BBMRI
Biobanking and Biomolecular Resources Research Infrastructure

CAPACITIES

BBMRI GA Nr. 212111
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New Models for Industry - Biobank Collaboration: The Experts Centre Concept

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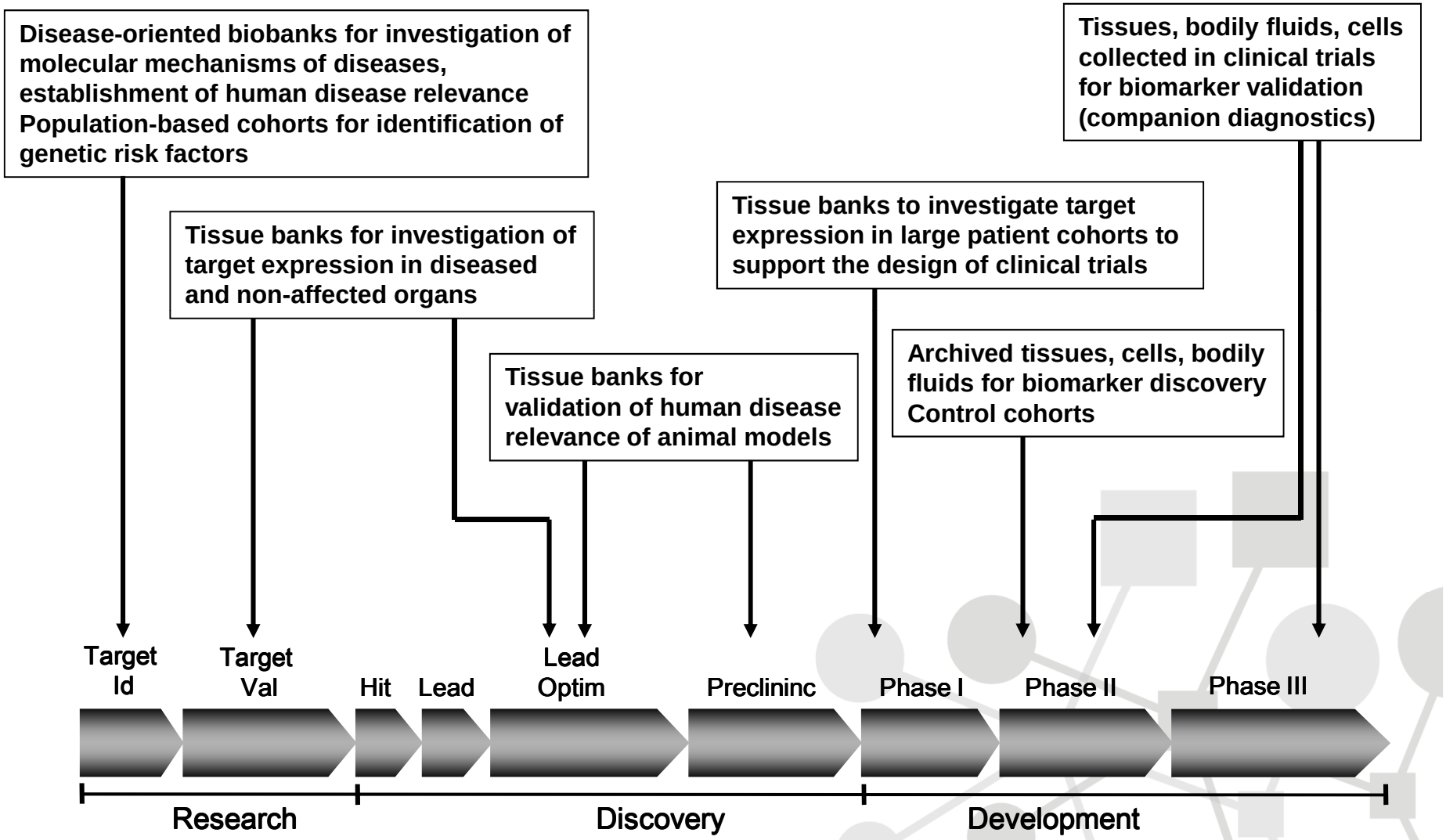
Montreal, April 27th 2010

Biobanks in Biomarker and Drug Development



Convention on Human Rights and Biomedicine (ETS 164) Oviedo, 4.4.1997

Article 21 – Prohibition of financial gain

The human body and its parts shall not, as such, give rise to financial gain.

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Biobanks need pharma

Which is why Europe's citizens need reassurance that their donations will be in the public interest.

Medical geneticist Thomas Meitinger remembers when biobanking was a simple craft. As a postdoc thirty years ago, he travelled from Oxford to Yugoslavia to track down a family afflicted with a rare disease causing blindness. The family listened enthusiastically as he explained his research over a fish dinner. He returned with blood samples and over the next decade used them to identify the single gene defect that caused the condition.

Biobanking — collecting tissue or body fluids alongside medical information — is now a large-scale affair. Genomics allows geneticists to track down not just the single genes that convey a strong risk of disease, but also the many low-risk genes associated with the diseases that kill most of us, such as cancer, diabetes and cardiovascular disease. But these very weak gene signals can be picked up only in studies of large populations of up to hundreds of thousands of people.

Europe leads the world in biobanking. It has more than 400 biobanks, some involving hundreds of thousands of diseased and healthy individuals. It is now seeking to make the most of that resource: the European Commission is funding a preparatory study aimed at linking the biobanks into one distributed infrastructure. Now Meitinger, who currently works at the Institute of Human Genetics in Neuherberg, Germany, and the rest of the scientific consortium driving the effort, called the Biobanking and Biomolecular Resources Research Infrastructure (BBMRI), must find stable funding for the project and arrange access for the scientific community.

That's a lot of tough challenges at a time when the general public is sensitive to any issue involving genes and biological material. Key concerns in biobanking are those of anonymity and whether true informed consent can be given by individual donors now too numerous to be educated over dinner.

Another, potentially incendiary, issue is whether the pharmaceutical industry should have the same access rights to biobanks as academic researchers. Europe's citizens could easily turn against biobanking if they start to feel exploited for financial gain. The BBMRI must accommodate industry while avoiding such a backlash.

Biobank resources may be fundamental to understanding the molecular bases of common complex diseases, but it is the pharmaceutical industry that will develop the treatments for such ailments. Companies generate their own biobanks, but these cannot reach the scale necessary to move forward. Industry wants access to large public biobanks, and the BBMRI recognizes its obligation to facilitate new medicines. The consortium hopes that relentless outreach and appropriate control of banked materials will achieve this without antagonizing the public.

At the consortium's first stakeholder meeting last week, patient groups declared that they don't care who gets hold of their diseased tissue "so long as it is out of our bodies and being used to do clinical good". But the large majority of healthy donors will need more persuading that profit-making industry should get access to their voluntary tissue donations.

The concept of expert centres, unveiled by the BBMRI at the meeting, should help. These would do all the molecular analyses on material requested for an approved study and provide data only to clients. Donors' material would not move out of the biobanking infrastructure, and data would be stored for re-use in other studies, so industry could not gain exclusive rights.

Industry must also be prepared to give something back, in the form of access to its own biobanks and their richly financed expertise. Research departments across all companies believe that biobanks and the molecular information generated from them are outside the competitive realm, but their managers tend to be wedded to secrecy. So managers must be persuaded to follow their researchers' instincts, before the public gets the idea that industry is there only to exploit, gets deterred from donating, and the whole enterprise becomes tainted with distrust. ■

Nature September 2009

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The Win – Win Situation

- Industry needs access to samples, data and scientific/medical expertise
- Industry can provide important know how and in-kind contribution

- Biobanks require involvement of industry to contribute to improved health care
- Biobanks require additional funds for sustainability

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BBMRI Expert Centres

A new model of public-private-partnership to improve efficacy of biospecimen research for academia and industry

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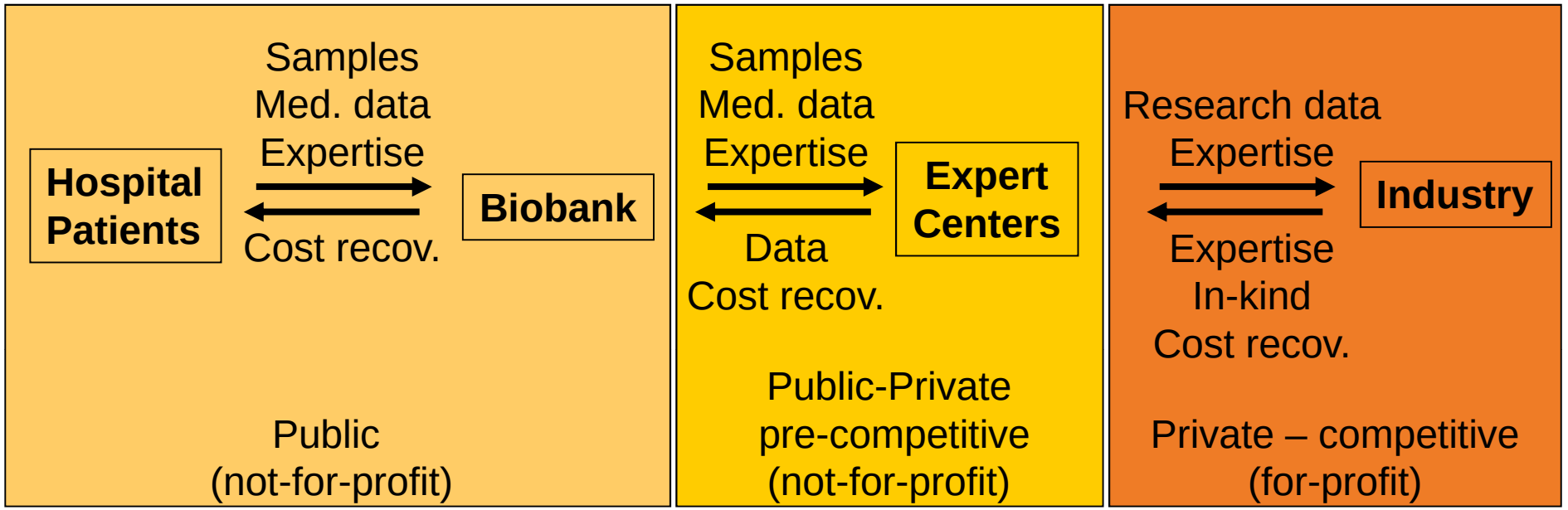
Expert Centers: Model A



Provides efficient access to samples, data and expertise
Mutual benefit from expertise and in-kind contributions
Joint generation of pre-competitive data and knowledge
Reduces requirements for sample shipment
Gateway for global collaborations

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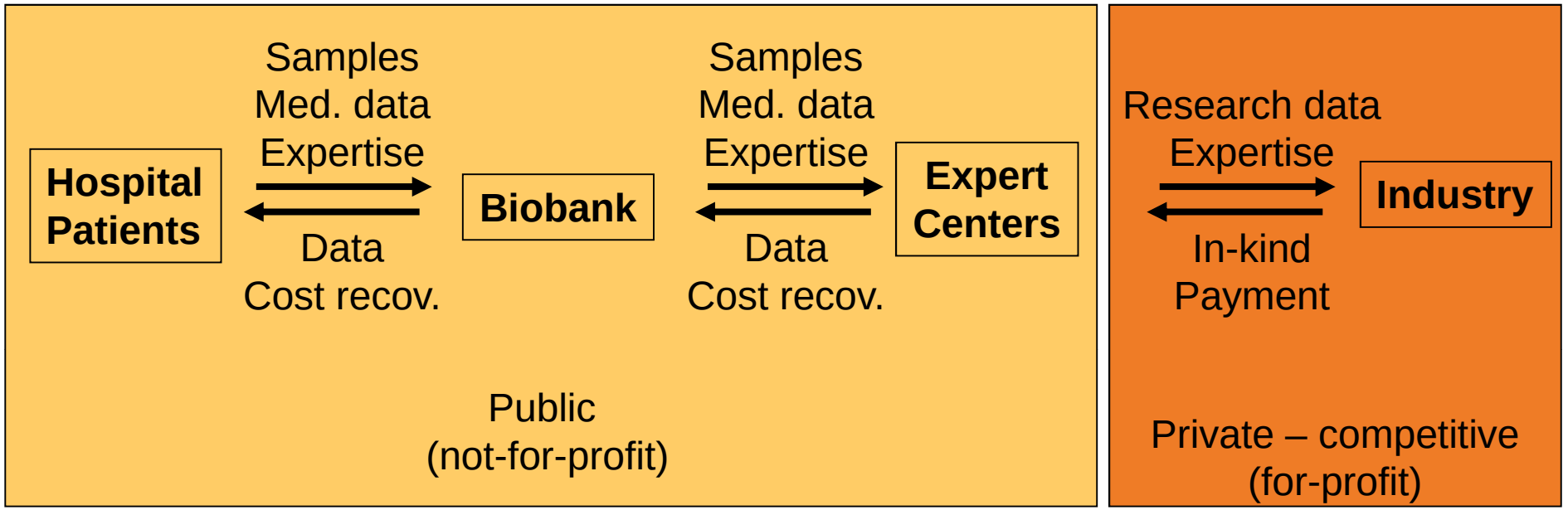
Expert Centers: Model B



Provides limited access to samples, data and expertise
Benefit from in-kind contributions
Generation of pre-competitive data and knowledge
Reduces requirements for sample shipment
Gateway for global collaborations

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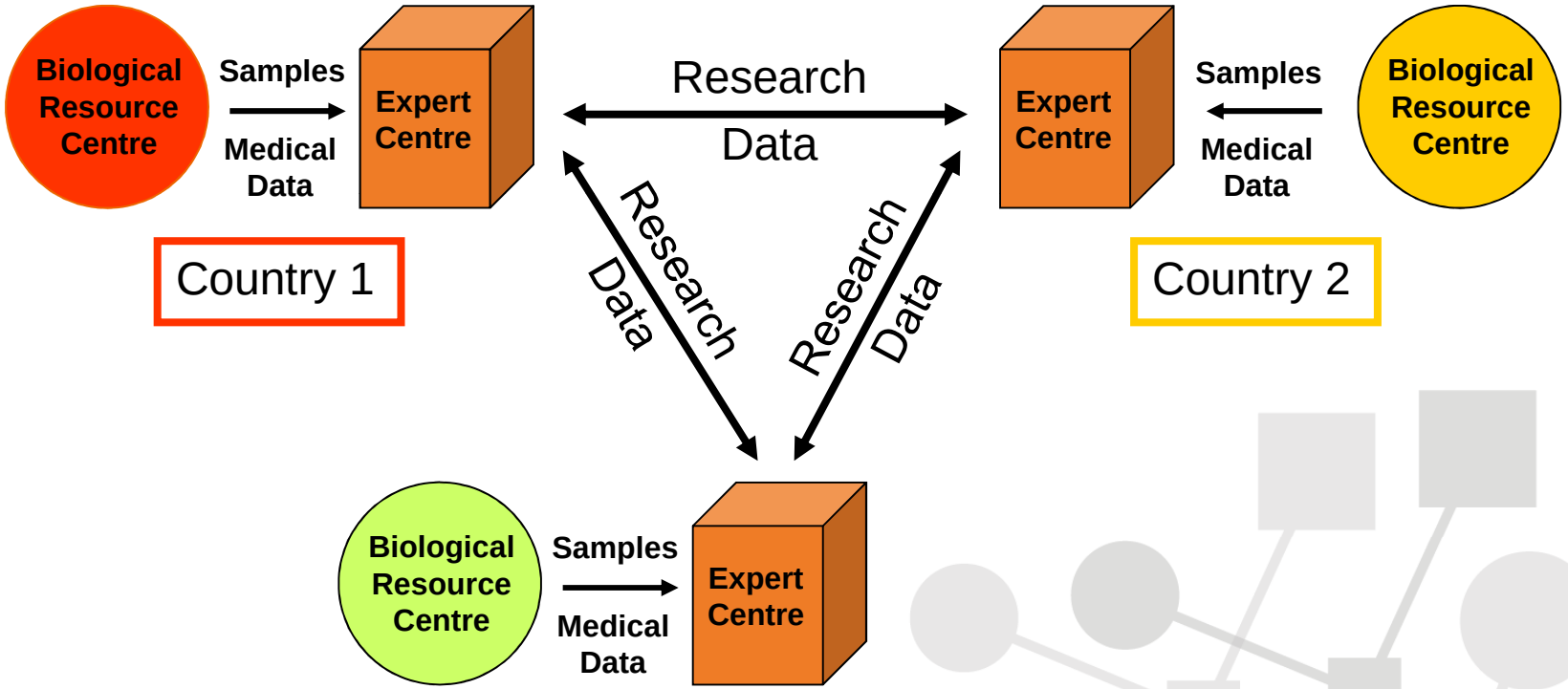
Expert Centres as Highways for Transnational Research Collaborations



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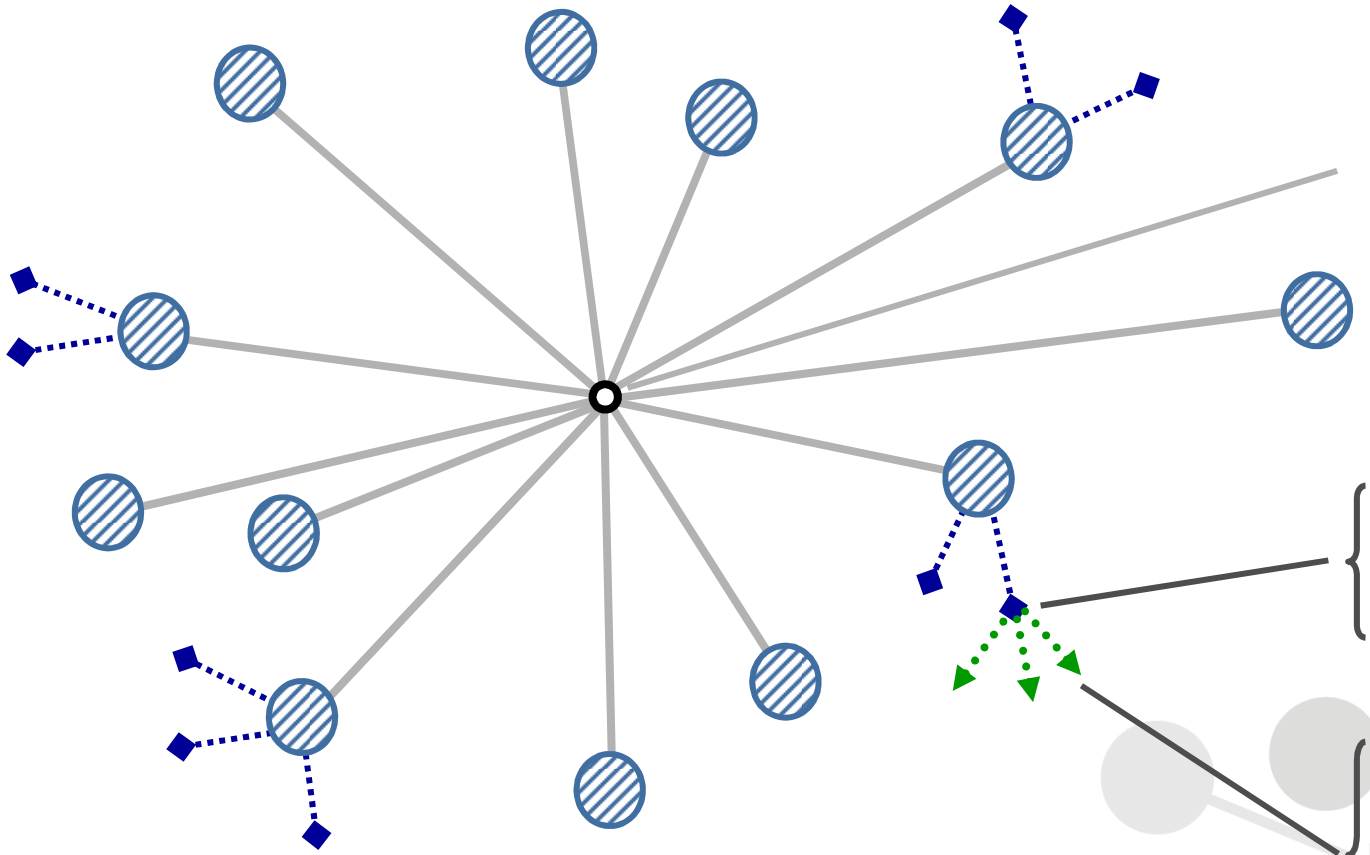
Expert Centres Linked to Biobanks

Distributed hub and spoke structure



Secretariat
(statutory seat)

Biobanks
Biomolecular res.
Technology centers

Associated partners
Hospitals
Universities
Service providers ...

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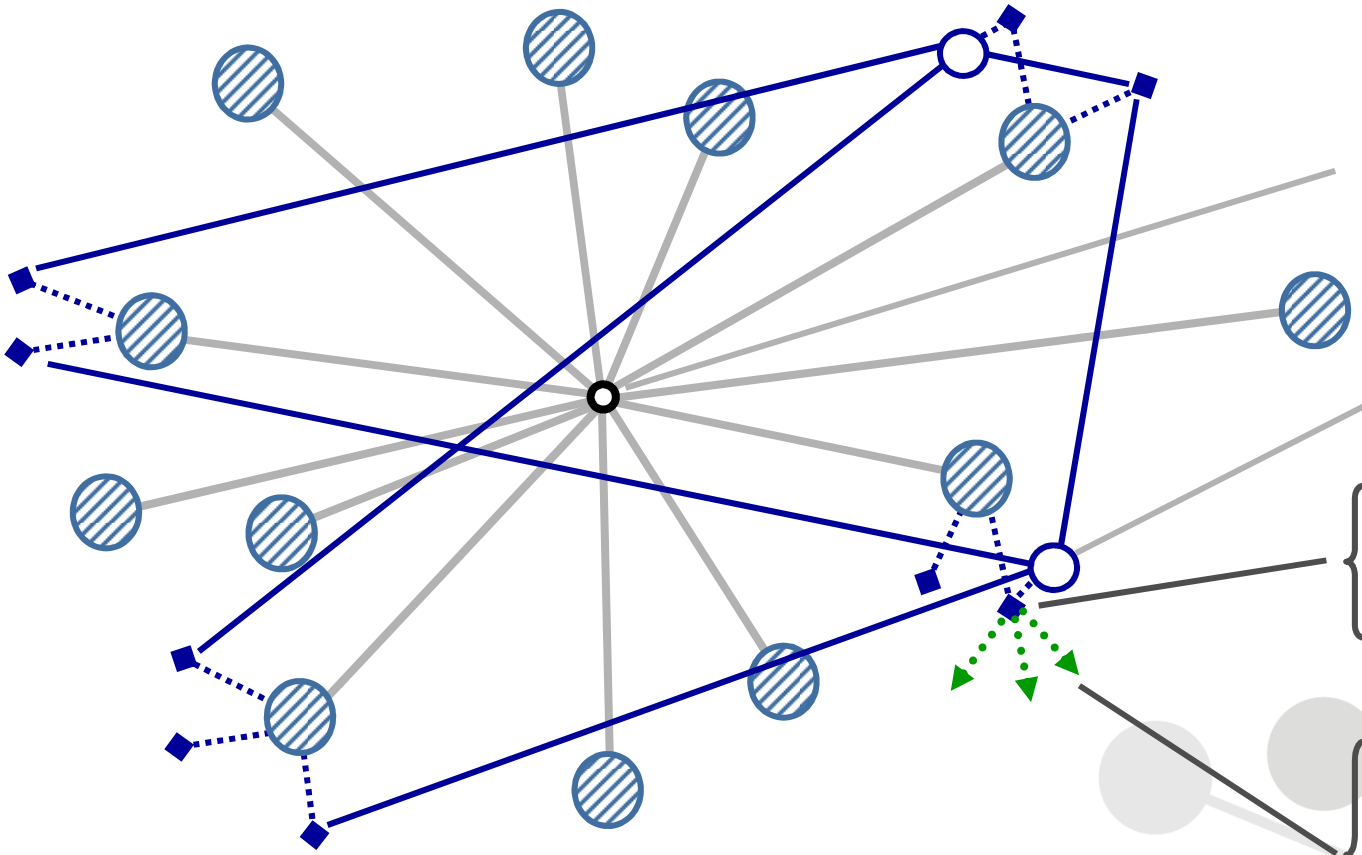

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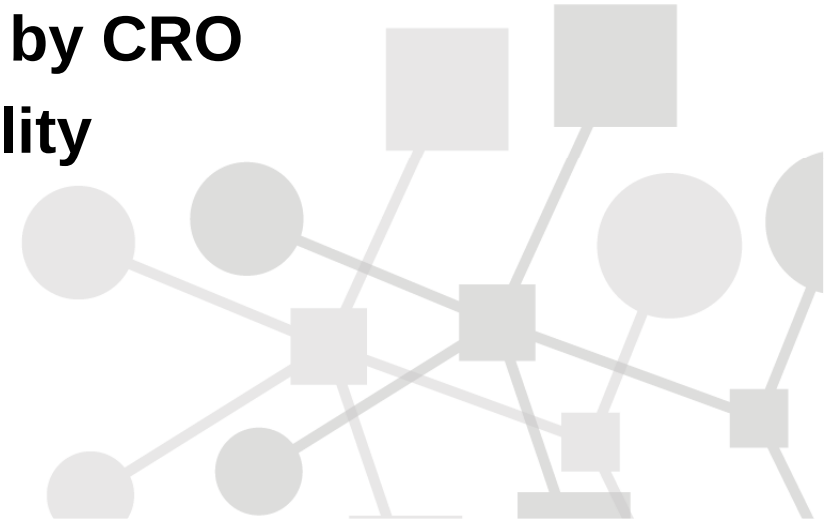
Expert Centers Features

- Expert centres for different fields
- Specifications defined together with industry
- Industry participates in QM
- Participation in “ring“ trials
- Common reference samples
- Certification / Accreditation / Brand
- Confidentialy guaranteed like by CRO
- Different models, great flexibility



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Thank you

www.bbmri.eu

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

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