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Innovation Policy Beyond Networks and Structure:

The Case of the Innovative Medicines Initiative

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Agenda

1. European Fragmentation as a Problem
2. New Approach
3. Study Design
4. Theory and Approach
5. Method and Data Collection
6. Case: The Innovative Medicines Initiative
7. Analysis Findings
8. Contributions and Conclusions

The Problem Defined by European Commission: **Fragmentation**

The European Commission: “Total European investment in R&D is lagging behind the US, moreover **Europe suffers from fragmentation of research** support, and from the **low level of interregional collaboration.**”

Solution: Integration via public-private collaboration

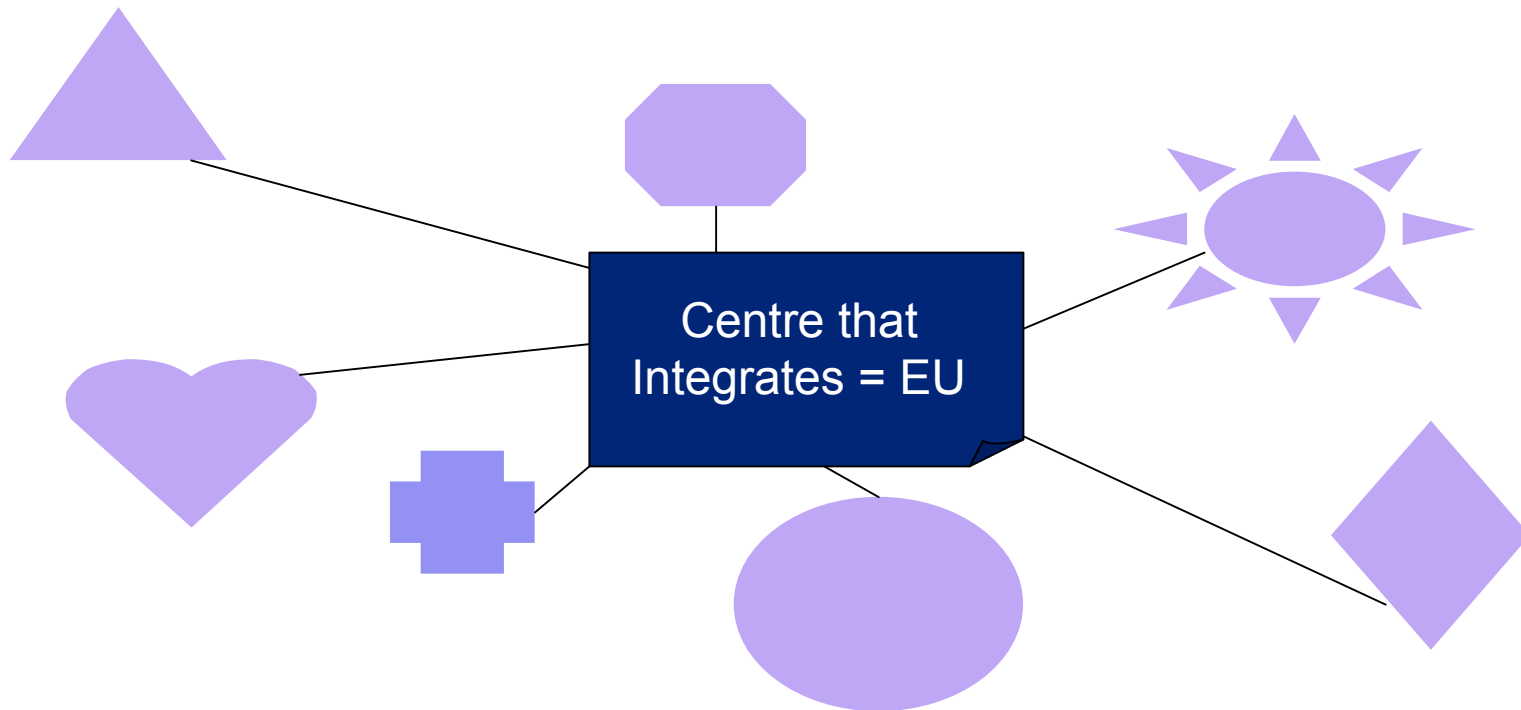
“European Framework Programmes for research (...) should reinforce R&D capacity and **help overcome existing fragmentation** of research policies and efforts... **Maximising collaboration and minimising duplication.**”

Com(2002) 27 final



But This way of thinking is a problem,

because it centralises power in the integrating core (Brussels) and marginalises the fragmented periphery. This increases fragmentation! (Greater power distance)





The Innovative Medicines Initiative (IMI)

- Policy instrument, **led and funded equally by the European Commission and the European Big Pharma Industry (EFPIA)**
- To unite scientists, businessmen, regulators, policy makers and patients in Europe for a revolution in the medicines development process and approval.

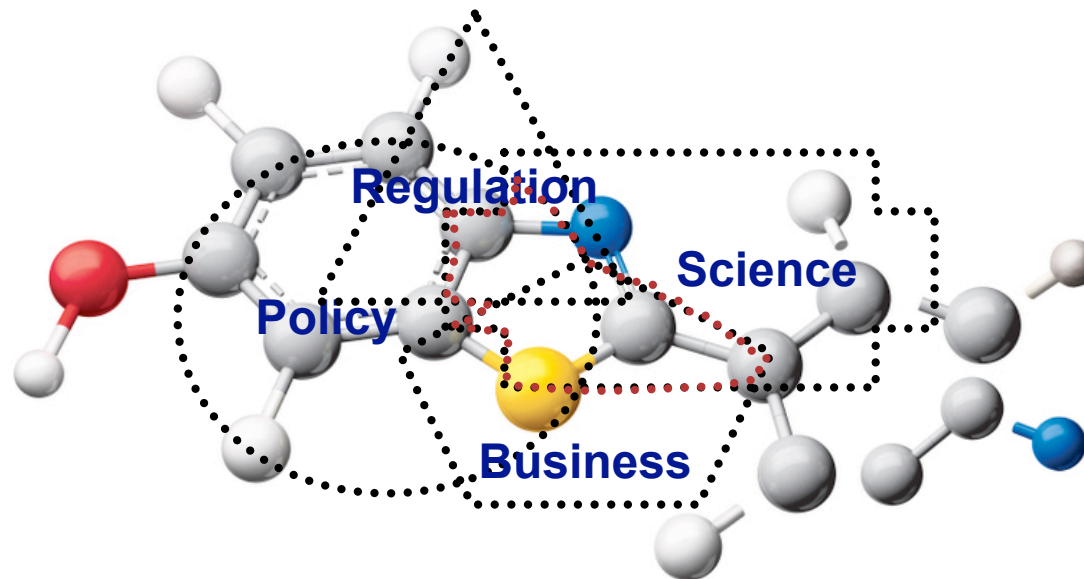


I propose a Different Way of Thinking

Wholeness is the European condition.

Problem: How do European Commission, Industry, Medicines Agencies, Researchers, Patients use collaboration to **draw boundaries** in medicines development? **Beyond Fragmentation and Integration**

This is a collective and knowledge intense process





2. Research Objectives

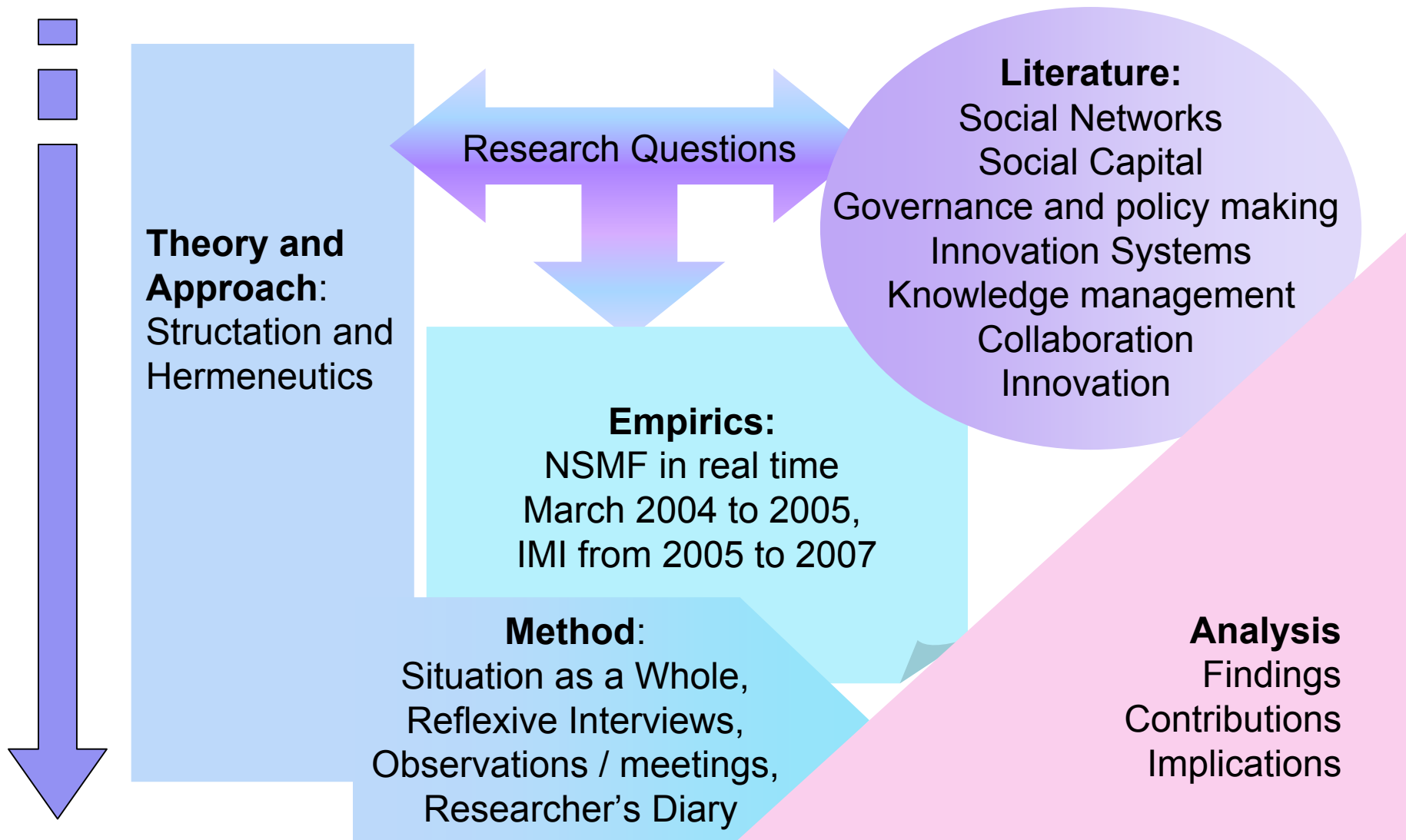
How will IMI manage innovation across Europe?

I analysed:

- ➔ Knowledge Creation and Sharing
- ➔ Organizing
- ➔ Innovation
- ➔ Policy Making and Governance



3. Study Design





Main Literature I argue with

Granovetter 1985, Powell et al 2005: Structure of social relations and the nature of the ties are more important than authority within firms in organizing economic life.

Carruthers & Uzzi 2000: Micro and macro embeddedness co-determine each other;

Coleman 1986: social capital makes relations productive.

Pisano 2006: the anatomy of biotech industry determines performance

Leonard 1995, Nonaka / Takeuchi 1995: Knowledge creation: through externalization, combination, internalization, socialization

Cooke 2001: Regional innovation systems at the heart of economic development;



4. My Theory: Structation

The Process of Structation: Agents mobilise structures via tools to leverage the time-space properties towards a goal:

- ⊙ Past-present-future
- ⊙ Simultaneity and sequence
- ⊙ Speed and acceleration
- ⊙ Rhythm, pace and timing
- ⊙ Expansion and shrinking
- ⊙ Distance and proximity (Fragmentation and Integration)
- ⊙ Direction and focus

Agency has focused intelligence, force, will and creativity.

Zooming is disconnecting and fragmenting the world into manageable entities. Allows seeing organizations as agents, implies a qualitative difference between an organisation and an individual₀



Hermeneutics:

- ➔ Focus on the creative capacity of language
- ➔ The interplay of text and context
- ➔ The meaning beyond “strategic talk”

Discourse:

- ➔ Attention to the said and the unsaid;
- ➔ Knowledge is Power

Wholeness and **uniqueness** of the research situation,
because **research is affected by the eyes that see
and hands that produce** the data.



5. Method and Data Collection

- **Documents on New Safe Medicines Faster (NSMF)** concept since 1997 used to reconstruct the process, on InnoMed and IMI
- **9 Observations of meetings** in 2004 and 2005
- **22 Reflexive Interviews** with experts and managers in Big Pharma, Medicines Agencies, Universities and research institutes, hospitals, policy makers, patient-led organisations, companies conducting clinical trials
- **Researcher's Diary** - organised as a reflexive observation and interpretation
- **Ca. 150 documents:** Industry and Policy Studies, Consultancy Reports, Analyses, documents by the European Commission



Main Theme in the Data: Overcoming Fragmentation

Of Organisations, Agency, Knowledge, Policies, Regions:

- Success depends on **drawing existing European organisations** involved in drug development **into the network**, including the EFPIA, EEB, EMEA, EFB, EACPT, EAFF.
- The future safety **scientist will have to integrate knowledge** accumulated from many **safety-relevant disciplines**
- The use of many new technologies calls for **greater integration of the activities** and a more **holistic view**
- It is necessary to **plan the future rules** for drug **development and approval some 10 years in advance** so the necessary research and validation can take place **in good time.**

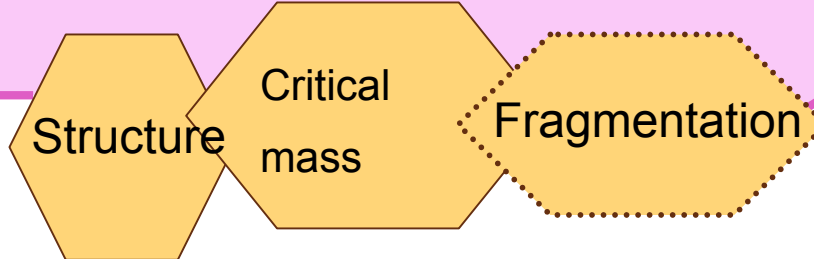


6. The IMI Story: Fragmentation

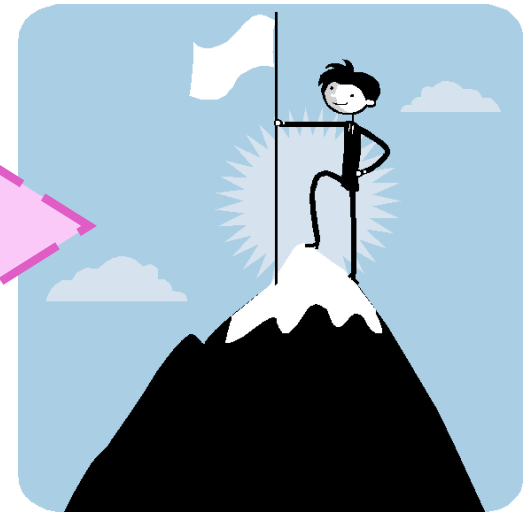


Protagonists
(EC, EFPIA, EMEA, EFB, Universities, Hospitals)

Action - Strategic Research Agenda



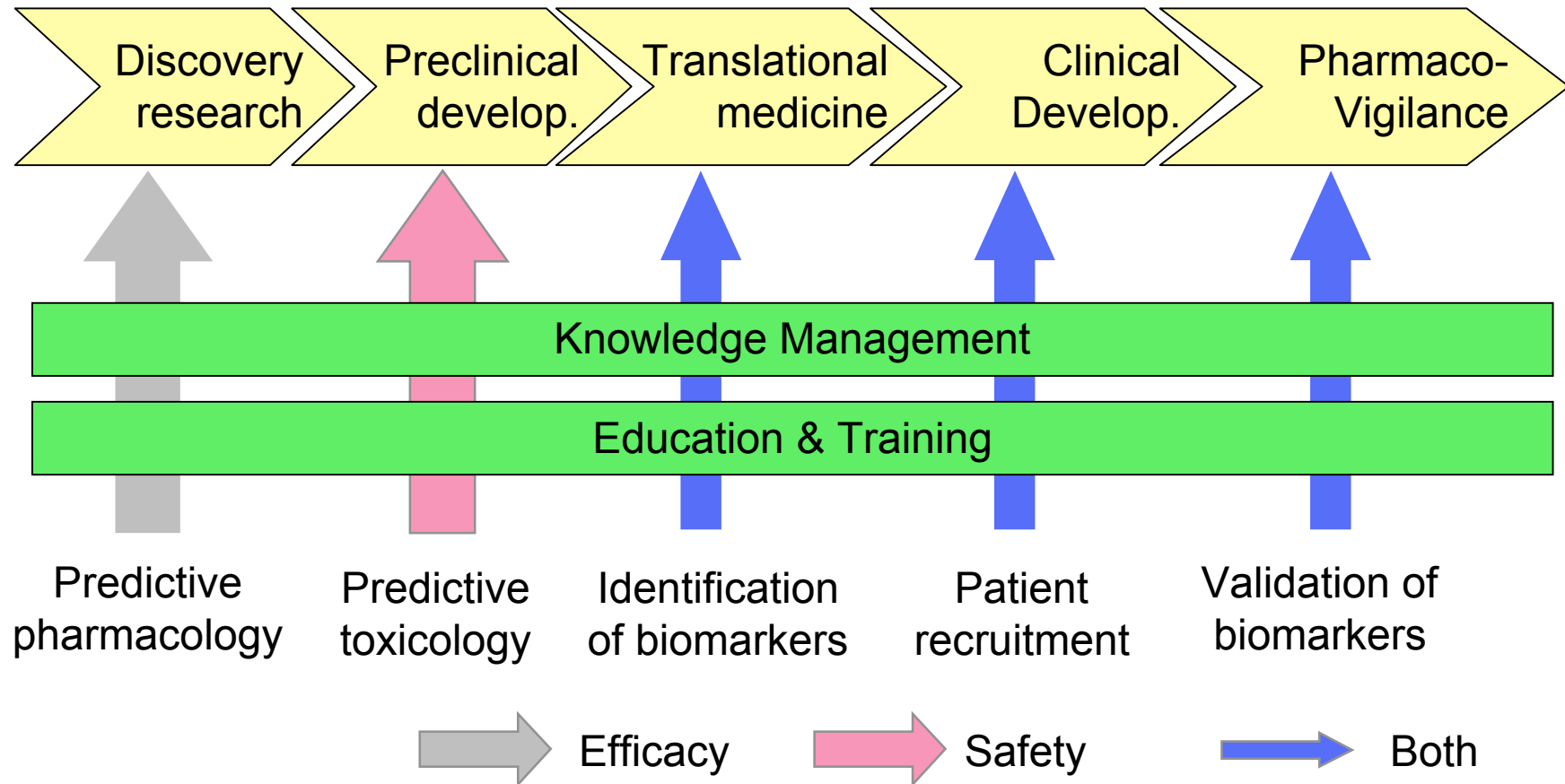
Obstacles



Leadership in bio-
medical Innovation



Medicines Development: Phases and Gaps





7. Analysis

- Knowledge Creation and Sharing
- Organising
- Innovation
- Policy Making and Governance



Knowledge Creation: Making Fragmentation Productive via Timing

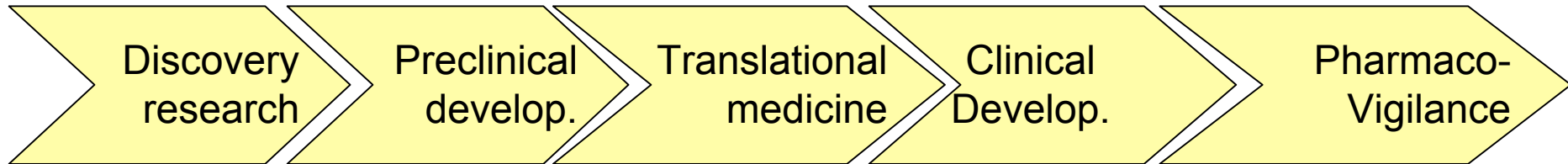
“Time and Money. **But it is not so much time, as it is timing**, because even though time is very much an issue often what you see sometimes in the Big Pharma there are strategic issues, priorities, changes in the organisation that change the process.

So even it seems that they want to **speed things up**, when the decision is made it seems that time is not an issue...”

When acceleration is a state of mind, timing becomes the principle of production.



Creating Knowledge via Simultaneity, Speed and Proximity



Simultaneity, Speed and Timing Turn **Data into Actionable Knowledge**

Holistic view in Education & Training **Enables Agency to Act**

Knowledge **improves the logistics of innovation**: availability, access, timing;

Knowledge **makes an object actionable**: expansion of scope, simultaneity

Translation means simultaneously **similarity** (consistency over phases) and **difference** (qualitative transition, change of status), **increased certainty**.



Knowledge Management as Simultaneity and Presence

Agents manage knowledge by being present simultaneously in the research project and in the knowledge management flow.

Close integration with the scientific projects is a prerequisite for **successful knowledge management**.

We therefore propose that KM staff be assigned to every project **providing close scientific support and at the same time** belong to the KM overview team, thus ensuring **consistency** among projects.

→ But: Simultaneity increases the frailty of knowledge



Organizing: Acceleration as a Shift to Predictability

Acceleration Emphasizes Prediction and Pre-emption

“Every effort must be made to make the drug development process more efficient, **faster and more predictable**. To be effective, the problem must be addressed by the active participation of all relevant stakeholders.

A **revolution of the model for healing diseases, focus on prediction and timing** of a packaged treatment **affecting the core of the disease**, not the symptoms.” (an interview)

It is necessary to plan the future rules for drug development and approval some 10 years in advance...



Organizing as Creating Proximity

Defining Boundaries as Collective Process: Defining what is reasonable

“For physicians to collect the data, the requirements have to be reasonable, because patients will not comply if gathering the data is difficult. **Authorities, physicians and patients have to agree on what is reasonable.**”

→ Reasonability becomes a problem of organising, of establishing simultaneity and proximity (closeness in the ‘neutral territory’, where ‘regulators, industry representatives and scientists could meet and prepare for a rational re-organisation of the drug-development and approval.



Organizing: Using Narratives to Stretch the Limits

“When you are moving towards a target, and that target you can stretch, you can take it to extremes to illustrate a point. You need to shape people’s minds. You have to get all the stakeholders getting used to thinking that way...”

- ➔ Extreme narratives focus energies towards a direction
- ➔ Emotional stories (we care for Europe and want it to succeed) help to embody the goal.
- ➔ Trigger joint action by a sense of urgency and create closeness (bonding).



Innovation Begins with the End of Development

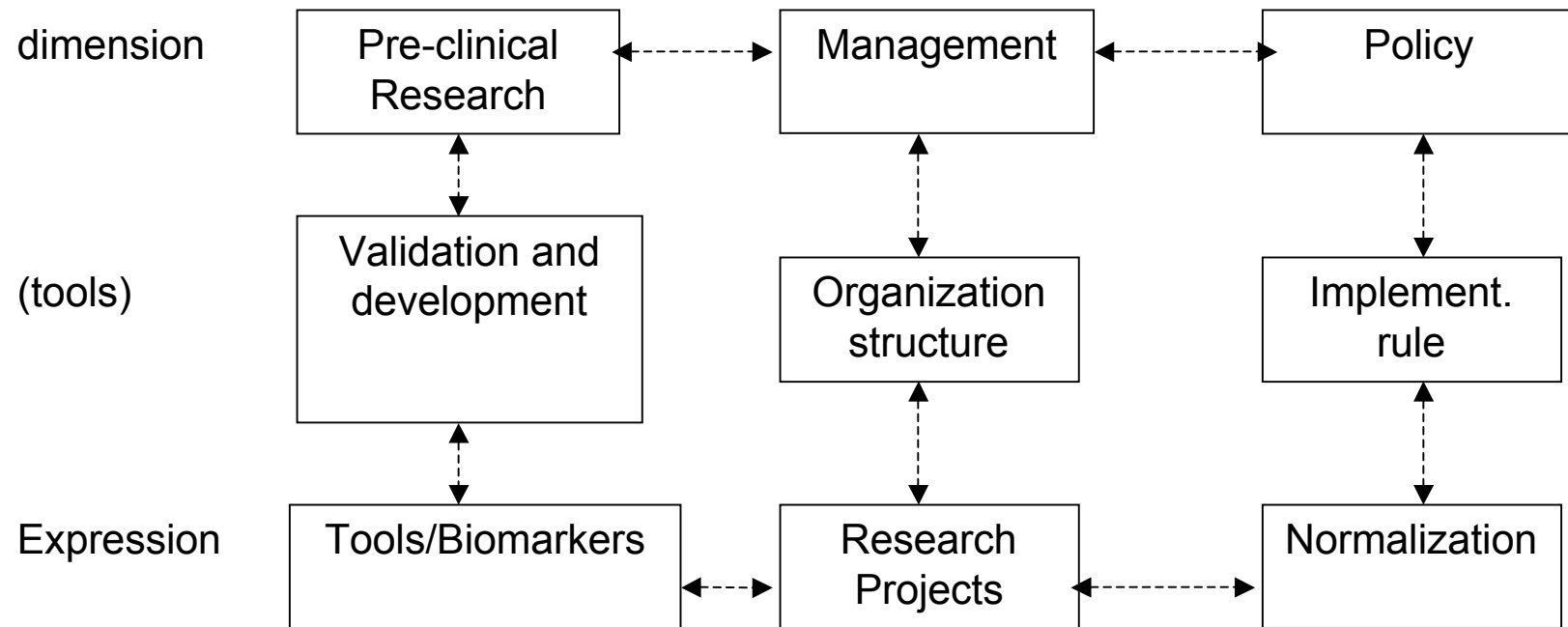
“The issue is really not to get something on the market; the issue is **life cycle management of the full innovation process. Innovation process for new medicines does not stop, when you get a drug on the market.** Then there will be a **portfolio**. For medicines it will be different formulations, for children, for other patient populations. So it is a rolling business, which can grow.”

- Innovation starts with the end of the development process.
- Timing, simultaneity (synergies) and circularity create value.



The Simultaneity of Structuration

Example: Testing a toxicity biomarker





I am not here to accept everything that EFPIA proposes. I mean we put tremendous work all of us here to put this forward, but **we have not come here to accept everything that EFPIA says, because we are in the IP.** No, **they have to come our way;** we invited them to come... we need them, they need us for the proposal.

I am not going to follow everything EFPIA says, **even if they come and do not move an inch from their initial decision** about the disease. I mean...

Drawing Boundaries



Governance: Fragmentation is a Tool in Realpolitik

“...This is what they (**European Commission**) have been doing.

They have been **pulling strings behind everybody's back.**

I mean, they cannot do that. This is not moral. They have a call and

then they move people and then you have selections and you change the call while you are having the selections. How can you

change the call while you are having the selections?

You are right. **I felt like being a football player, where they are changing the rules all the time.”**



8. Main Contributions

1. My **Theory of Structation**: Agents create and mobilise devices (IMI) via tools such as language to leverage the properties of time-space for a goal in a **world that is a seamless whole**.
2. Concept of Zooming as fragmenting the world to see organizational and individual agents.
3. **Focus on Agency and using properties of Time-Space to explain:**
 - a) Knowledge creation and sharing
 - b) Organizing the participants
 - c) Transforming the Innovation Process
 - d) Governing the European territory



Main Conclusions

Fragmentation is a Resource, not a Problem.

The problem is to create the “right” type of fragments.

This is the goal of IMI, and the New Paradigm for Medicines Development;

Agents **uses language** to leverage fragmentation via the properties of time space: distance and proximity, simultaneity and presence, expansion and shrinking, direction, speed and acceleration.

These properties are the focus of agents’ action. They make the European territory available and productive.

Innovation starts with the end of the development process.



Other European Networks

The Clinical Trials Unit (CTU) is a centre for clinical research which is supported by the Medical Research Council (MRC). The Medical Research Council is a non-departmental public body with purpose to encourage and support high quality research with the aim of improving and maintaining the health of the public and of contributing to national health and quality of life.

EBN - the European BIC Network - is a non profit making association based in Brussels. EBN offers services aiming at co-ordinating the activities of the BICs, developing and promoting the BIC concept within and outside the European Union.

ENIC: European Network of National Information Centres on academic recognition and mobility, created by the Council of Europe and UNESCO. The Council and UNESCO/CEPES jointly provide the Secretariat for the ENIC Network. The ENIC Network cooperates closely with the NARIC Network of the European Union.

NARIC network is an initiative of the European Commission and was created in 1984. The network aims at improving academic recognition of diplomas and periods of study in the Member States of the EU.

EUREKA: A network for market oriented R&D.

EUNITE - the European Network of Excellence on Intelligent Technologies for Smart Adaptive Systems - has started. It is funded by the Information Society Technologies Programme (IST) within the European Union's Fifth RTD Framework Programme.

DANTE (Delivery of Advanced Network Technology to Europe) plans, builds and operates advanced networks for research and education. It is owned by European NRENs (national research and education networks), and works in partnership with them and in cooperation with the European Commission.