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# Translational Research: A New Form of Governance for Genomic Medicine?

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<http://trigen.isi-projekt.de>

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# What is TR?

- 1992: NCI SPOREs
- 2003: NIH Roadmap
- 2004: FDA Critical Path Report / Initiative
- 2005: Clinical and Translational Science Awards (CTSA)
- 2007: German *Roadmap Health Research*
- 2010: German *Health Research Framework Programme*
- 2009-2012: German Centres for Health Research
- 2012: National Centre for Advancing Translational Sciences (NCATS)
  
- Proliferation of initiatives to intensify the movement from “bench to bedside”; proliferation of meanings: TR as buzzword.

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# Interrogations

Change in governance form? :

- Advocates „have been doing TR all their life“; TR not linked to specific experimental platform and practices such as –omics;
- Organisational, coordinative, collaboration practices change with TR?
- Different understandings of legitimate scientific inquiry?
- New politics of biomedical research ?

Title potentially misleading: the advent of “genomic medicine” a result of the TR enterprise for advocates of the later;

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# Research strategy

- Argumentative Policy Analysis (Fischer, Gottweis, Hajer): TR as policy narrative constructed by discourse coalitions;
- Each policy narrative linked to :
  - problematizations;
  - models of action;
  - discourse coalitions;
- repertoires of legitimate practices : forms of governance;
- Empirical material: document analysis and interviews in the USA and in Germany.

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# The weight of past promises: making genomic medicine a reality

## **Problematization:**

“Although the parallels are not precise, the field of translational science today faces some challenges that are similar to those of the genomics field in 1990. For example, little focused effort has been devoted to the translational process itself as a scientific problem amenable to innovation. As was the case with genomics, translational science needs to shift from a series of one-off solutions toward a more comprehensive approach”  
(Collins 2011, p. 2).

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# The weight of past promises: making genomic medicine a reality

## Models of action:

- National Centre for Advancing of Translational Sciences (USA);
- Innovative Medicine Initiatives (EU);
- Health Research programmes in Germany;
  
- Large-scale data-driven initiatives;
- Extension of the concept of „speed genomics“ (Fortun 1998) to clinical practice?
- Involvement of former leaders (Francis Collins; Rudi Balling) of national Human Genome projects.
  
- TR as „scientific breakthrough“

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# Reforming academic medicine

## **Problematization:**

- Wyngaarden 1979: Clinician-scientists as endangered species;
- Coller 2008: “Translational Research - Forging a New Cultural Identity” – the translational investigator ;
- Germany: the legacy of the Flexner report!
- See Wilson-Kovacs and Hauskeller (forthcoming);

## **Models of action:**

- CTSAs as systems integrators;
- OncoRay Dresden; TRAIN; German Centers for Health Research;
- Different epistemic practices – Marincola (2011).
  
- TR as experimental medicine

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# R-D crisis: leaky pipelines in the pharmaceutical industry

## Problematization:

The New York Times Reprints

March 6, 2011

### Drug Firms Face Billions in Losses in '11 as Patents End

By DUFF WILSON

At the end of November, Pfizer stands to lose a \$10-billion-a-year revenue stream when the patent on its blockbuster cholesterol drug Lipitor expires and cheaper generics begin to cut into the company's huge sales.

- “This is panic time, this is truly panic time for the industry... I don't think there's a company out there that doesn't realize they don't have enough products in the pipeline or the portfolio, don't have enough revenue to sustain their research and development” (researcher from the Tufts Centre for the Study of Drug Development quoted in Wilson 2011, p. A1).



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# R-D crisis: leaky pipelines in the pharmaceutical industry

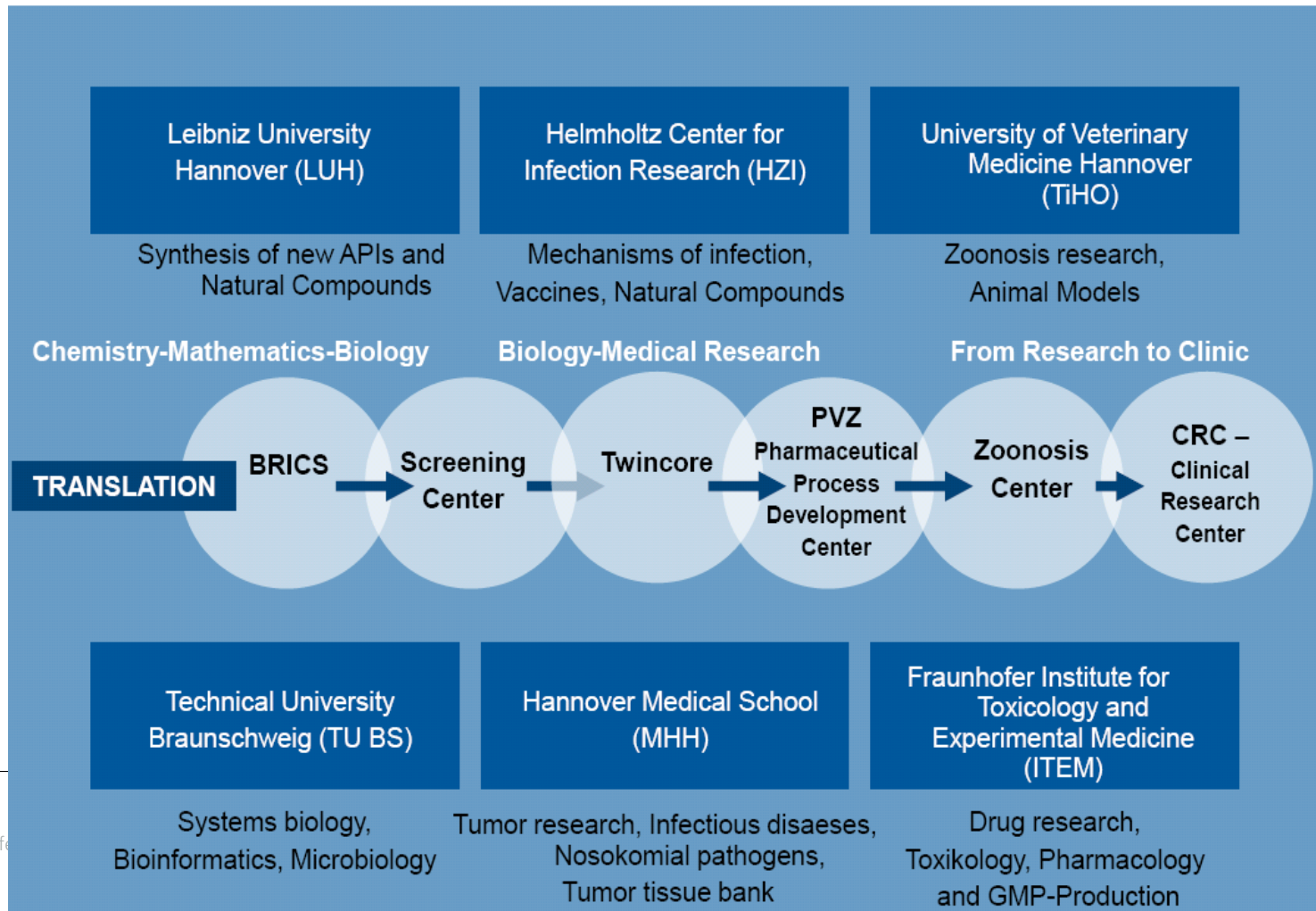
## Models of action:

- Large-scale “academic pipelines” : NCATS, TRAIN, German Centre for Health Research
  - Highly integrated work;
  - Large equipment traditionally found in industry;
  - Focuses on drug development (rather than say biologics, gene therapy, stem cell therapies, genetic diagnostic for monogenic conditions or genomic risk assessments) ;
  
- TR as an assembly line

# The playing out of narratives in practice

**Taken from:** Hentz M. 2011. *Novel translational infrastructures in academia*. VPM Days, Sep. 2, 2011, Hannover.

**TRAIN partners co-operate in state-of-the-art facilities.**



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# Conclusions

- „Former regime“ : the genomic medicine vision?
- Newer regimes : academic pipelines and reformed academic medicine;
- Certain epistemic, institutional and material practices privileged in each policy narrative;
- Single actors and „institutions“ articulate and combine narratives (NCATS: academic pipelines, genomic medicine), TRAIN (all 3).
- Tensions between the narratives and their privileged practices;

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# Thank You!

## Questions?

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