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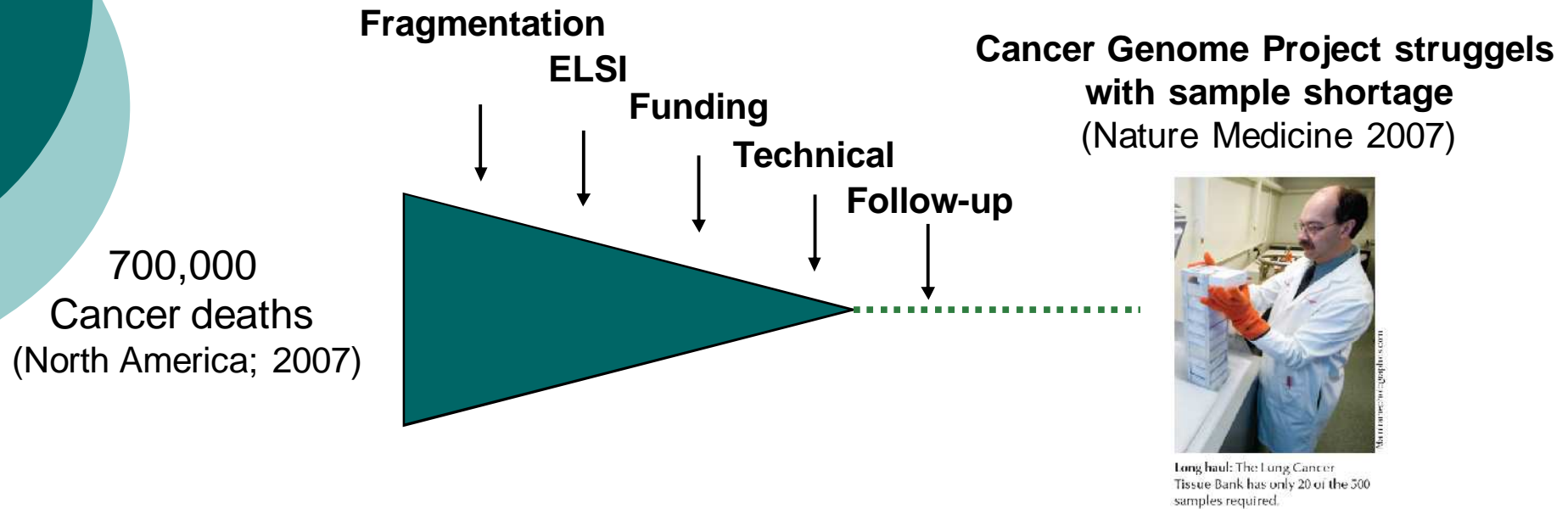
# **The European Research Infrastructure for Biobanking and Biomolecular Resources (BBMRI)**

Kurt Zatloukal, Medical University of Graz, Austria

**Grant Agreement 212111**

October, 2008

# Biobanks in Cancer Research



- **NCI**: Biological samples are #1 roadblock
- **OECD**: Global Biological Resource Centre Network
- **WHO/IARC**: Standards for biological resource centres
- **ESF**: Science Policy Briefing: Need for integration
- **EU/ESFRI**: Research infrastructure for Biobanks and Biomolecular Resources (BBMRI)



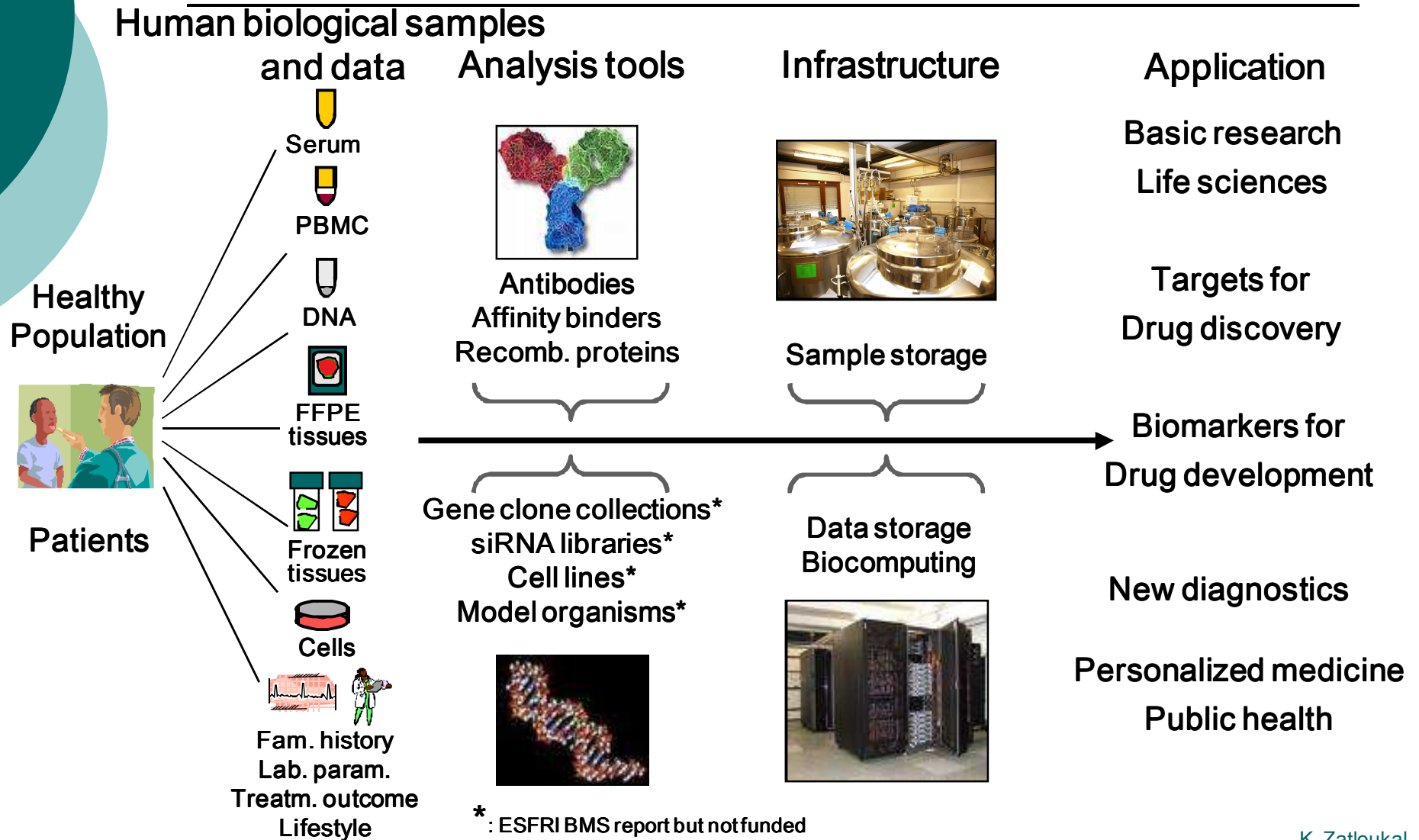
EUROPEAN ROADMAP  
FOR RESEARCH  
INFRASTRUCTURES

Report 2006

## **The facility**

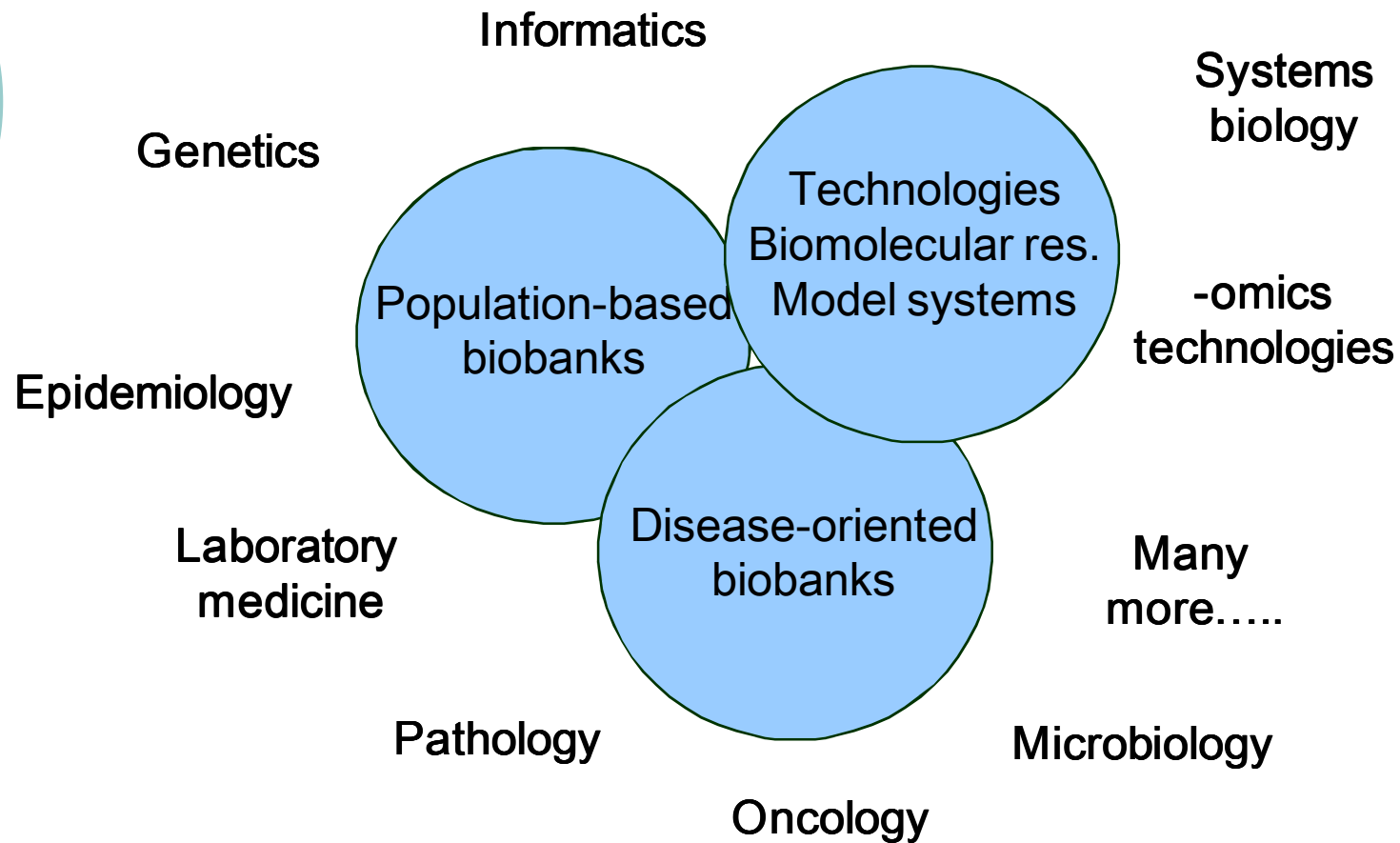
**A pan-European and broadly accessible network of existing and de novo biobanks and biomolecular resources. The infrastructure will include samples from patients and healthy persons, molecular genomic resources and bioinformatics tools to optimally exploit this resource for global biomedical research.**

# Key Components of BBMRI



# The Added Value of Cooperation

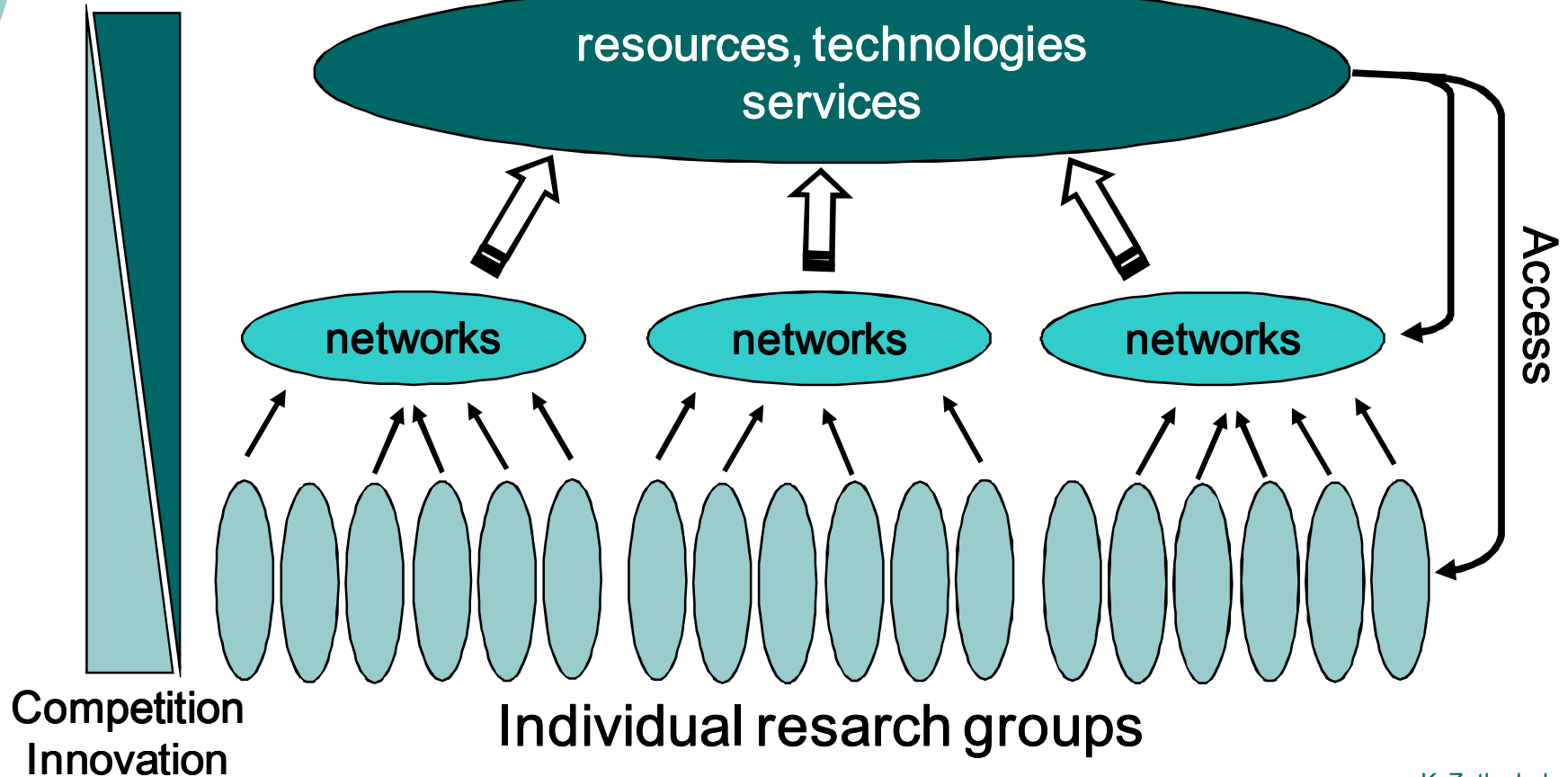
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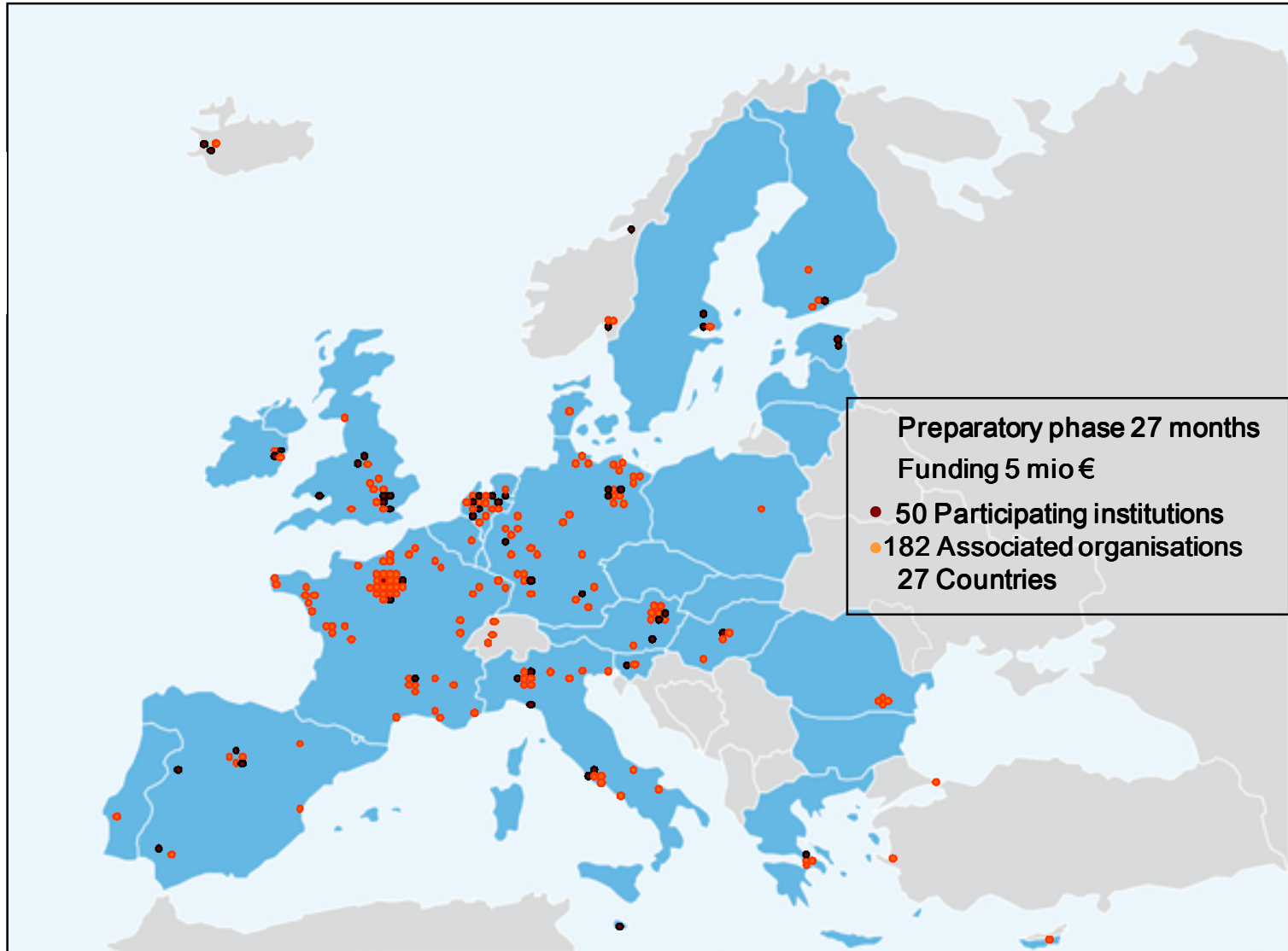
# Research Infrastructures: The new dimension in life sciences research

Cooperation  
Integration  
Harmonization

pan-European research infrastructures

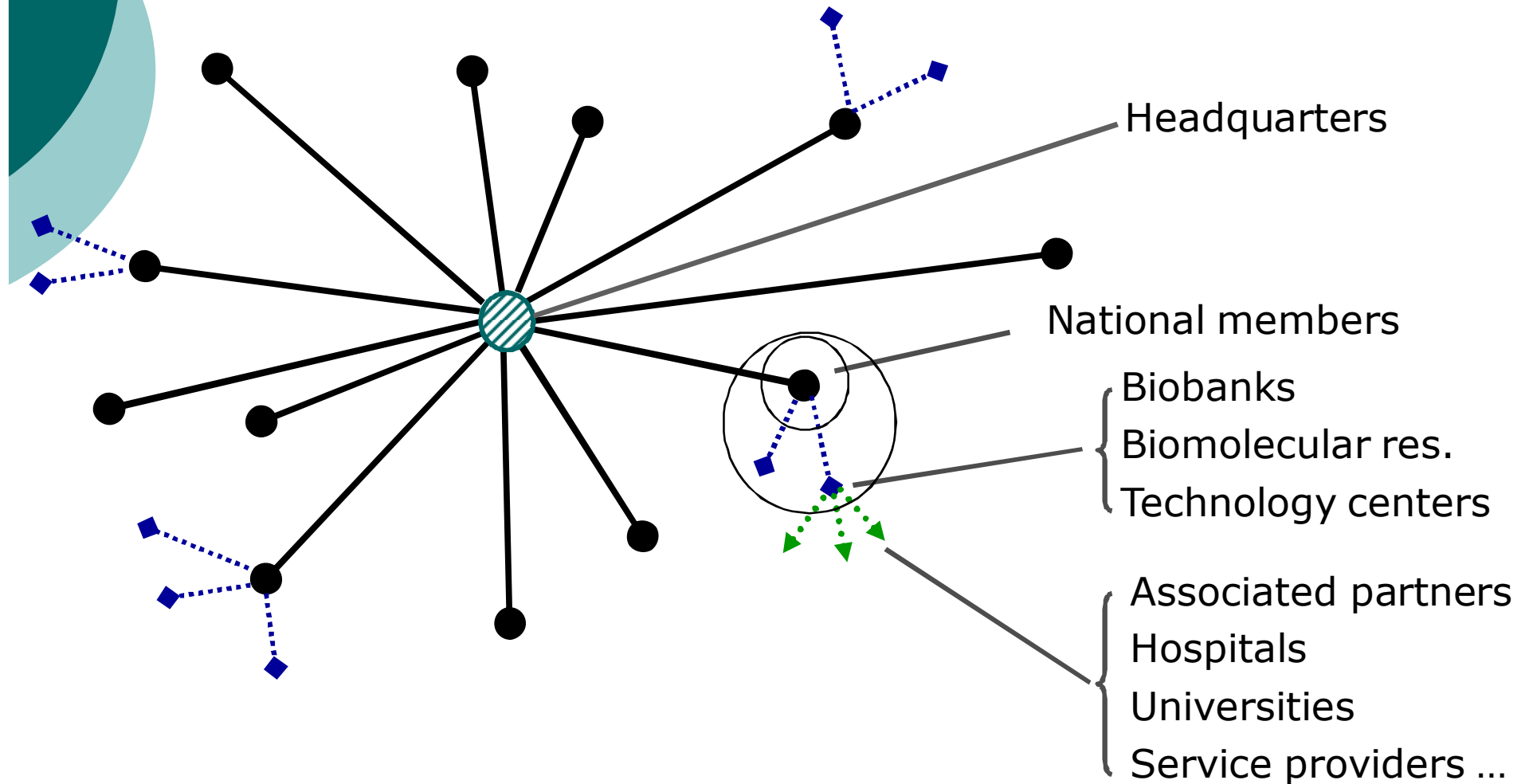


# The Starting Point for a pan-European BBMRI



# The Legal Structure of BBMRI (ERI)

## *Distributed hub and spoke structure*







# Legal Entity for European Research Infrastructures (ERI)

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## Pros

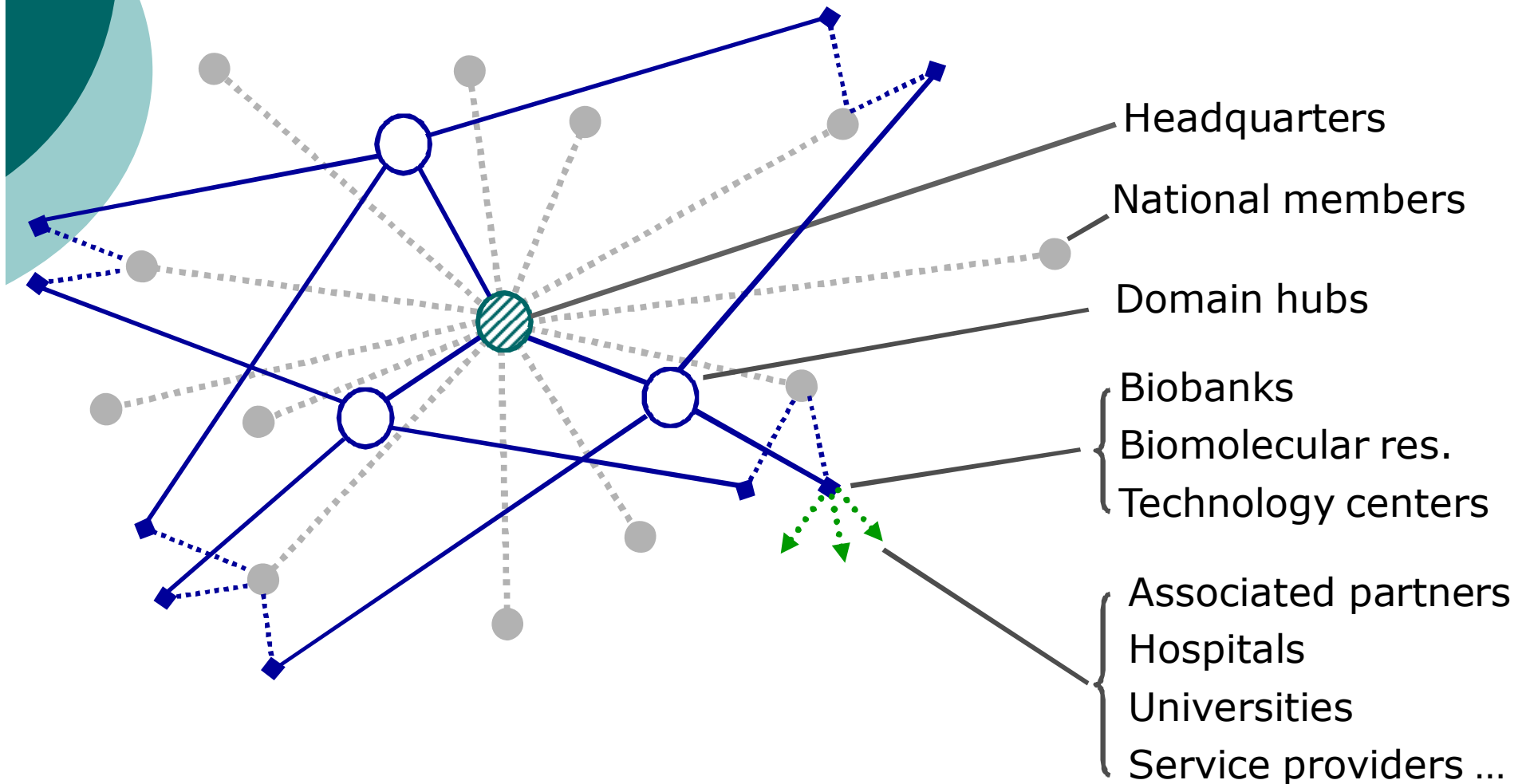
- Generates new brand for RI
- One legislation for operation of RI in different Member States
- Benefits of international organization
  - Tax exemptions

## Contras

- Requires separation of biobank from administrative environment of universities and hospitals
- Member States are the members of ERI
  - Involvement of stakeholder difficult
- Reporting to Commission

# The Operational Structure of BBMRI

## *Distributed hub and spoke structure*



# Organization (prep phase)

Strategic

Executive

Operative

Science  
Industry  
ELSI

Advisory board

Governance council  
(participants, ass. organizations)

Stakeholder  
forum

Funders  
Patients  
Clinicians  
Industry  
Partners  
Users

Coordination board  
(external projects)

Steering committee  
(WP leaders, chairs)

Participants

Project  
Management  
WP1

Executive  
Management

Funding  
Financing  
WP7

Participants

Population-based  
Biobanks  
WP2

Disease-oriented  
Biobanks  
WP3

Biomolecular resources  
Technologies  
WP4

Data bases  
Biocomputing  
WP5

ELSI  
WP6

Participants

Participants

Participants

Participants

Participants

# The Process



Evaluation of existing resources and solutions  
Identification of open issues

Concept for:

Integration of existing resources  
Integration of future resources  
Process standardization, certification  
Access rules  
Incentives and benefit sharing  
International exchange of samples and data

Operational concept

Financial Plan

Implementation Plan

MoU, Contracts



# Starting Points

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- OECD best practice guidelines for Biological Resource Centres
  - Facilitate and regulate international cooperation of biobanks
  - Define common minimal standards on sample quality and data
  - Define high standards on traceability and biosecurity
  - Foresee certification
  - International consensus achieved (declassified by CSTP)
  - However no implementation plan !
- P3G
  - International harmonization of biobanking
- FP5+FP6, national programs
  - Existing biobanks, resources and networks



# Differences and Similarities of the OECD GBRCN and HBGRD Documents

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## **GBRCN**

- Facility
- Personnel
- Biosecurity
- Traceability
- MDS,RDS
- Data protection
- Certification
- (Old collections)

## **HBGRD**

- Informed consent
  - IC process
  - IC document
- Governance
- Stakeholder
- Involvement of donors
- Data protection
- Change of scope
- (Old collections)



# Advantages of a Joint Planning of BBMRI and the OECD GBRCN

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- Guarantees proper coordination of investments into biological resources in Europe
- Reduced costs of a joint coordination secretariat
- Win-win situation:
  - Rapid implementation of OECD GBRCN
  - Global integration of BBMRI



# The Questionnaire

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- Evaluation of:
  - Available samples: type, quality, quality
  - IT infrastructure, database, data protection
  - Governance structure
  - Access rules
  - Pertinent ELSI
  - Funding



- Inventory
  - Identify candidates for prototype and demonstration project
  - Identify candidates for future members
  - Basis for construction and operation plan





# BBMRI Prototype

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- To accomplish a great vision in a series of specific steps
- Most advanced biobanks should start the construction of a prototype infrastructure already during preparatory phase on a voluntary basis
- Requires support from national Funders and Ministries



# Demonstration Project (use case)

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- To demonstrate how BBMRI might increase scientific excellence and efficacy of European research in the life sciences.

# Time Lines

BBMRI PP

Inventory	Concept	Contracting	Construction
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Prototype (voluntary)

Concept/Constr.	Operation
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Demonstration project (voluntary)

Design	Analysis
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# Specific Challenges for International Networking

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- Harmonization of technical guidelines and standards
- Guidance through the heterogeneous ethical and legal frameworks of European Member States
- Implementation of harmonized data protection and informed consent standards



# Clinical Samples: Critical Issues

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- Collected in routine medical service
  - Limited possibilities for standardization
    - Processes are directed by patient needs (surgery, pathology etc.)
    - Differences in European health care
    - Modifications are difficult and expensive
- Many stakeholders
  - Patients
  - Health care funders
  - Medical professionals (surgeons, pathologists, radiologists, lab.medicine, internist etc.)
- Incentives for Contributors
- Limited resource (access rules)



# Need for Evidence-Based Biobanking and Biospecimen Research Standards

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- Basis for harmonization of guidelines
- Requires global cooperation
- Implementation by journals
- Implementation by funders
- Integral part of good scientific practice

Caveat: misuse of standards to generate competitive advantage

# The Adaptor Approach of BBMRI

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- Define criteria
  - Which samples and data can be combined?
  - Need for evidence-based standards
- Develop tools
  - Data exchange
  - Sample transport
- Provide Access



# Incentives for Contributors

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## Scenarios

- Research collaboration
- Independent research interest
- No research interest





# Incentives for Contributors

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- Added value of cooperation
- BBMRI provides framework for high calibre research collaborations
- Access to assets of BBMRI
- Recognition as qualified resource provider
- Qualification for public funding
- Financial benefits



# Involvement of Industry

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- Role of BBMRI
  - Resource provider
  - Strategic partner for developments
  - Customer
- Role of industry
  - Income and support essential for sustainability
  - Key user to improve health care



# Building the Resources for the Future

## Can we really do this?

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- How to foresee the sample and data requirements for projects performed in 20 years?
- Several new preservation methods
  - How to do stability testing?
  - Good experience for DNA and RNA
  - Little experience for proteins, protein modifications, protein complexes, metabolites



# What is the Best Strategy?

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- **Very high sample quality criteria from biobank studies**
  - Outmost scientific value
  - Only few samples fulfill criteria
  - Strong selection bias
  - Not relevant for medical routine
  - Expensive
- **Samples from routine health care**
  - Variable quality
  - Available in sufficient quantity
  - Required for biomarker validation studies

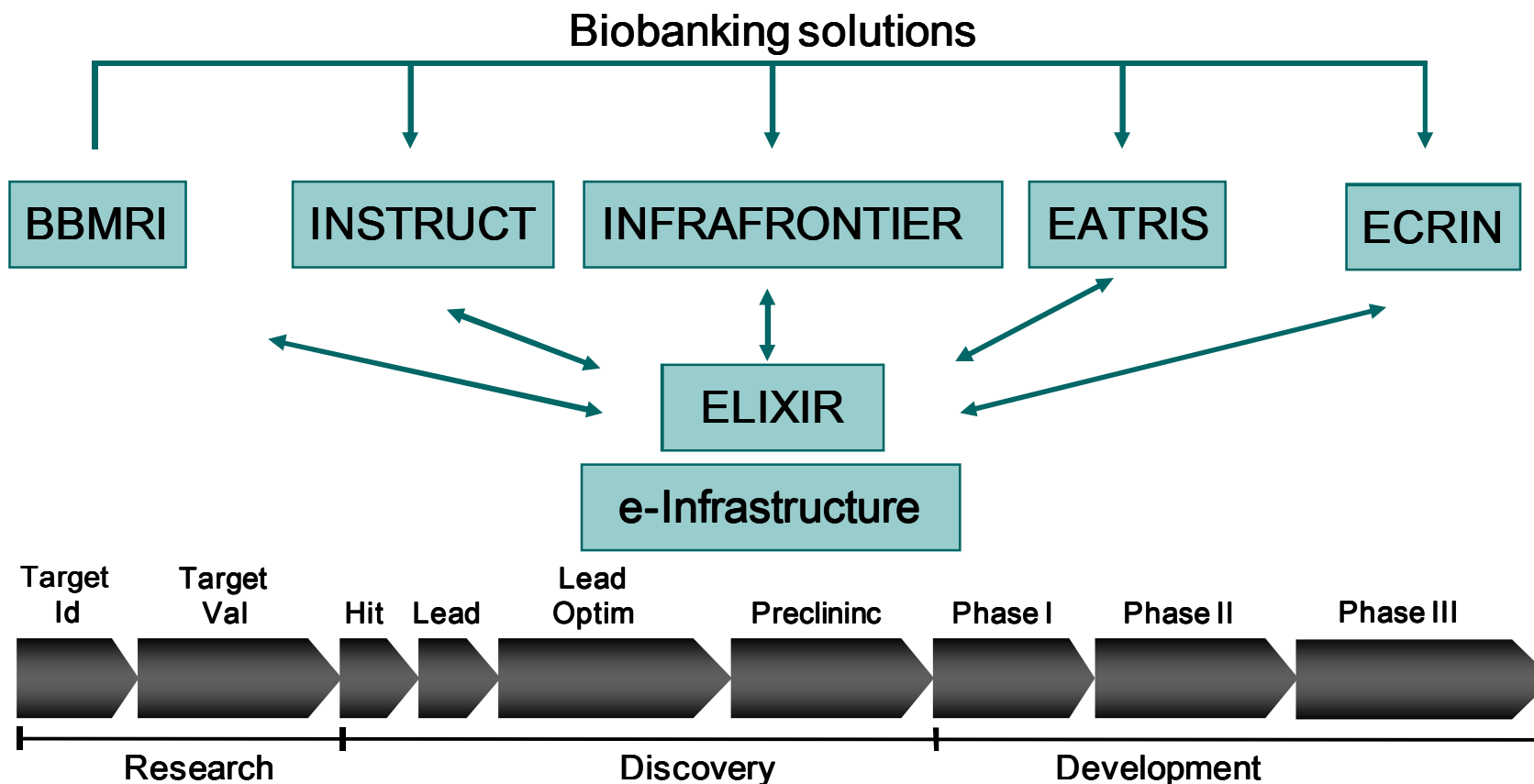


# Communication Strategy

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- Coordinated communication strategy of all BMS Research Infrastructures
- Cooperation with Commission
  - Expected impact of European RIs on science industry and society
  - Impact of individual RIs

# Synergies of Research Infrastructures and Technology Platforms



INNOVATIVE MEDICINES INITIATIVE

# Communication Strategy

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- Professional support (task force)
- Feedback from focus groups



Websites, flyers  
of Research Infrastructures



# The Vision

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BBMRI will sustainably secure access to biological resources required for health-related research and development intended to improve the prevention, diagnosis and treatment of disease and to promote the health of the citizens of Europe





# Expected Impact of BBMRI

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- BBMRI provides framework to foster excellence in biomedical research
  - Better projects, faster, cheaper
- Certified biobanks & biological resource centres
- Globally harmonized processes
- Access to high quality resources, technologies, services
- Partner for academia and industry
  - SMEs: Strategic partner, customer
  - Pharma: Biomarker and drug development



# If Competitors (have to) Collaborate

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4. Juni 2008, Neue Zürcher Zeitung

**Wenn Konkurrenten kollaborieren  
(müssen)**

***Der schwierige Balanceakt zwischen  
Teamarbeit und persönlicher  
Profilierung***



## Acknowledging BBMRI in FP7 proposals

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- "Dr/Mr/Ms N.N. is a participant/associated partner in BBMRI (Biobanking and Biomolecular Resources Research Infrastructure, Call Identifier FP 7 INFRA-2007-2.2.1.x; Grant agreement 212111). N.N. has informed the BBMRI Steering Committee of his/her participation in this application. If the proposal will be funded, N.N. will act in such a way that the relevant activities described in this application are coordinated with BBMRI as will be indicated in the final technical annex."



# Upcoming Activities

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- Networking of EU-funded Biobank Projects, Brussels, 20.-21.11.08
- ECRI Conference, Paris, 9.-11.12.08
- Joint BBMRI, P3G, PHOEBE Conference, Brussels, 24.-26.3.09
- Communication strategy for all life science infrastructures
- Socio-economic impact study
- Interphases Systems Biology, BSL4 Laboratories
- IMI Education and training platform (call 14)
- Medical data management (ELIXIR, IMI, P3G)

# The Team: WP Leaders and Chairs

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Coordination/Executive Mgmt.

K. Zatloukal, AT; E. Vuorio, FI

M. Yuille, UK; M Pasterk, FR

Population-based Biobanks:

L. Peltonen, FI/UK; A. Metspalu, EE

Disease-oriented Biobanks:

E. Wichmann, GER, T Meitinger, GER

Biomolecular Resources:

U. Landegren, SE; M. Taussig, UK

Databases & Biocomputing:

J-E Litton, SE

Ethical, Legal and Societal Issues:

A. Cambon-Thomsen, FR

Funding and Financing:

G. Dagher, FR; J. Ridder, NL

C. Brechot, FR;

Governance Council Chair:

L. Peltonen, FI

Advisory Board Chair:

G-J van Ommen, NL

Coordination Board Chair:

K. Zatloukal, AT

Stakeholder Forum Chair:

M. Griffith, IR

50 Participants (6 Ministries, 18 Funding Organizations)

182 Associated Organizations 27 Countries



# Further Information

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Kurt Zatloukal, M.D.  
Institute of Pathology  
Medical University of Graz  
Auenbruggerplatz 25  
A-8036 Graz  
Austria

Tel: +43 316 380 4404  
E-mail: [kurt.zatloukal@meduni-graz.at](mailto:kurt.zatloukal@meduni-graz.at)

[www.bbmri.eu](http://www.bbmri.eu)

M. Yuille et al. *Briefing in Bioinformatics* 9: 14-24 (2008)