

European Life Science Forum

Vienna, June 5-6, 2006

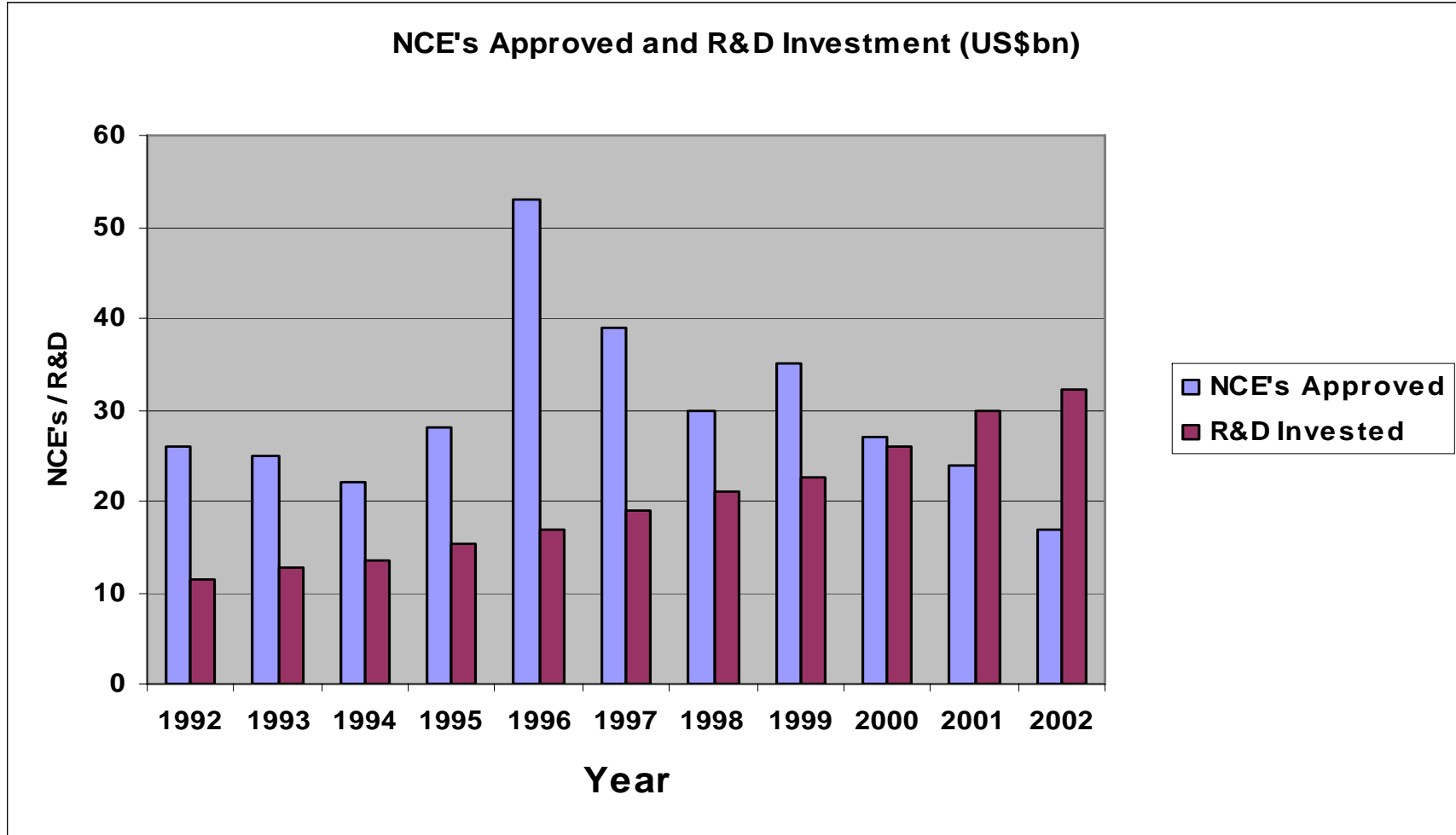
***Why is there a need for distributed
infrastructures in biomedical research ?***

Jacques Demotes
INSERM & ECRIN

1 - Why infrastructures for biomedical & clinical research ?

- High social & economical impacts : patients as end-users / economic actors / participants in research
- Health care improvement
- Treatment of pathologies with strong unmet needs (Cancer, neurodegenerative diseases,...)
- Competitiveness of drug discovery and development of new innovative therapeutic molecules in Europe require to work
 - faster (even with high costs)
 - with high quality data (clinical and biobank) and IMPs
 - in compliance with requirements of the EU Directives protection of patients

Cost-effectiveness of medicines R&D : a challenge addressed by the IMI SRA



Why *distributed* infrastructures ?

- Because *patients are distributed*
 - > access to patients is the limiting rate for faster development of new medicines (studies on the mechanism of disease, on biomarkers, and therapeutic trials) : distributed EU infrastructures take advantage of the EU population
 - > distributed EU infrastructures unlock latent scientific and medical competences
 - > national regulations on clinical research remain fragmented
 - > *Distributed* research infrastructures :
 - 1 – Network of clinical research centres : high quality clinical data
 - 2 – Network of biobanks : high quality biological data
 - 3 – Network of GMP facilities : high quality IMP

Architecture of distributed infrastructures

Local level : access to patients

Regional-national level : based on national-regional regulation and organisation of research

EU level : allows for EU integration and multinational cooperation



1 - Connecting national networks of Clinical Research Centres

Other regions

Other EU MS :
Ireland, Netherlands
UK, Belgium
Hungary, Austria

Spain
SCReN

France
CIC & UEC

Germany
KKS

Denmark
DCRIN

Sweden
SweCRIN

EFGCP

Italy
CIRM & IRFMN

ECRIN, an integrated infrastructure for clinical trials in the EU

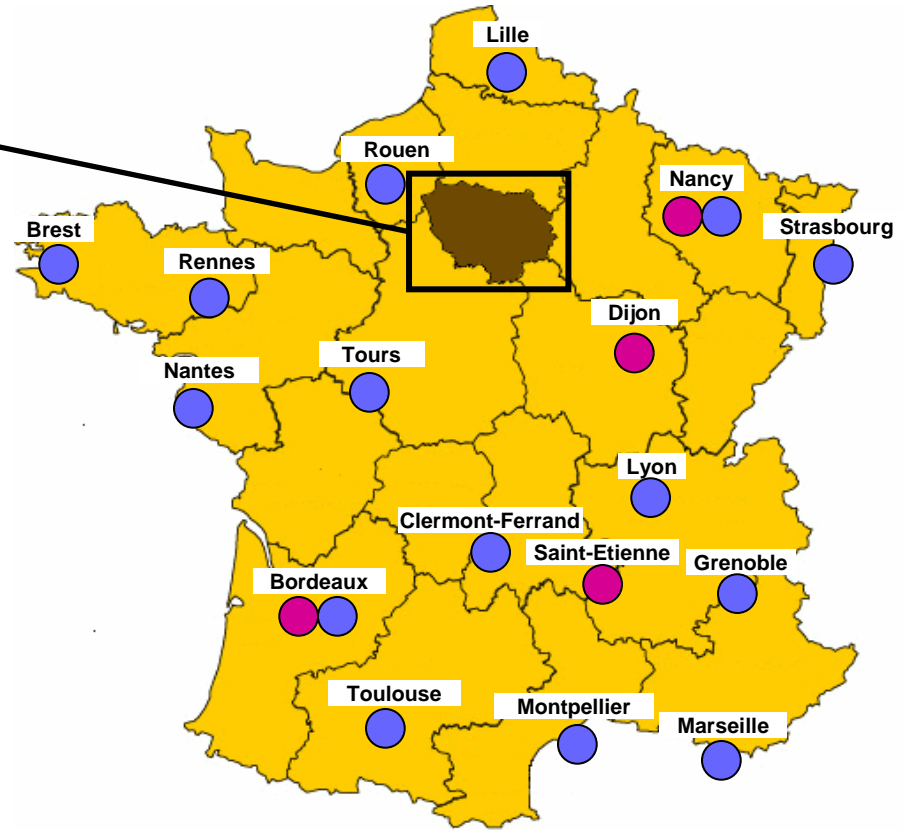
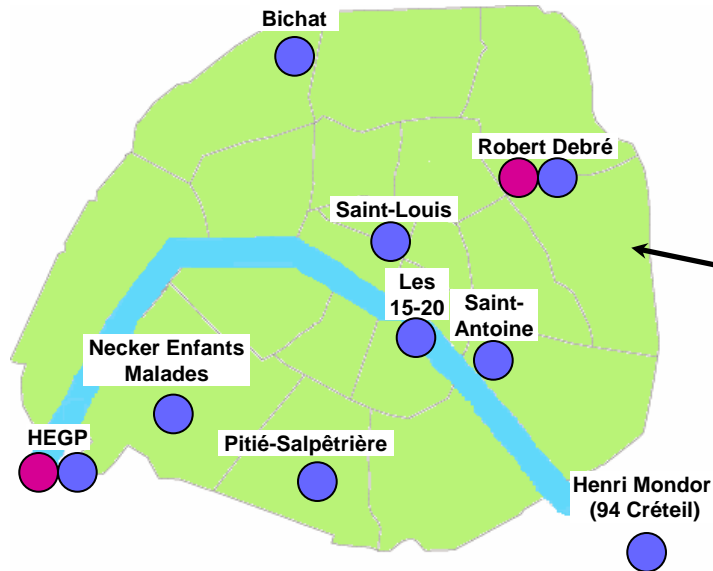
- ECRIN-1 (2004-2005) :
 - Identifying bottlenecks
- ECRIN-2 (2006-2008) :
 - Preparing the infrastructure
- ECRIN-3 (2008 ->) :
 - Running the infrastructure supporting multinational clinical trials in the EU
- In line with expectations of FP7 'Innovative Medicines Initiative'



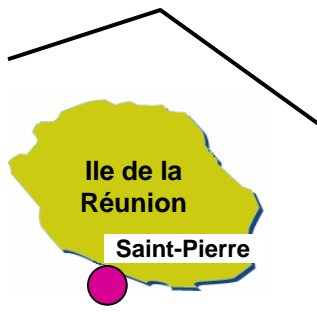
ECRIN-3 (2008-) : Integrated services to multinational studies

- Flexible, integrated services (one-stop shop) in the conduct of the study
 - 1 - interaction with ethics committees
 - 2 - interaction with competent authorities, regulatory affairs
 - 3 - drug dispensing
 - 4 - adverse event reporting
 - 5 - data management
 - 6 - data monitoring
 - 7 - management of biological samples

National networks : access to patients support to investigators

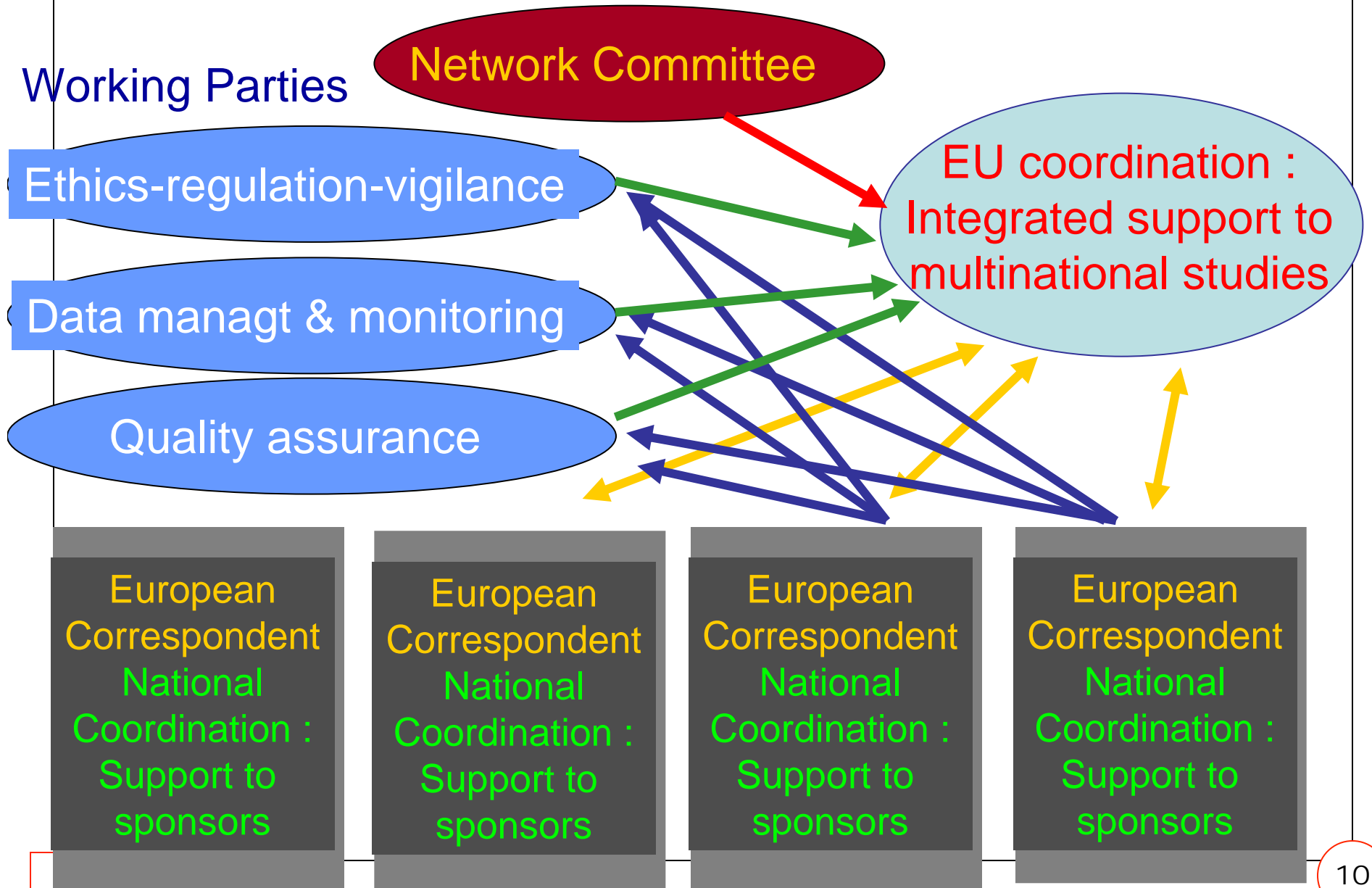


- CIC (24)
- CIC-EC (7)



5 June 2006

National coordination and European coordination



2 – Network of Biological Resources Facilities

- **Science Case:**

- A European network to coordinate European Scientific programs and policies
- Innovative targets, biomarkers, clinical studies
- Technology transfer, dissemination of knowledge, valorisation

- **Technical case:**

- Repositories for qualified biological samples (DNA, RNA, proteins,...), coupled to clinical data.
- Providers/distributors of samples within scientific project objectives
- Development of QA standards for European BRCs
- To store samples for the future (heritage)
- Distributed facilities / centralised database

3 - *EU network of GMP Facilities*

- **Science Case:**

- Reinforcing clinical research and translation of basic research to therapy
- **Production** and evaluation of **innovative** therapeutic and diagnostic agents : biomarkers and biotherapy / regenerative medicine : cell therapy, gene therapy, tissue engineering

- **Technical case:**

- Production of new therapeutic/diagnostic agents from biotechnologies
- Products for Cell and Gene therapy
- Good Manufacturing Practices (*GMO dissemination regulation*), in line with national legislation, able to cooperate across the borders
- **Direct links with Clinical Research Centres (CRC - ECRIN)**

Integrated model

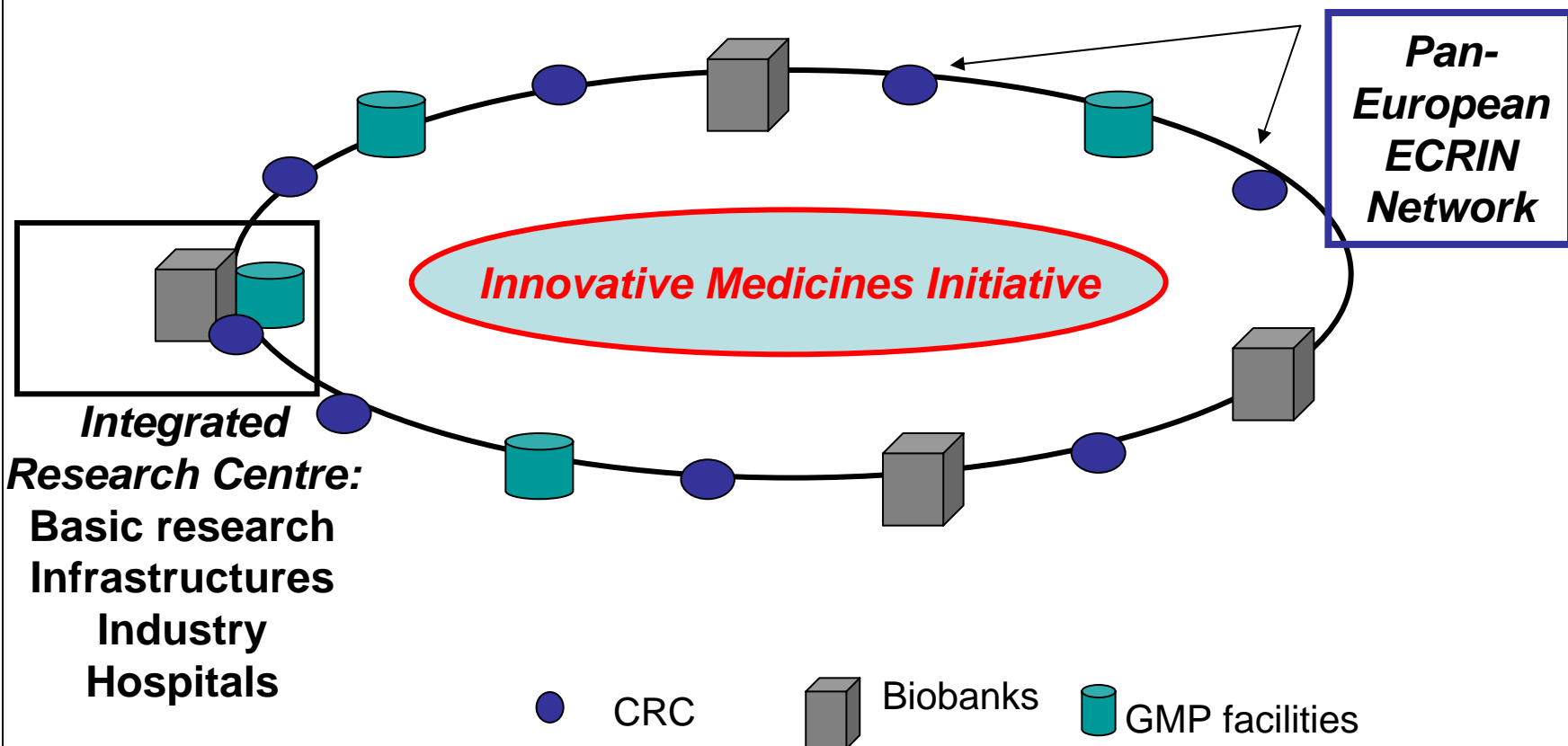
Pan-European
*Network of Clinical
Research Centres*

+

associated with
*distributed GMP
facilities*

+

Network of
Biobanks



Infrastructures and Innovative Medicines Initiative

