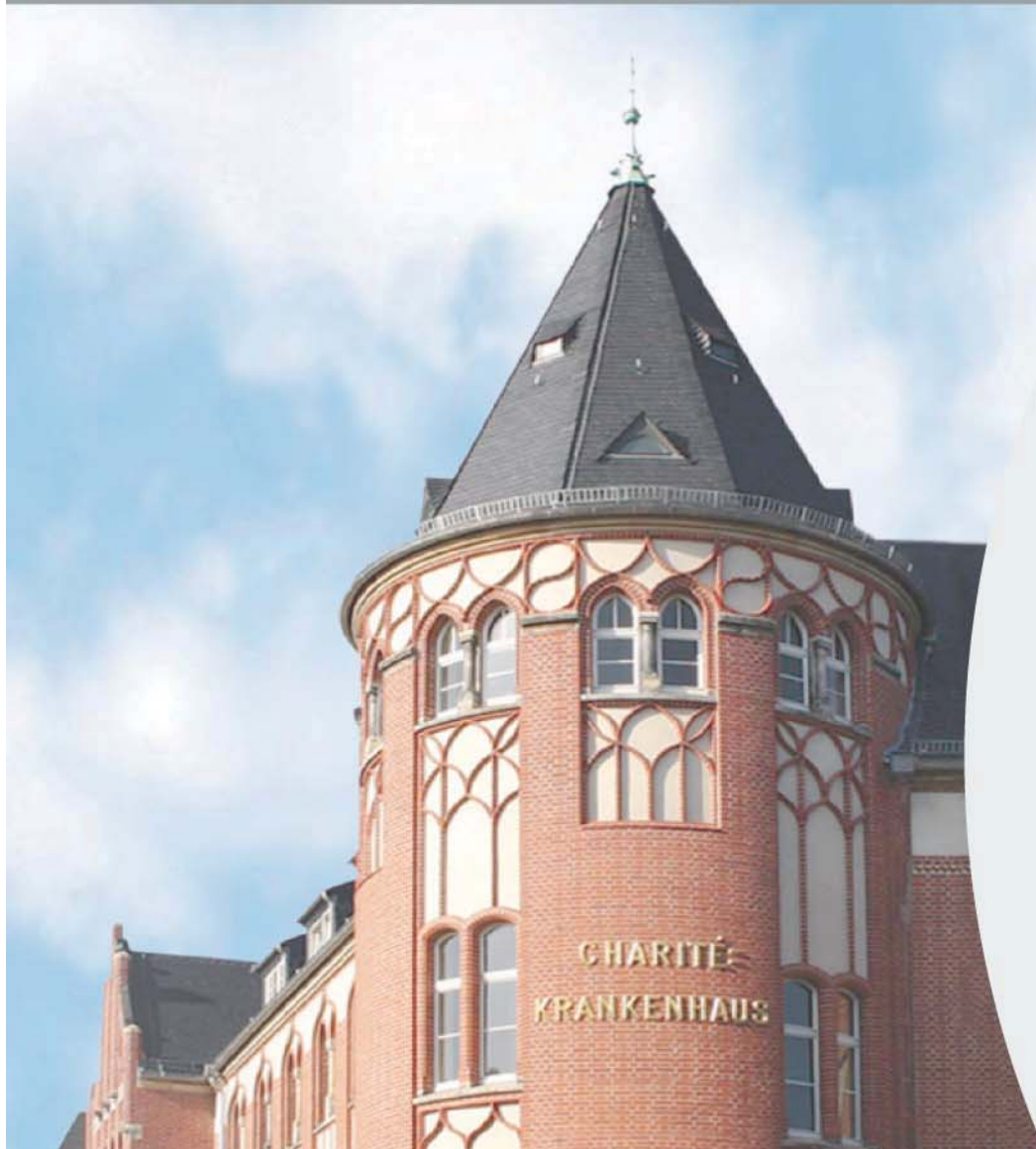


IP and monetization in academic medicine

Dr. Jekyll and Mister Hyde meet bench to bedside translation



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IP and monetization in academic medicine

Bench to
beside
translation

Disease
prevention,
improved
outcome

Reflow of
funds for
further
academic
R&D



Biased research

*Conflict of
interest*

*Distraction of
the researcher
and clinician*

*Less or even
un-affordable
treatment*

*Misappropriation
of public funding*



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IP, universities, and pharma: Where do we stand?

- Trouble in paradise: Big pharma's pipeline is drying up, while IP for today's blockbusters is expiring
- Costs in the health sector are exploding. Treatments become unaffordable, not only, but especially in 'third world' countries.
- Inhouse R&D of big pharma contributes little to innovation. Innovation usually originates in academic research.
- More than 90 % of academic researchers are completely ignorant concerning issues of IP and TT.
- A substantial fraction of the remaining 10 % are frustrated by the current IP and TT process.
- The dream: Bayh-Dole, ArbNErfG (§42), 'Verwertungsinitiative', etc.: IP as a horn of plenty for Universities!
- The reality: Budget of German Universities > 30 Mrd €, but practically 0 revenue from IP!



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Why an academic medical researcher (or a medical faculty) should care about IP

- [Financial interest]
- In most fields, without IP an idea, treatment principle, or therapeutic compound is 'lost in translation'. If there is no way to recover the costs incurred in clinical testing, no one will pay for it.
- A large fraction of the results of basic research in the life sciences of Universities enters the public domain via publication (without claiming IP) and is thus lost for translation.
- Paradox: Not claiming IP in many instances may be unethical!



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Why an academic researcher should prevent the University from claiming IP

- IP and TT- issues are time consuming and distract from research or patient care (despite, or *because* of TTOs).
- IP generates bias towards results that favor monetization, and bias against those that may harm a commercial interest.
- It generates conflicts of interest.
- Disclosure of IP may have negative effects on the review process of papers or grants.
- Publication delay, change in publication strategy.
- Society pays for research (via University, DFG, etc.), but by claiming IP (and exclusive licensing) society is excluded.
- A patent excludes others from making, using, selling, offering for sale, or importing the patented invention for the term of the patent. However, results of public research should benefit everyone.



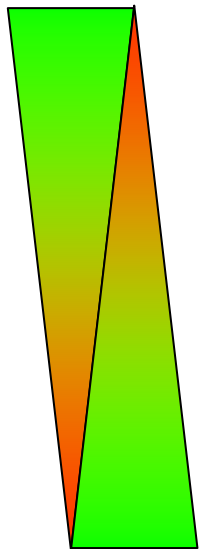
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Why an academic researcher should urge the University to claim IP

- Without IP no bench to bedside translation:
- 'Without IP no pharmaceutical company will test efficacy in Phase III'.
- Not claiming IP in the current system may be unethical.

Critical steps in bench to bedside translation – Barriers for the academic researcher

Academic medicine



Big pharma

- Discovery of a pathophysiological principle or therapeutic agent
- Preclinical testing
- Safety 'first in man' (Phase I)
- Safety in patients (Phase IIa)
- Proof of concept (Phase IIb)
- Efficacy (Phase III)

High cost:

- Public funding (??)
- VC, big pharma

Bureaucracy:

- IRB (Ethics)
- BfArM, EMEA

Risks:

- Financial
- Legal

Bring out Dr. Jekyll - / Why most academic TTOs should be closed

- Most academic TTOs are subcritical, i.e. they do not make money and therefore cannot attract top professionals, or pay for high level outsourcing. Almost 80% of US academic TTOs report losses, only a handful generate substantial revenue
- Consequence: Faulty patents (which will eventually not hold up in court). Heavy load on and distraction of academic inventor. No or rather unattractive commercialization and slow or no progression into clinical trials due to lack of experience and contacts with VC, private equity, or big pharma.



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Bring out Dr. Jekyll - //

- Universities should outsource TT to one of the few, big and successful players (e.g. Max-Planck 'Garching' innovation: low pressure polymerisation, FLASH; FhG: MP3)
- This saves money (by not inventing the wheel many times, reducing overhead etc.), and professionalizes the process



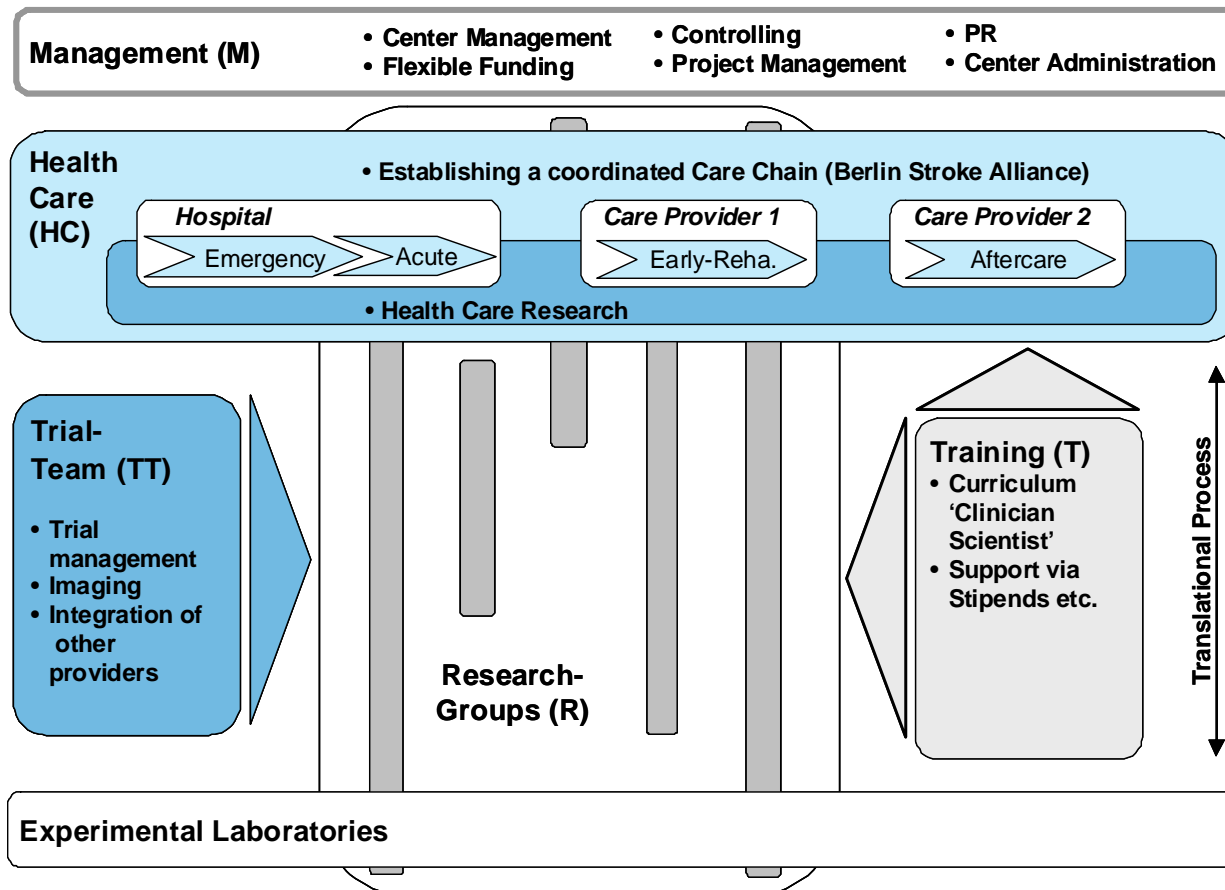
Bring out Dr. Jeckyll - III

- The problem: Phase III only funded by industry. DFG/BMBF program serves as a fig leaf and is a drop in the ocean.
- Required action: Public funding of clinical trials on a grand scale. Collect money from stake holders in the health industry (in particular health insurers). They will be rewarded by less expensive medicines.
- The public should hold the IP, and grant equitable licences (not only to third world countries).
- As a spin off, this may also solve the problem of an overwhelming of the health system by exploding costs.



A role for clinical research centers (IFB, BCRT, NCRC-NEUROCURE, ECRC etc.)

IFB – Center for Stroke Research Berlin



- Own small TT office, help with bureaucracy and liaison to TTO
- Advisory (Patent, Pharma, VC, health sector, ...)
- Own trial team
- Internal funds for trials (up to IIb)
- Coordinated care chain (includes insurers!)

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Conclusions

- IP is key to translation
- Academic TTOs are ineffective
- The TT process must be professionalized
- The public should fund clinical trials and hold IP



**Verwertungspotential an Hochschulen liegt brach,
ausseruniversitär ist die Situation besser**

- 330 Unis in Deutschland mit insgesamt 360.000 Beschäftigten, davon 125.000 Wissenschaftler. Budget 25 Milliarden €, prakt. 0 Erlös aus Wissenstransfer
- Helmholtz, Leibniz, Fraunhofer, Max Planck: 60.000 Beschäftigte, 8.000 Wissenschaftler; Budget 5 Milliarden €, 45 Mio p.a. Euro Lizenzerlöse, im wesentlichen aus 2 (!) Erfindungen
- MPG hat PVA seit mehr als 30 Jahren (Garching Innovation), und Profit mit wenigen Erfindungen (Niederdruckpolymerisation, FLASH).
- FhG hat PVA seit mehr als 10 Jahren, und Profit mit wenigen Erfindungen (MP3).



Danksagung

Jürgen Tägert, Verwaltungsdirektor m.S.F., Charité

Quellen

OECD Bericht 'Turning Science into Business – Patenting and Licensing at Public Research Organisations' 2003

Schwerpunktstudie 'Erfindungen contra Patente' FhG für das BMBF 2003

Technologietransfer in Deutschland, Vortrag Dr. Christian Kilger bei der Deutschen Vereinigung für gewerbl. Rechtsschutz und Urheberrecht, Nov.2004

**The Bayh Dole Act – A guide to the Law and Implementing Regulations. Council on Governmental Relations 1999.
<http://www.ucop.edu/ott/bayh.html>**

Schlussbericht 'Zur Einführung der Neuheitsschonfrist im Patentrecht – ein USA- Deutschland-Vergleich bezogen auf den Hochschulbereich. BMBF 2001