
- All data belong to the university
- Publication of the data is required and the researcher/clinician/institution remains responsible
- Costs can be shared between the university and companies
- Companies are involved in the design of the study and have access to the original data



A trusted long term institutionalized interaction between the partners is required

Participation of Academia in other company-sponsored clinical studies

- Requires expert centers with direct access to large, well characterized patient cohorts
- Requires an organized structure within the participating departments with sufficient long term employed PI's
- Requires the vote of the ethical commission
- Requires full cost funding including the overhead (40%) for the institution
- Distribution of the overhead between the individual departments and the central institution needs to be negotiated. A complete transparency of the resources is required.

Challenges for clinical trials in Europe and the US

- Increasing legal requirements
- Overgrowing bureaucracy
- Expensive training and early drop out of clinical investigators
- Complicated patient compliance

What can we do?

- Develop national/international networks for certain diseases (do not forget rare diseases and the need of underprivileged countries)
- Create state-of-the art Clinical Trial Centers at the universities
- Universities need to take the sponsorship for IIT`s
- Influence politics for funding clinical research, patient cohorts, registries and IIT´ s

Most important tasks

- We need to resolve the conflict of interest in academia-industry relationships on all levels
- We need to build up long term relationships
- We need to guarantee that patient welfare is the final goal in all medical oriented research