From collaboration to innovation

the role of networks in regulatory science and innovation

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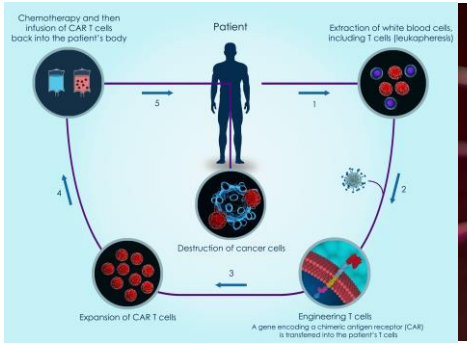
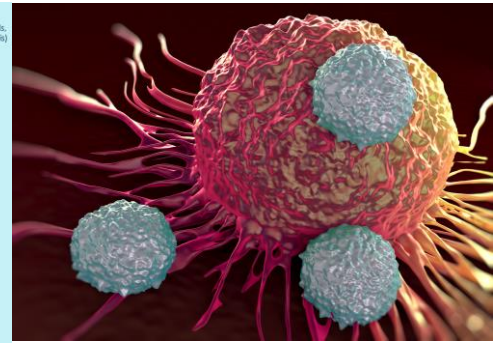
“Biomedical advancements and innovations often do not fit well with existing regulatory frameworks”

THERAPIES





Alongside this high-expectation is a prevalent discourse of concern. This is that scientific advancements will fail to translate into useful RM therapies, or that the rate of translation will be laboriously slow, due to its novelty and apparent incommensurability with existing biomedical and health delivery infrastructures. Healthcare systems and infrastructure, as well as regulatory systems, have emerged to accommodate conventional therapies based on drugs and devices, and may then be poorly suited to the governance and delivery of RM (Tait, 2007).

Gardner J, Webster A. Social Science and Medicine 156 (2016): 90-97

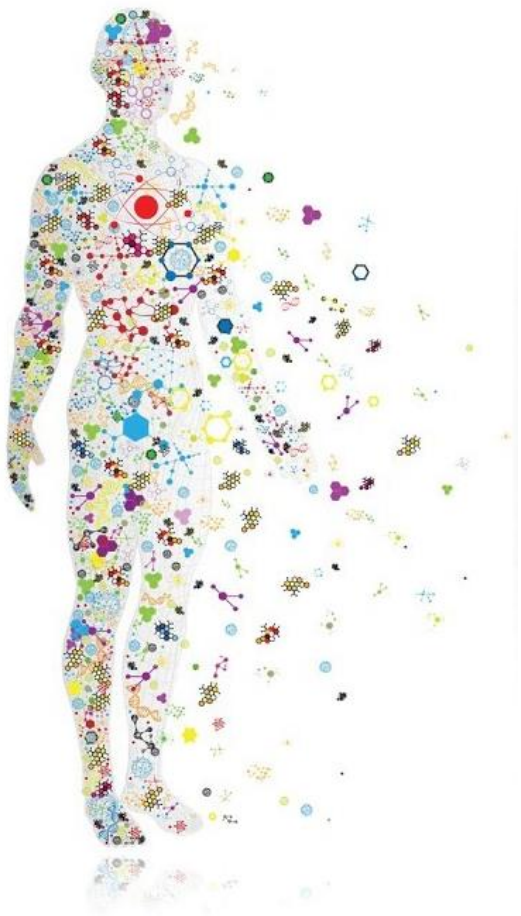
Literature and conference discussions on GCT development express concerns that the number of centrally marketed GCTs in Europe so far is disappointing when compared with clinical trial activity [2,3][xiv]; it is

Ten Ham et al. Trends in Pharmaceutical Sciences 41 (2020): 67:70

The field of advanced therapy medicinal products (ATMP) is scientifically progressing at a very fast pace, as demonstrated by the number and variety of clinical trials conducted over the last five years, yet there are numerous factors that have complicated the translation from research into patient access.

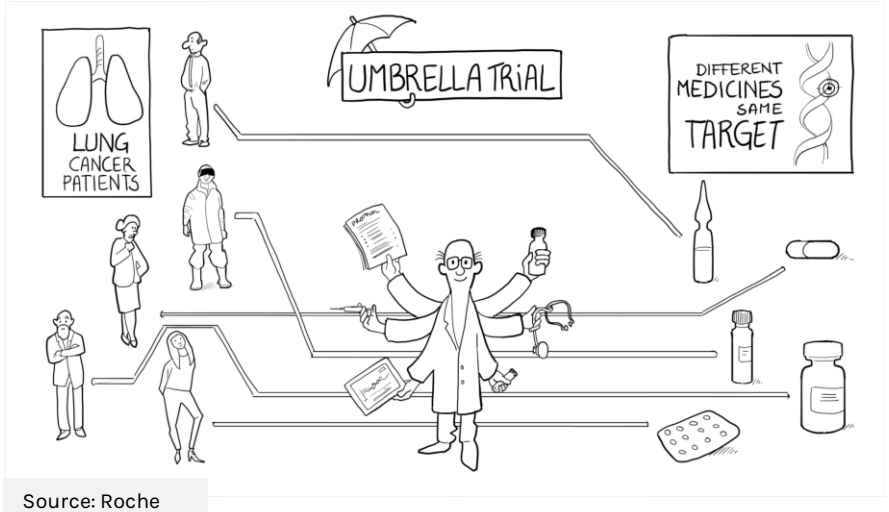
IMI Advanced Therapies Concept Paper: Facilitating the translation of advanced therapies to patients in Europe

TOOLS



Source: Certara

Model-informed drug development



Source: Roche

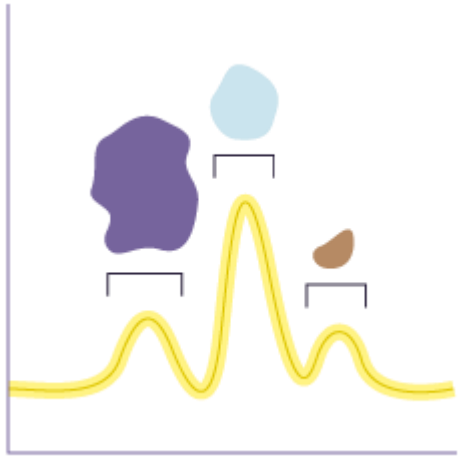
Innovative trial design

Source: Alamy

Benefit-risk assessment

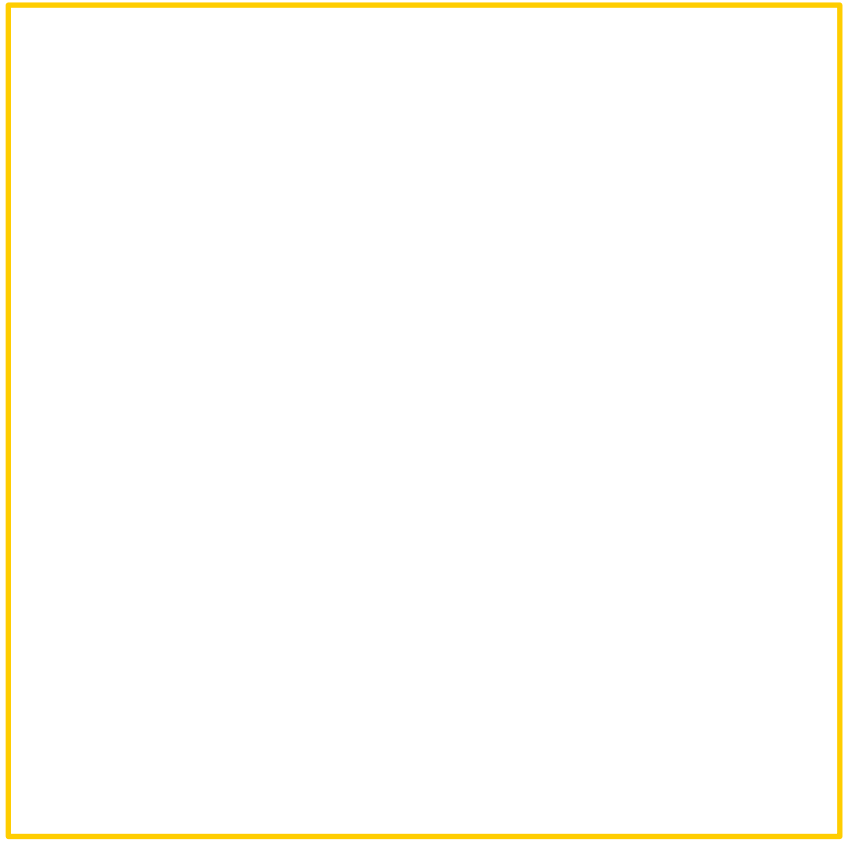
Source: CHCUK

Real-world evidence



Source: Euretos

Biomarker use



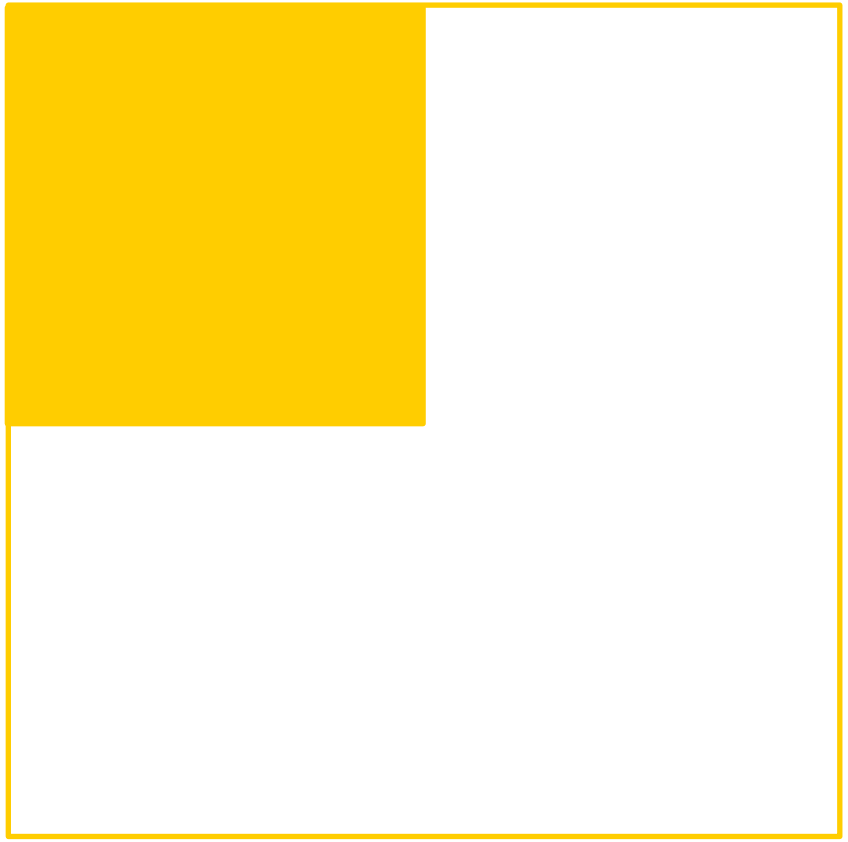
Pacing problem

Research and innovation moves faster than regulation

Yes

Research and innovation is distantiated from regulation

Yes



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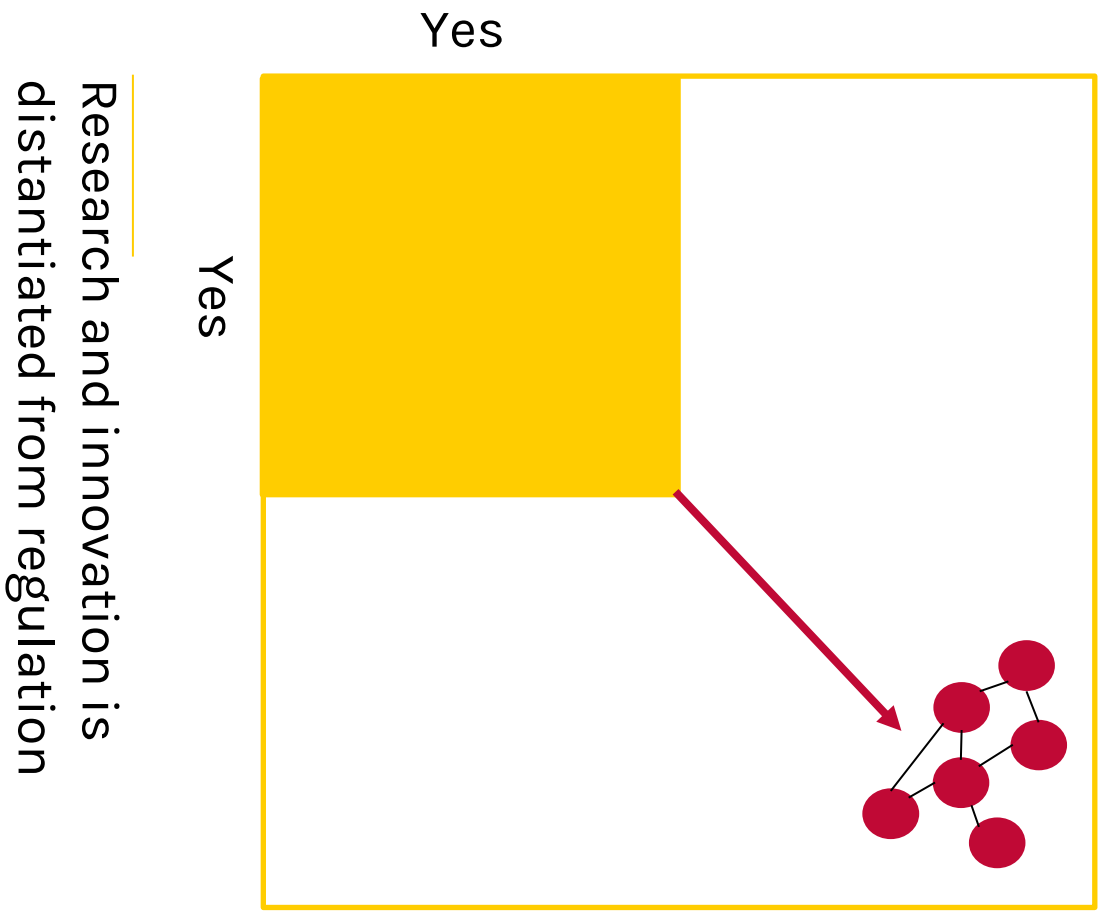


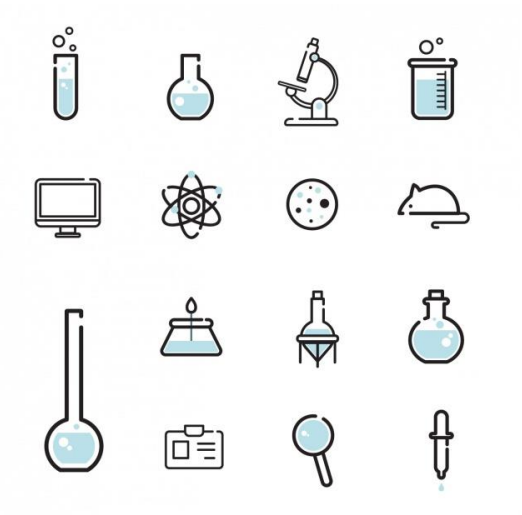
NETWORK INSTRUMENTS

- Network-led partnerships
- Collaborations between regulators, academia and learned societies
- Knowledge exchange & dissemination in shared and open environment

"How can we think about the role of networks in regulatory science?"

DIVERSITY

Stakeholders



Knowledge & Expertise

Geography

Experience

MAKING SENSE OF INNOVATIONS

SCIENCE

- Knowledge production
- Understanding
- Predictive value
- Validity

INNOVATION

- Unmet needs
- Market value
- Institutional readiness

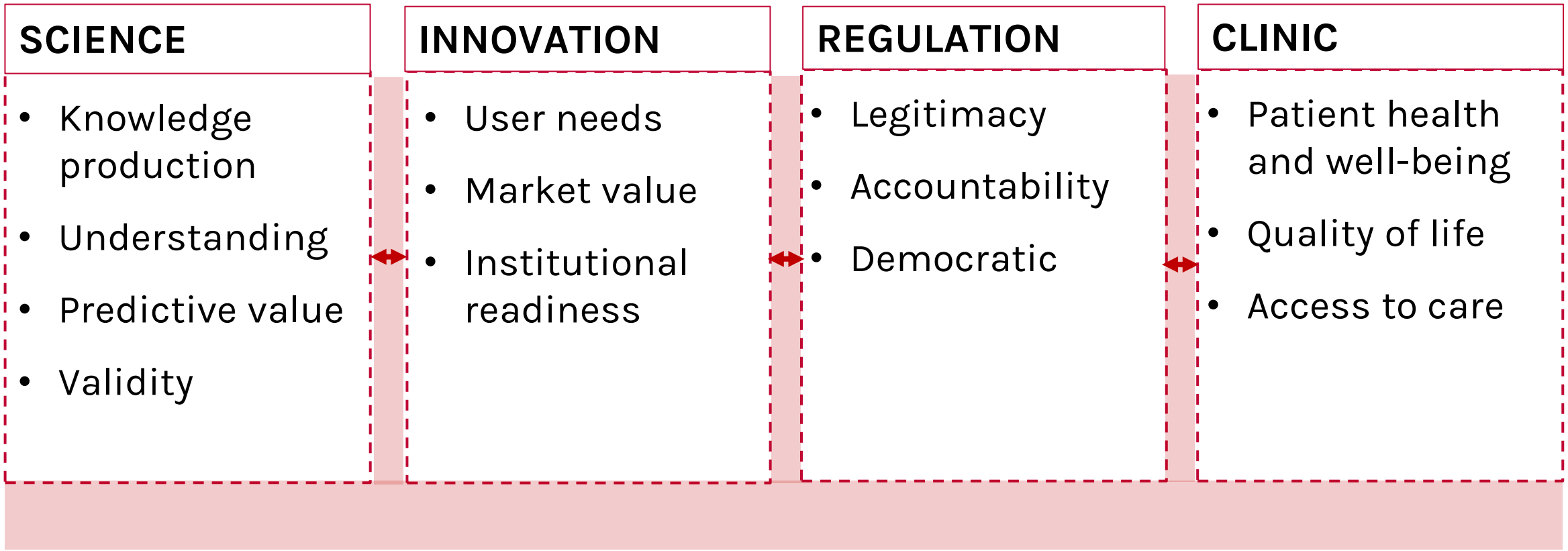
REGULATION

- Legitimacy
- Accountability
- Democratic

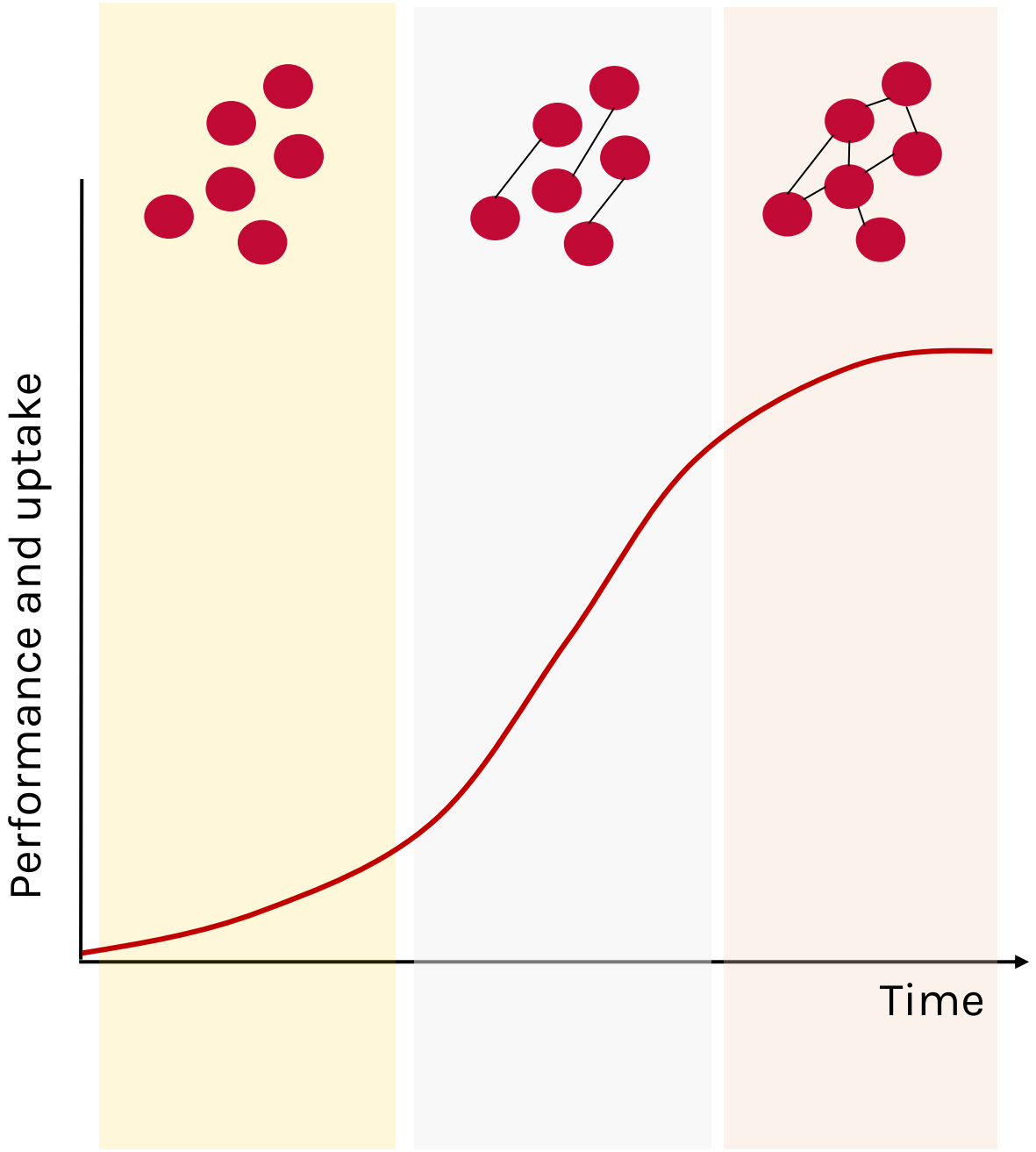
CLINIC

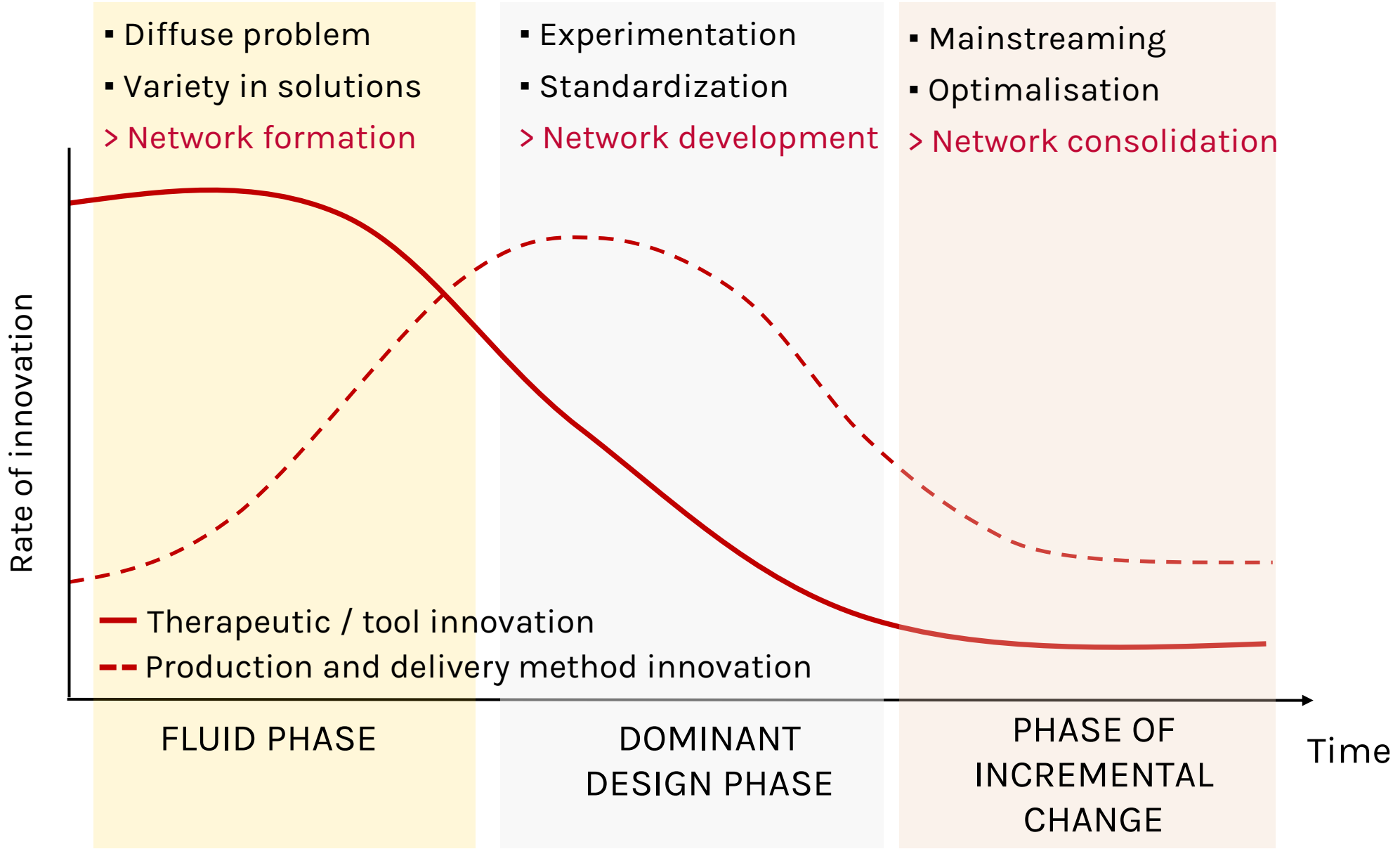
- Patient health and well-being
- Quality of life
- Access to care

BOUNDARY SPANNING CAPABILITIES

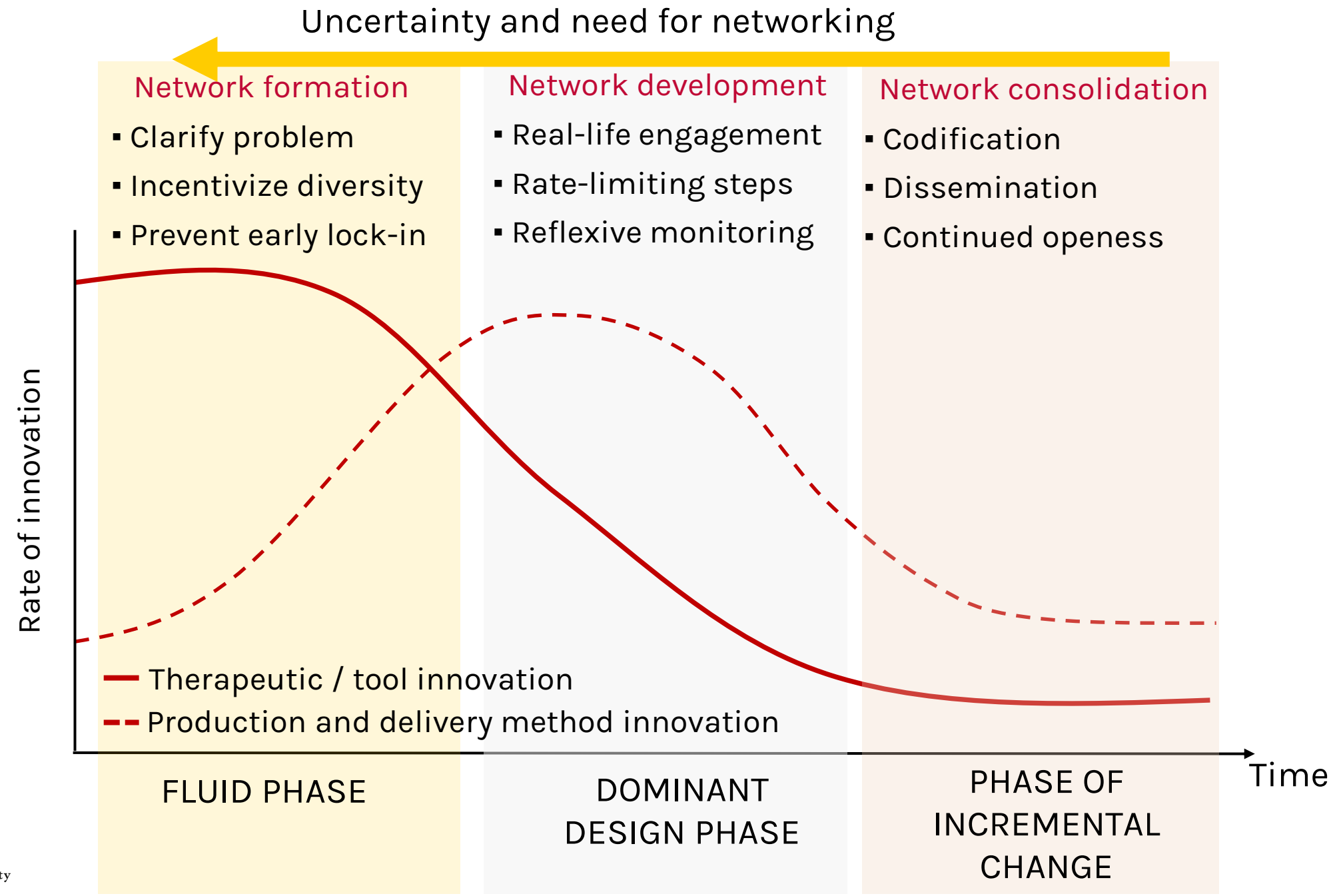


Network dynamics over the innovation lifecycle





Source: Figure adapted from Abernathy and Utterback (1978)

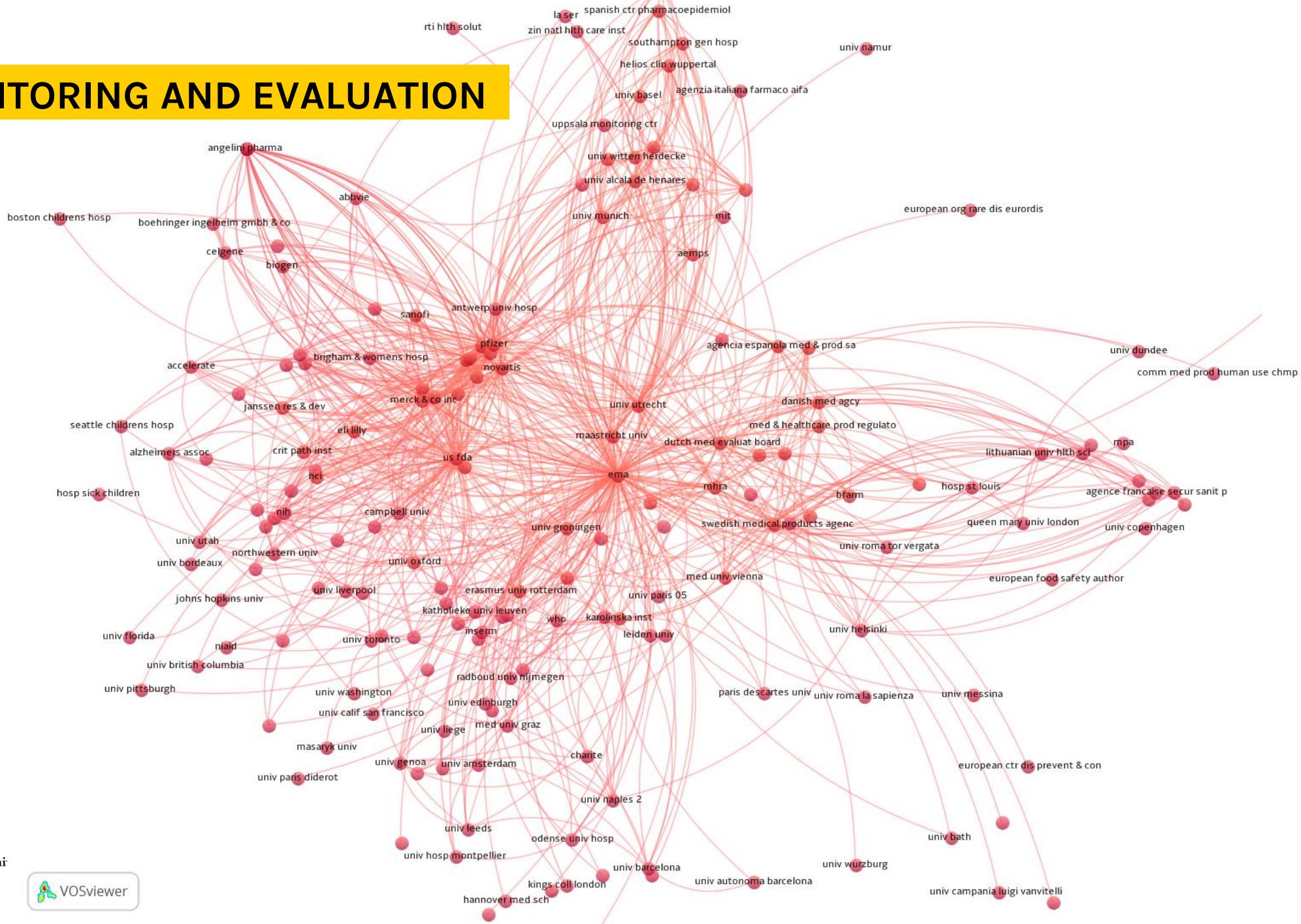


Source: Figure adapted from Abernathy and Utterback (1978)

EVALUATION AND MONITORING

- Public-private partnerships
  - Innovative Medicines Initiative
- Networking instruments
  - Innovation Task Force
  - Scientific advice procedures
  - regulator-funded studies

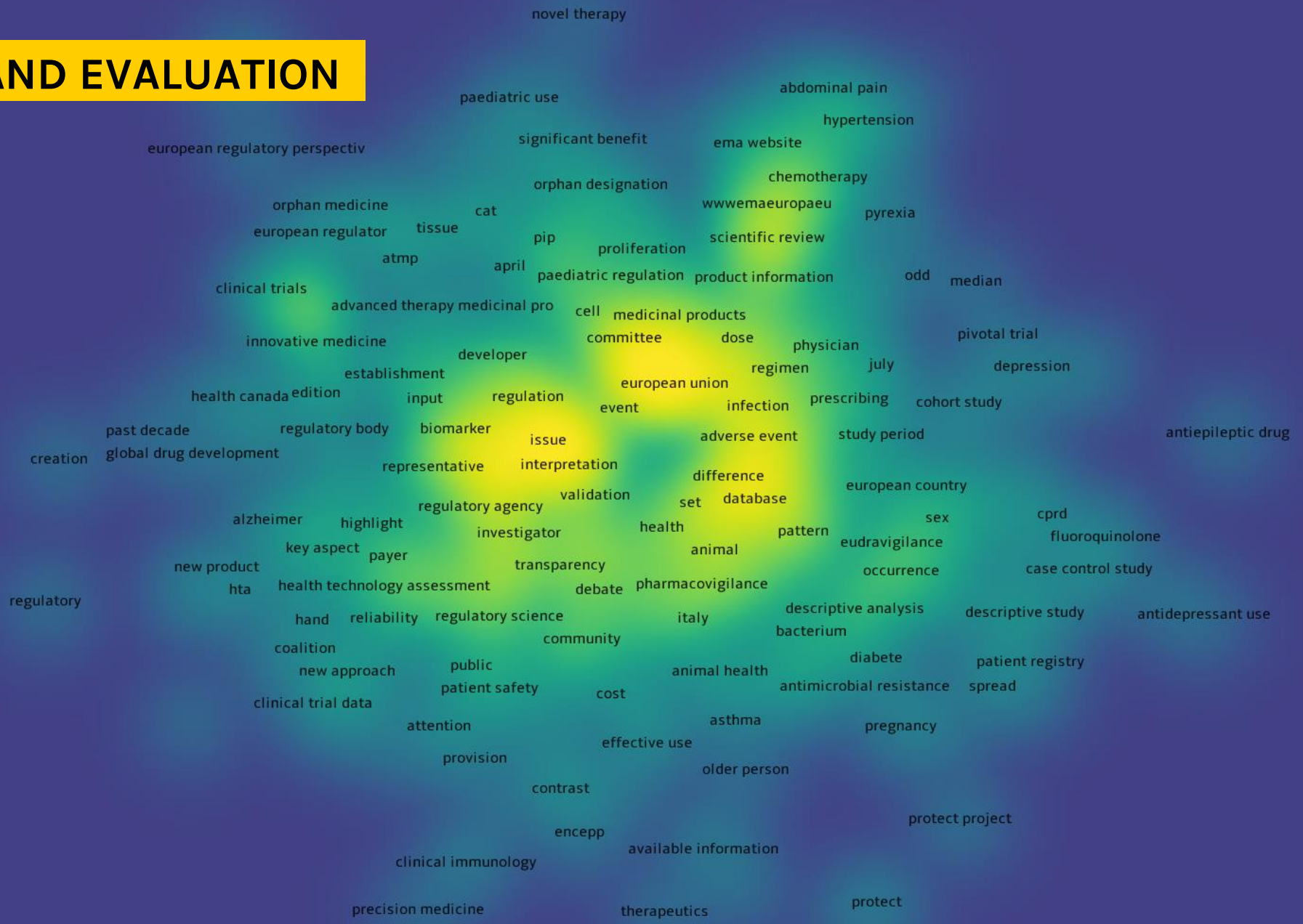
MONITORING AND EVALUATION



Utrecht Uni

VOSviewer

MONITORING AND EVALUATION



VOSviewer

SUMMARY

- Tackling the pacing problem
- Network diversity
  - Boundary spanning needs and capabilities
- Network dynamics
  - Life-cycle approach with end-in-mind
- Evaluation and monitoring
  - Knowledge and trust-building

Thanks for your attention

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