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Staff briefing at the US congress

***European Clinical Research Infrastructure
Network (ECRIN)
an instrument for international cooperation in
clinical trials***

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Need for international cooperation in clinical trials

- **Clinical trials are tools for evidence-based medical practice**

“what is the best treatment option for this patient / condition ?”

➤ high return on investment for health professionals, health systems, patients, society

- **International cooperation is required**
 - Share resources
 - Access to patients
 - Access to medical expertise
 - Share costs
 - Disseminate best practices

Obstacles to international cooperation in clinical trials

- **Legislation / regulation / oversight**
 - insufficient harmonisation
 - no risk adaptation
- **Infrastructures**
 - interoperability
 - insufficient development
- **Fragmentation of funding**
- **Differences in health systems**
- **Education**
- **Culture**
- **Ethics, transparency**
- **Patients and citizens awareness**
- **Language**

Legislation / regulation / oversight

- **Harmonisation within Europe**
 - 2001/20/EC Directive on clinical trials on medicinal products
 - Transposed into national legislations
 - Revision : Regulation
- **Harmonisation with other world regions**
 - Towards similar requirements for international trials: ethics committee/ IRB, regulatory authority, sponsor, insurance, adverse event reporting
 - EU: same provisions for registration and non-registration studies
 - need for a better alignment with IND / non-IND system
- **No risk adaptation**
 - Same requirements for CT on
 - new molecular entities
 - authorised medicines used outside licensed indication
 - authorised medicines used within licensed indication
 - risk-based approach (OECD working group)



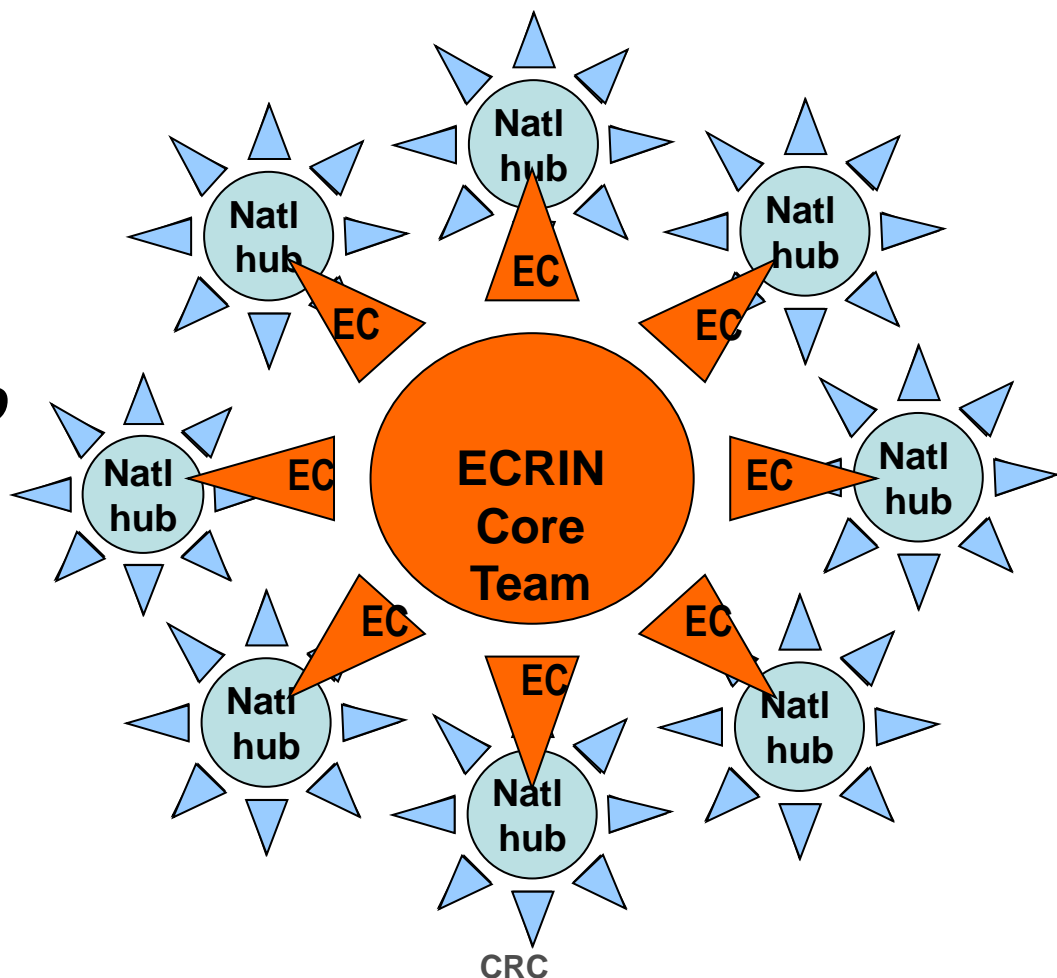
ECRIN, a distributed infrastructure supporting multinational trials in Europe

- ECRIN ERIC
- Scientific Partners
(national networks & hubs)

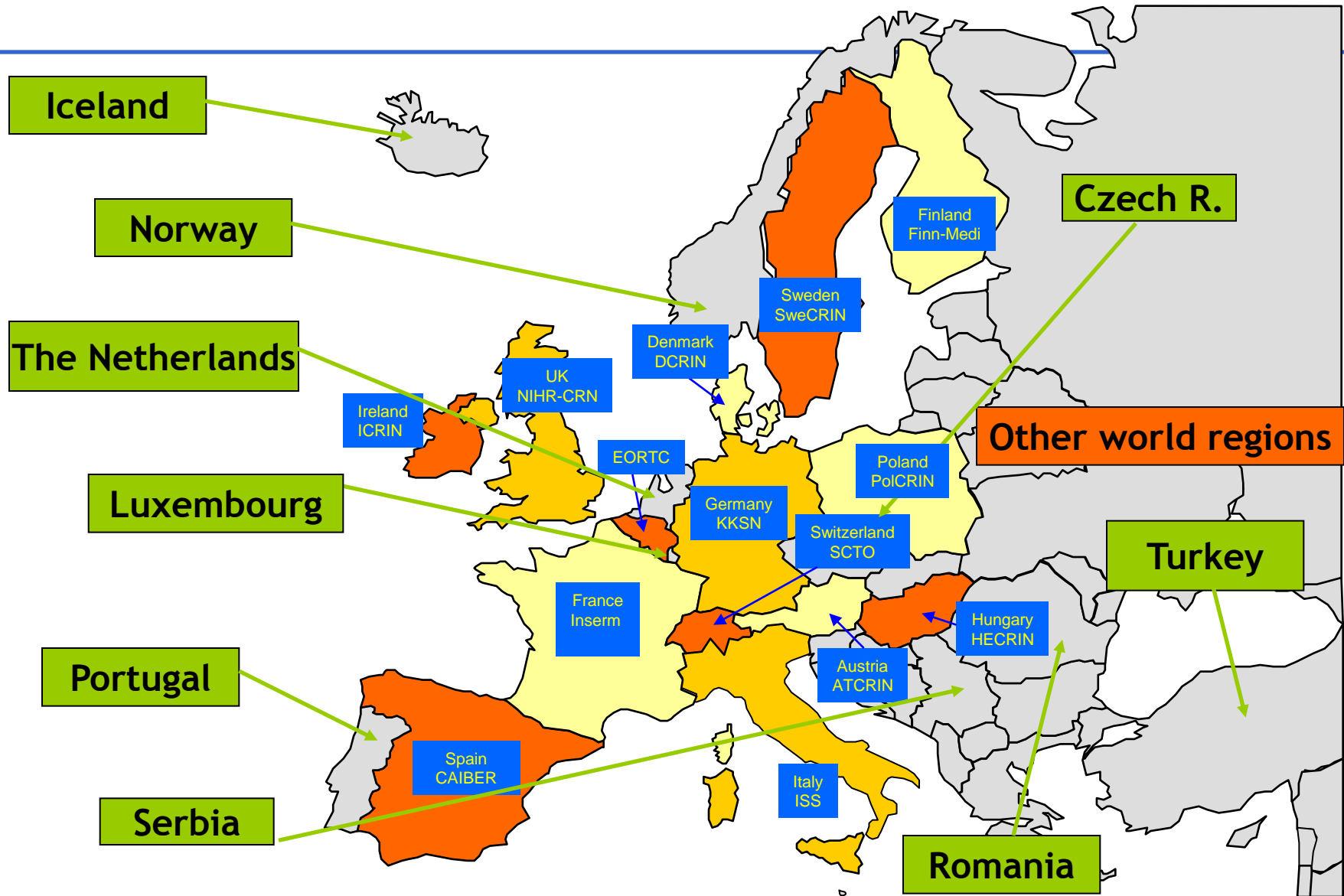
➤ *coordinated services to multinational trials*

Framework contracts on

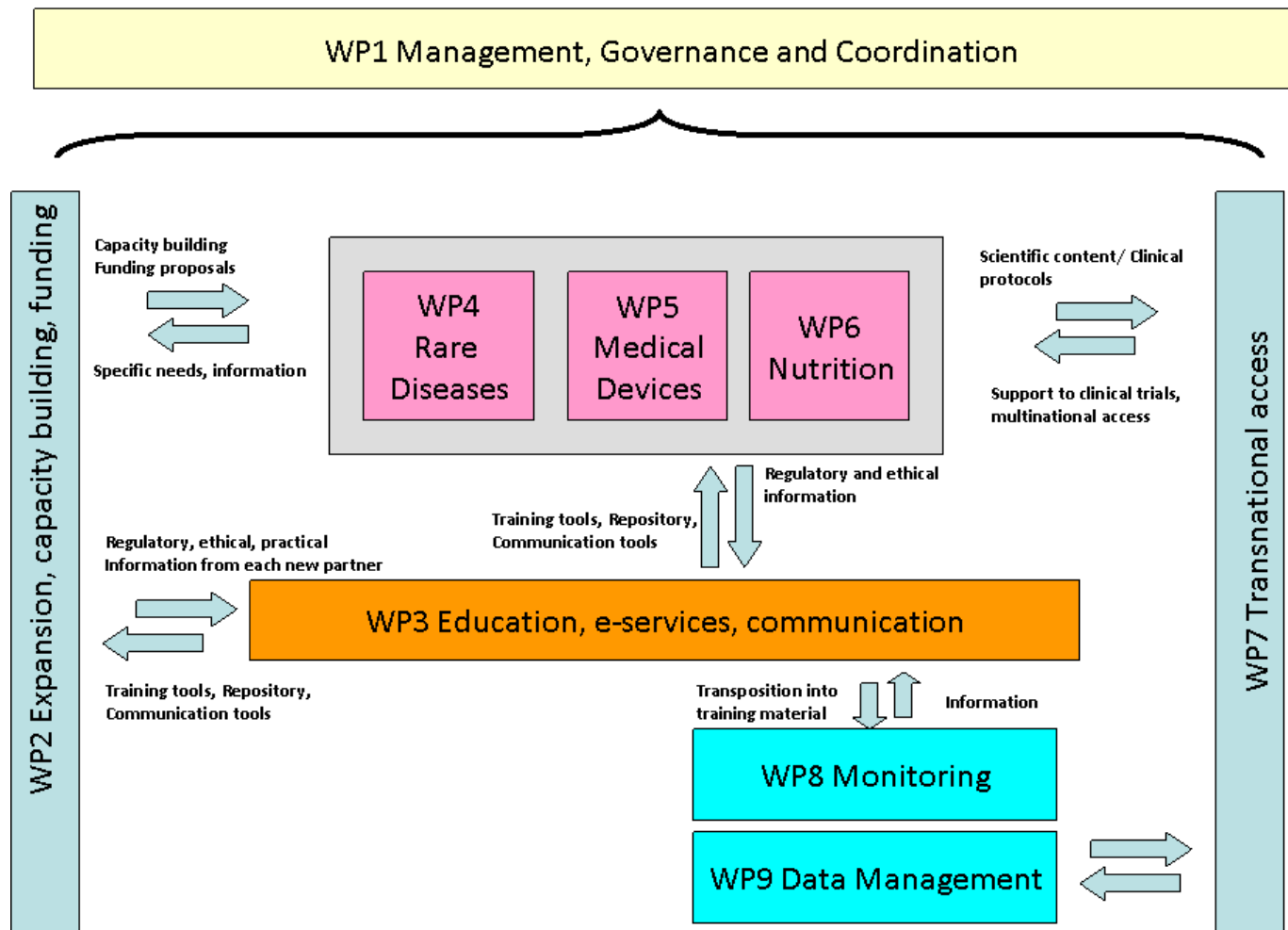
- Provision and costs of services
- Quality assurance



Network expansion



ECRIN-IA (2012-16): structuring pan-European investigation networks



Perspectives

- **Legal status ('ERIC', sustainable support by EU countries)**
 - Founding members : Germany, Italy, Spain, France
- **Acting as a sponsor (instead of service provider to sponsors)**
- **Acting as the sponsor's representative in Europe for trials initiated outside Europe**
- **Developing procedures for EU-US collaboration**
 - Identification of obstacles
 - Development of tools, establishment of procedures
 - Run pilot trials
 - Stable partnership agreements with non-EU partners (NIH)