ECRIN Meeting in Estonia
Tartu, June 15th, 2017

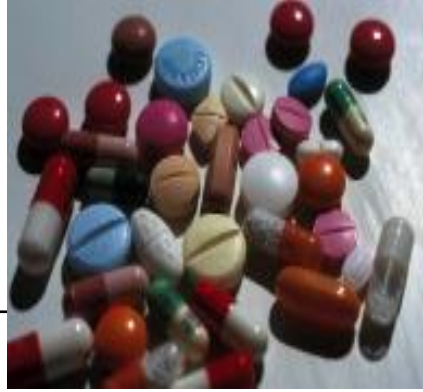
ECRIN
(European Clinical Research Infrastructure Network)
the pan-European network for clinical research

www.ecrin.org
jacques.demotes@ecrin.org

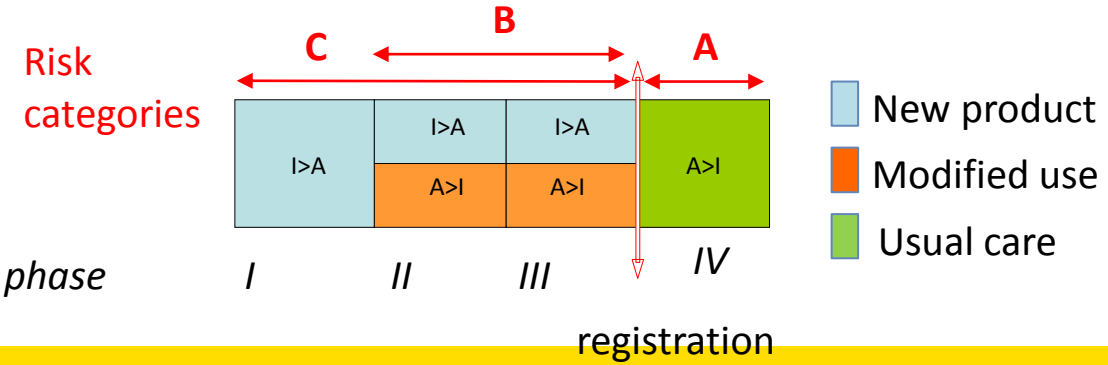
ECRIN
EUROPEAN CLINICAL RESEARCH INFRASTRUCTURE NETWORK

15 June 2017

Need for clinical trials

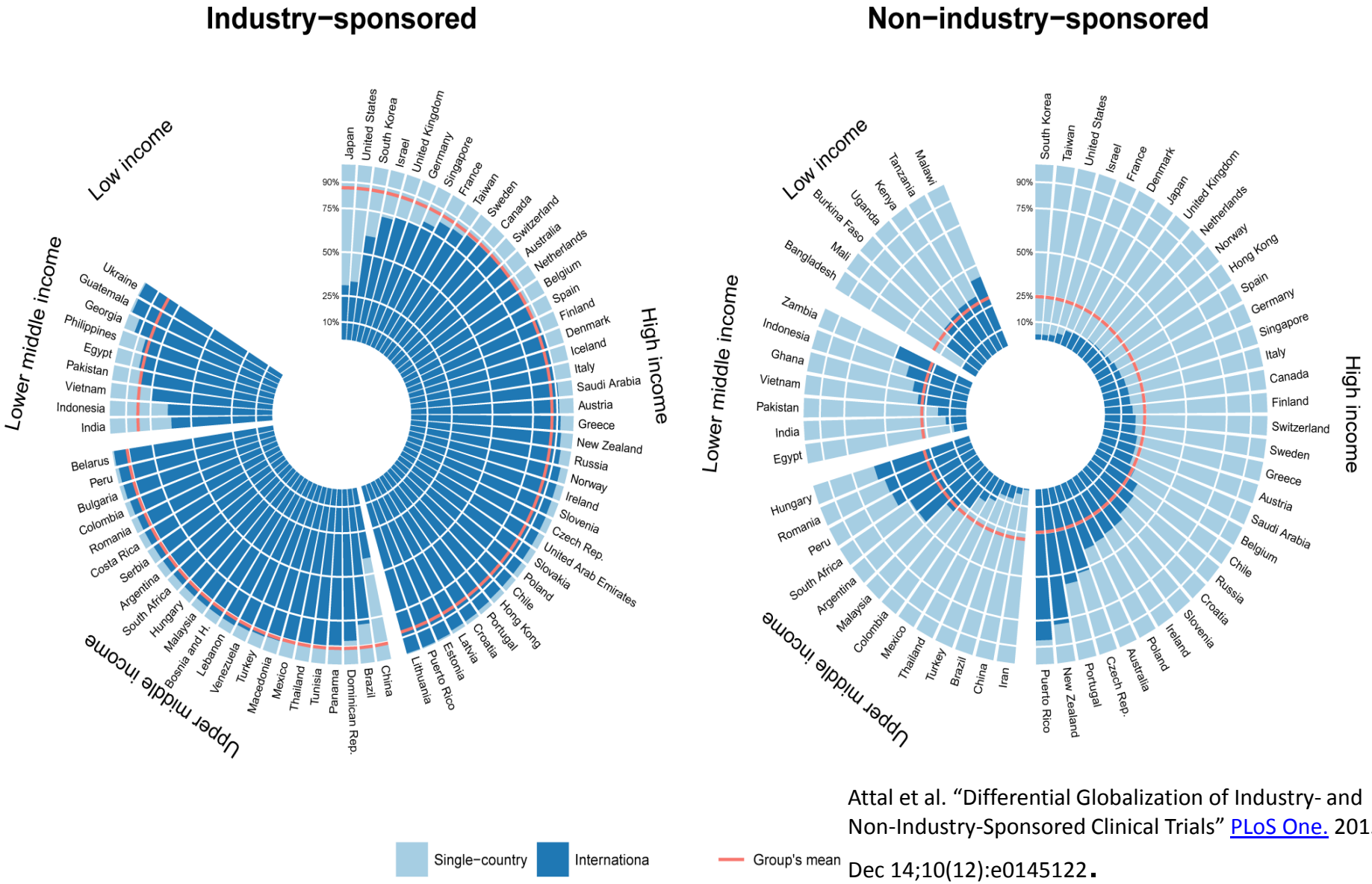


- **1 - Development of innovative health products**
  - registration trials
  - phase I – II – III
- **2 - Repurposing trials**
  - exploring new indications for authorised products
  - phase II - III
- **3 - Comparative effectiveness trials**
  - compare efficacy and safety of authorised healthcare strategies
  - phase IV



ECRIN
EUROPEAN CLINICAL RESEARCH INFRASTRUCTURE NETWORK

International cooperation : industry-sponsored vs. academic trials



Attal et al. “Differential Globalization of Industry- and Non-Industry-Sponsored Clinical Trials” PLoS One. 2015 Dec 14;10(12):e0145122.

ECRIN model : distributed infrastructure

Coordinating services provided by national partners

- **National partner :**

  network of clinical trial units (CTUs) able to manage trials in the country

- **National hub**

- **European Correspondent**

  hosted in national hub (ECRIN staff)

ECRIN
EUROPEAN CLINICAL RESEARCH INFRASTRUCTURE NETWORK

EU Commission funding

- 2004 ECRIN-RKP
- 2006 ECRIN-TWG
- 2008 ECRIN-PPI
- 2012 ECRIN-IA
- 2017 PedCRIN

SEVENTH FRAMEWORK PROGRAMME

HORIZON 2020

ECRIN
EUROPEAN CLINICAL RESEARCH INFRASTRUCTURE NETWORK

(multi) national funding

ECRIN-*ERIC* 2013

ESFRI
P Projects
L Landmarks
ROADMAP 2016

COMMISSION IMPLEMENTING DECISION

of 29 November 2013

on setting up the European Clinical Research Infrastructure Network (ECRIN) as a European Research Infrastructure Consortium (ECRIN-ERIC)

(2013/713/EU)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Regulation (EC) No 723/2009 of 25 June 2009 on the Community legal framework for a European Research Infrastructure Consortium (ERIC) [1], and in particular point (a) of Article 6(1) thereof,

Whereas:

(1) The Federal Republic of Germany, the Kingdom of Spain, the French Republic, the Italian Republic and the Portuguese Republic requested the Commission to set up the the European Clinical Research Infrastructure Network (ECRIN) as a European Research Infrastructure Consortium (ECRIN-ERIC).

(2) The French Republic has been chosen by the Federal Republic of Germany, the Kingdom of Spain, the Italian Republic and the Portuguese Republic as the Host Member State of ECRIN-ERIC.

(3) The measures provided for in this Decision are in accordance with the opinion of the Committee established by Article 20 of Regulation (EC) No 723/2009,

HAS ADOPTED THIS DECISION:

Article 1

1. The European Clinical Research Infrastructure Network as a European Research Infrastructure Consortium named ECRIN-ERIC is hereby established.

2. The Statutes of ECRIN-ERIC are set out in the Annex. These Statutes shall be kept up to date and made publicly available on the website of ECRIN-ERIC and at its statutory seat.

3. The essential elements of the ECRIN-ERIC Statutes for which amendments shall require approval by the Commission in accordance with Article 11(1) of Regulation (EC) No 723/2009 are provided for in Articles 1, 2, 3, 11, 12, 14, 15, 19 and 20.

Article 2

This Decision shall enter into force on the third day following that of its publication in the *Official Journal of the European Union*.

Done at Brussels, 29 November 2013.

For the Commission

The President

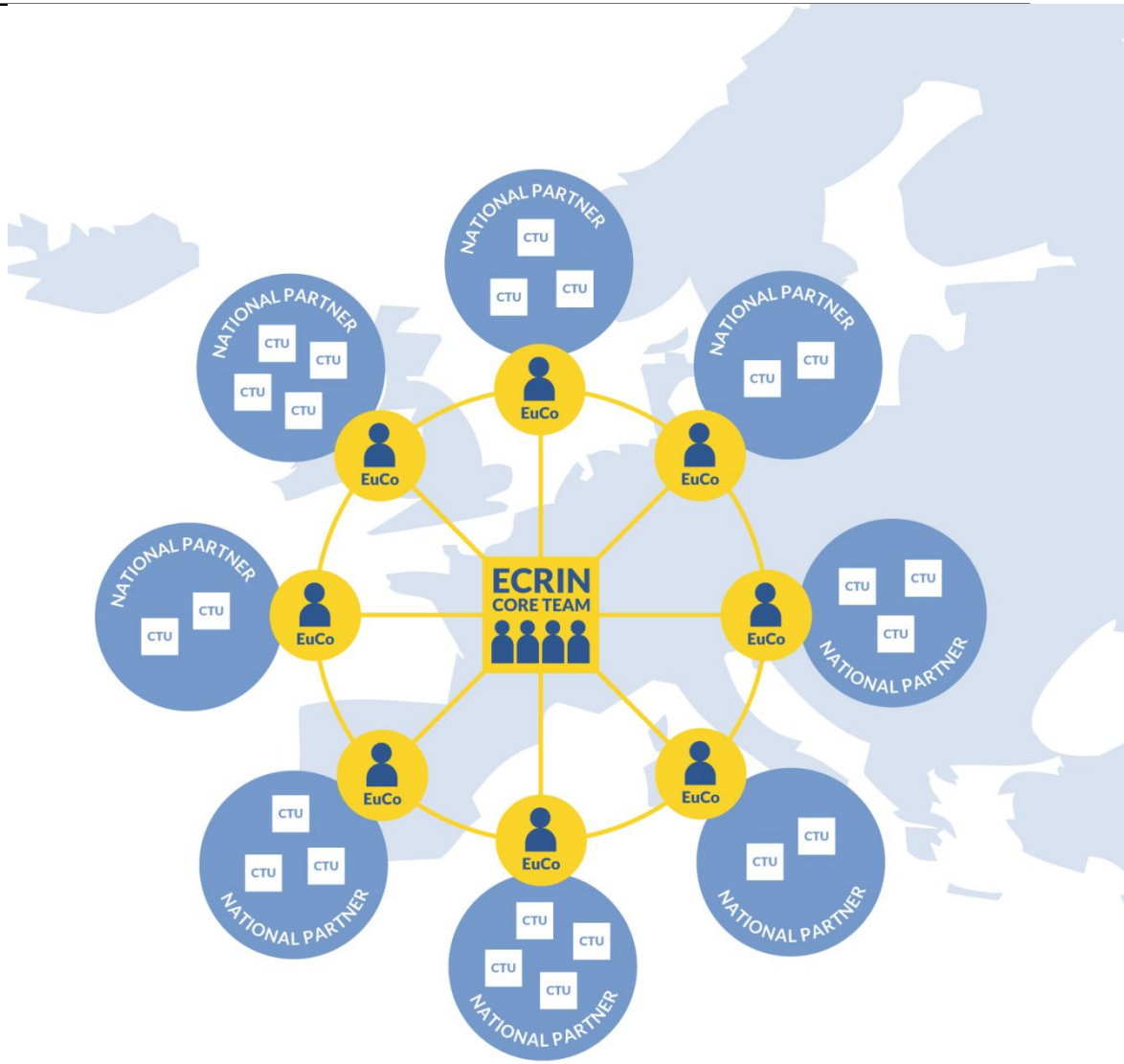
José Manuel BARROSO

ECRIN and its national scientific partners

Core Team, European Correspondents, national hub, CTU networks

Framework contracts with national scientific partners

- ✓ provision of services
  -> “linked third party”
- ✓ non-profit cost
- ✓ hosting the European Correspondent



ECRIN
EUROPEAN CLINICAL RESEARCH INFRASTRUCTURE NETWORK

ECRIN and its national scientific partners

Linked through framework agreements

Country	*National hub*	*National CTU Network*	*Host Institution (linked third party)*
Czech Republic	Brno	CZECRIN	Masaryk University
Germany	Cologne	KKSN	Universität Klinik Köln
Spain	Barcelona	SCReN	ISCIII
France	Toulouse	F-CRIN	INSERM
Hungary	Pecs	HECRIN	HECRIN
Italy	Rome	ItaCRIN	ISS
Norway	Trondheim	NORCRIN	St Olav's Hospital
Portugal	Lisbon	PtCRIN	Nova University
Switzerland	Basel	SCTO	SCTO

ECRIN
EUROPEAN CLINICAL RESEARCH INFRASTRUCTURE NETWORK

Distribution of roles in multinational trials : trial management vs. investigation

Investigator-initiated or SME-sponsored trial

Industry-sponsored trial

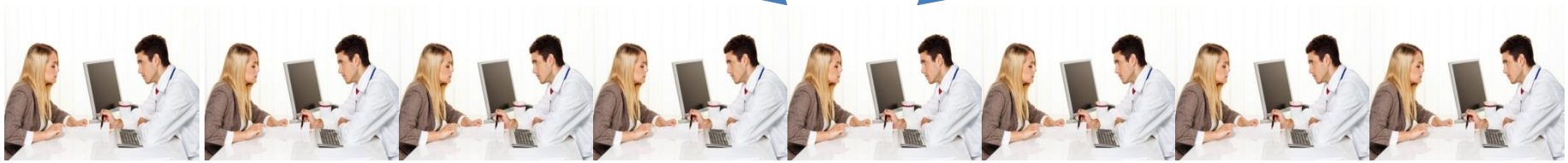
PI

Trial management

Sponsor CTU

ECRIN
EUROPEAN CLINICAL RESEARCH INFRASTRUCTURE NETWORK

+/- CRO



Investigation

ECRIN
EUROPEAN CLINICAL RESEARCH INFRASTRUCTURE NETWORK

Credits to: Jacques Demotes

ECRIN SUPPORT SERVICES

1 PREPARATION: ADVICE & INFORMATION

- Trial design and methodology
- Funding sources and costs
- Investigation sites and patient recruitment
- Task distribution for multinational trial management
- Funding applications
- Regulatory, ethical and insurance requirements

2 REVIEW: PROTOCOL & FEASIBILITY

- Scientific and methodological evaluation of the protocol
- Assessment of project implementation plans

3 IMPLEMENTATION: TRIAL MANAGEMENT

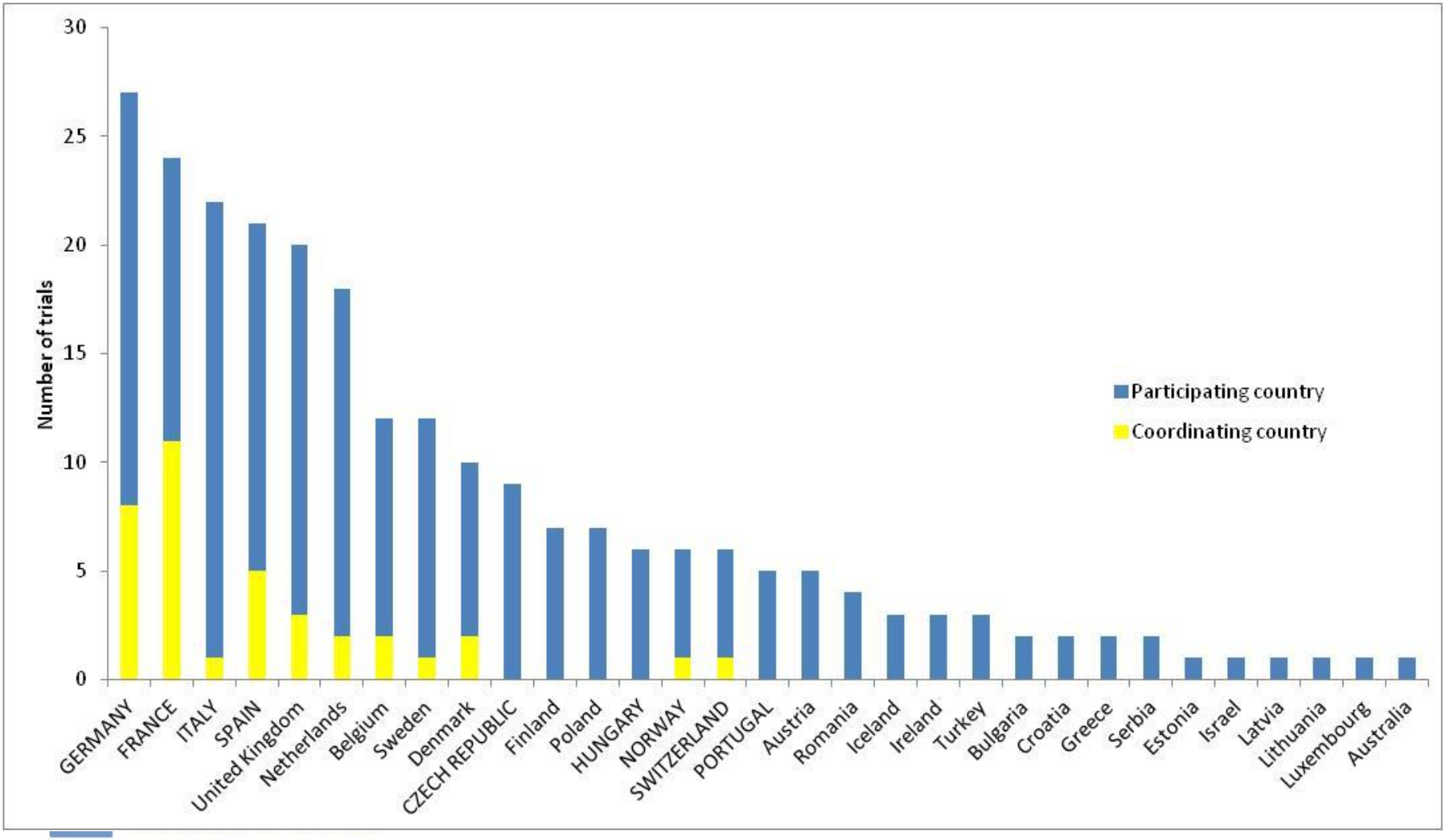
- Project management and trial coordination
- Clinical study authorisations (regulatory, ethical) and follow-up
- Monitoring
- Vigilance
- Data management
- Health product and biosample management

ECRIN trial portfolio

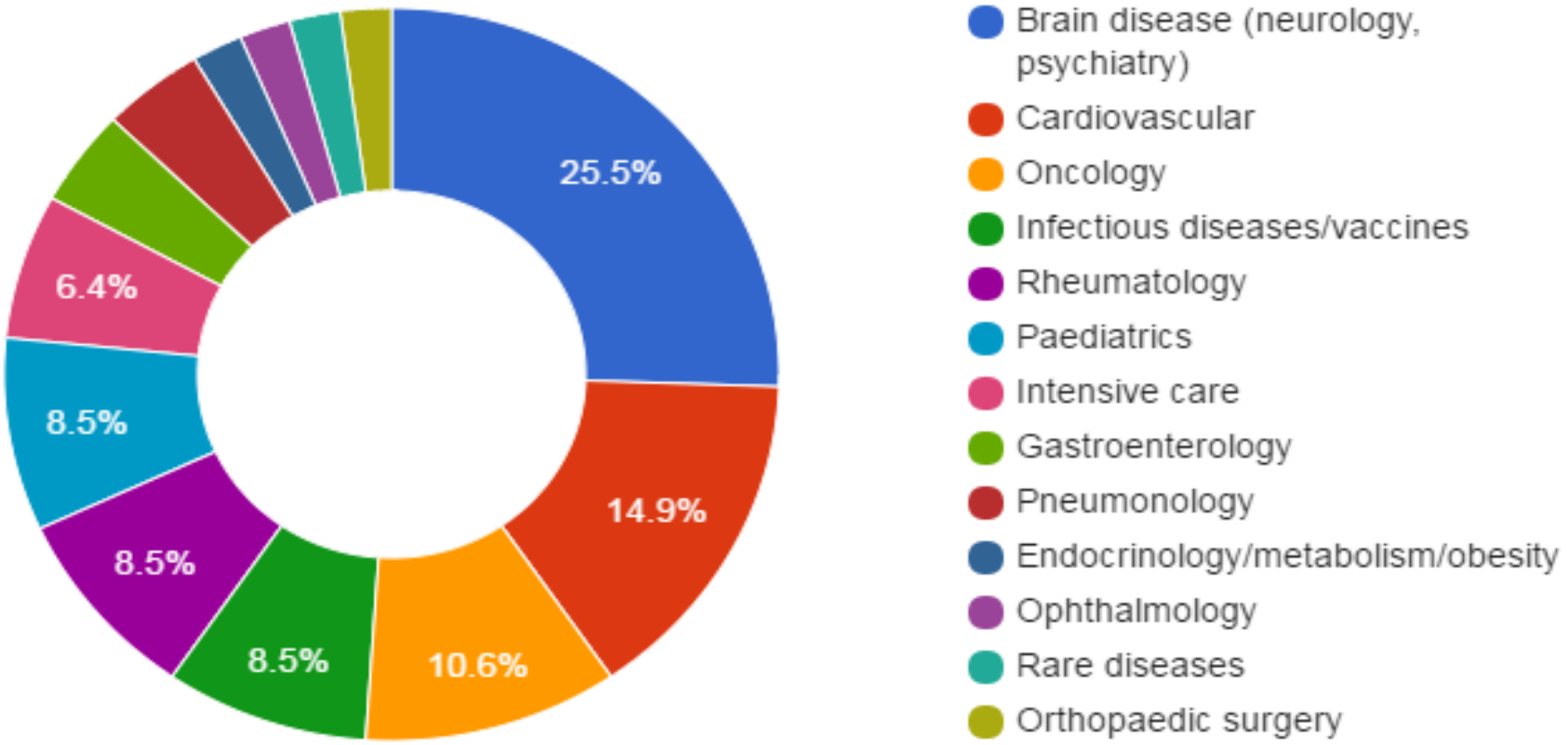
	CZ	FR	DE	HU	IT	NO	PT	ES	CH	AT	BE	BG	HR	DK	EE	FI	GR	IS	IE	IL	LV	LT	LU	NL	PL	RO	RS	SE	TR	UK	AU
6S														C		P		P													
ADIPOA2		C	P		P														P					P						P	
AETIONOMY		C	P					P																				P			
BETA3_LVH		P	P		P		P			P	C						P								P					P	
BIO-RAIDs		C	P								P													P		P	P				
BIOCHIP			P		P				C				P																		
CAPP3			P											P		P												P		C	P
ChildInnovac		C	P																									P			
DISCHARGE	P	P	C	P	P		P	P		P	P			P		P			P		P	P		P		P	P			P	
EORTC 40091		P	P			P		P	P	P	C													P						P	
ESCALE					P		P	C																P					P		
EUROHYP-1	P	P	C	P	P	P		P			P	P	P	P			P		P					P	P	P		P	P	P	
FAIR-PARK II	P	C	P				P	P		P														P						P	
IMPACTT		P	C	P	P			P		P	P														P			P			
LEAN																														C	
MEDIT-AGEING		C	P					P																						P	
MENAC						C			P																					P	
NISCI	P		C		P			P	P																						
POEM vs LHM	P		C		P						P													P				P			
PRECARDIA		C	P		P			P						P										P						P	
PRECIOUS		P	P	P	P	P									P									C	P					P	
RESCUE ESES		P	P		P			P			P	P		P		P								C		P				P	
SABATO			C					P																P						P	
SECURE	P	P	P	P	P			C																	P						
STRONG TREAT					C			P			P																			P	
TINN		C			P			P			P													P							
TINN2		C	P	P	P																			P				P		P	
TRIHEP 3		C																						P							
TRISS						P								C		P		P										P			
TTM	P				P	P			P					P		P		P					P	P				C		P	
VISION-DMD	P	P	P		P			P			P			P						P				P	P			P	P	C	P
RESPINE		C	P		P			P																							
PAPA ARTIS		P	C		P																			P	P			P		P	
PROOF	P	P	C					P	P		P					P												P			
LIVERHOPE		P	P		P		P	C						P																P	
ORTHOUNION		P	P		P			C																							
HIVACAR		P						C			P			P																	

ECRIN trial portfolio

average 7 countries per trial



ECRIN trial portfolio



ORIGINAL ARTICLE

Hydroxyethyl Starch 130/0.4 versus Ringer's Acetate in Severe Sepsis

Anders Perner, M.D., Ph.D., Nicolai Haase, M.D., Anne B. Guttormsen, M.D., Ph.D., Jyrki Tenhunen, M.D., Ph.D., Gudmundur Klemenzson, M.D., Anders Åneman, M.D., Ph.D., Kristian R. Madsen, M.D., Morten H. Møller, M.D., Ph.D., Jeanie M. Elkjær, M.D., Lone M. Poulsen, M.D., Asger Bendtsen, M.D., M.P.H., Robert Winding, M.D., Morten Steensen, M.D., Pawel Berezowicz, M.D., Ph.D., Peter Søe-Jensen, M.D., Morten Bestle, M.D., Ph.D., Kristian Strand, M.D., Ph.D., Jørgen Wiis, M.D., Jonathan O. White, M.D., Klaus J. Thornberg, M.D., Lars Quist, M.D., Jonas Nielsen, M.D., Ph.D., Lasse H. Andersen, M.D., Lars B. Holst, M.D., Katrin Thormar, M.D., Anne-Lene Kjældgaard, M.D., Maria L. Fabritius, M.D., Frederik Mondrup, M.D., Frank C. Pott, M.D., D.M.Sci., Thea P. Møller, M.D., Per Winkel, M.D., D.M.Sci., and Jørn Wetterslev, M.D., Ph.D., for the 6S Trial Group and the Scandinavian Critical Care Trials Group*

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Lower versus Higher Hemoglobin Threshold for Transfusion in Septic Shock

Lars B. Holst, M.D., Nicolai Haase, M.D., Ph.D., Jørn Wetterslev, M.D., Ph.D., Jan Wernerman, M.D., Ph.D., Anne B. Guttormsen, M.D., Ph.D., Sari Karlsson, M.D., Ph.D., Pär I. Johansson, M.D., Ph.D., Anders Åneman, M.D., Ph.D., Marianne L. Vang, M.D., Robert Winding, M.D., Lars Nebrich, M.D., Helle L. Nibro, M.D., Ph.D., Bodil S. Rasmussen, M.D., Ph.D., Johnny R.M. Lauridsen, M.D., Jane S. Nielsen, M.D., Anders Oldner, M.D., Ph.D., Ville Pettilä, M.D., Ph.D., Maria B. Cronhjort, M.D., Lasse H. Andersen, M.D., Ulf G. Pedersen, M.D., Nanna Reiter, M.D., Jørgen Wiis, M.D., Jonathan O. White, M.D., Lene Russell, M.D., Klaus J. Thornberg, M.D., Peter B. Hjortrup, M.D., Rasmus G. Müller, M.D., Morten H. Møller, M.D., Ph.D., Morten Steensen, M.D., Inga Tjäder, M.D., Ph.D., Kristina Kilsand, R.N., Suzanne Odeberg-Wernerman, M.D., Ph.D., Brit Sjøbø, R.N., Helle Bundgaard, M.D., Ph.D., Maria A. Thyø, M.D., David Lodahl, M.D., Rikke Mærkedahl, M.D., Carsten Albeck, M.D., Dorte Illum, M.D., Mary Kruse, M.D., Per Winkel, M.D., D.M.Sci., and Anders Perner, M.D., Ph.D., for the TRISS Trial Group* and the Scandinavian Critical Care Trials Group

OPEN ACCESS Freely available online

PLOS ONE

A Phase I Clinical Study of a Live Attenuated *Bordetella pertussis* Vaccine - BPZE1; A Single Centre, Double-Blind, Placebo-Controlled, Dose-Escalating Study of BPZE1 Given Intranasally to Healthy Adult Male Volunteers

Rigmor Thorstensson[1]*, Birger Trollfors[1], Nabil Al-Tawil[2], Maja Jahnmatz[1,3], Jakob Bergström[1], Margaretha Ljungman[1], Anna Törner[1], Lena Wehlin[1], Annie Van Broekhoven[4], Fons Bosman[4], Anne-Sophie Debrie[5,6,7,8], Nathalie Mielcarek[5,6,7,8], Camille Locht[5,6,7,8]

1 Swedish Institute for Communicable Disease Control, Solna, Sweden, 2 Karolinska Trial Alliance, Karolinska University Hospital, Stockholm, Sweden, 3 Department of Microbiology, Tumor and Cell Biology, Karolinska Institutet, Stockholm, Sweden, 4 Q-Biologicals, BioIncubator, Zwijnaarde, Belgium, 5 Inserm, Lille, France, 6 National Center for Scientific Research, Lille, France, 7 Université Lille-Nord de France, Lille, France, 8 Center for Infection and Immunity of Lille, Institut Pasteur de Lille, Lille, France

The NEW ENGLAND JOURNAL of MEDI

ORIGINAL ARTICLE

Targeted Temperature Management at 33°C versus 36°C after Cardiac Arrest

Niklas Nielsen, M.D., Ph.D., Jørn Wetterslev, M.D., Ph.D., Tobias Cronberg, M.D., Ph.D., David Erlinge, M.D., Ph.D., Yvan Gasche, M.D., Christian Hassager, M.D., D.M.Sci., Janneke Horn, M.D., Ph.D., Jan Hovdenes, M.D., Ph.D., Jesper Kjaergaard, M.D., D.M.Sci., Michael Kuiper, M.D., Ph.D., Tommaso Pellis, M.D., Pascal Stammet, M.D., Michael Wanscher, M.D., Ph.D., Matt P. Wise, M.D., D.Phil., Anders Åneman, M.D., Ph.D., Nawaf Al-Subaie, M.D., Søren Boesgaard, M.D., D.M.Sci., John Bro-Jeppesen, M.D., Iole Brunetti, M.D., Jan Frederik Bugge, M.D., Ph.D., Christopher D. Hingston, M.D., Nicole P. Juffermans, M.D., Ph.D., Matty Koopmans, R.N., M.Sc., Lars Køber, M.D., D.M.Sci., Jørund Langørgen, M.D., Gisela Lilja, O.T., Jacob Eifer Møller, M.D., D.M.Sci., Malin Rundgren, M.D., Ph.D., Christian Rylander, M.D., Ph.D., Ondrej Smid, M.D., Christophe Werer, M.D., Per Winkel, M.D., D.M.Sci., and Hans Friberg, M.D., Ph.D., for the TTM Trial Investigators*

thebmj

BMJ 2015;350:g7635 doi: 10.1136/bmj.g7635 (Published 5 January 2015) Page 1 of 11

RESEARCH

Cerebral near infrared spectroscopy oximetry in extremely preterm infants: phase II randomised clinical trial

OPEN ACCESS

Simon Hyttel-Sorensen *research fellow*[1], Adelina Pellicer *associate professor*[2], Thomas Alderliesten *research fellow*[3], Topun Austin *consultant neonatologist*[4], Frank van Bel *professor of Neonatology*[3], Manon Benders *consultant neonatologist*[3,5], Olivier Claris *professor*[6], Eugene Dempsey *professor*[7], Axel R Franz *associate professor*[8], Monica Fumagalli *consultant neonatologist*[9], Christian Gluud *head of department*[10], Berit Grevstad *trial manager*[11], Cornelia Hagmann *consultant neonatologist*[12], Petra Lemmers *consultant neonatologist*[3], Wim van Oeveren *managing director*[13], Gerhard Pichler *associate professor*[14], Anne Mette Plomgaard *research fellow*[1], Joan Riera *biomedical engineer*[2,15], Laura Sanchez *consultant neonatologist*[2], Per Winkel *senior researcher*[10], Martin Wolf *professor*[16], Gorm Greisen *professor*[1]

11 new clinical trials funded in 2016

- 6 clinical trials (out of 16)

- 1 clinical trial

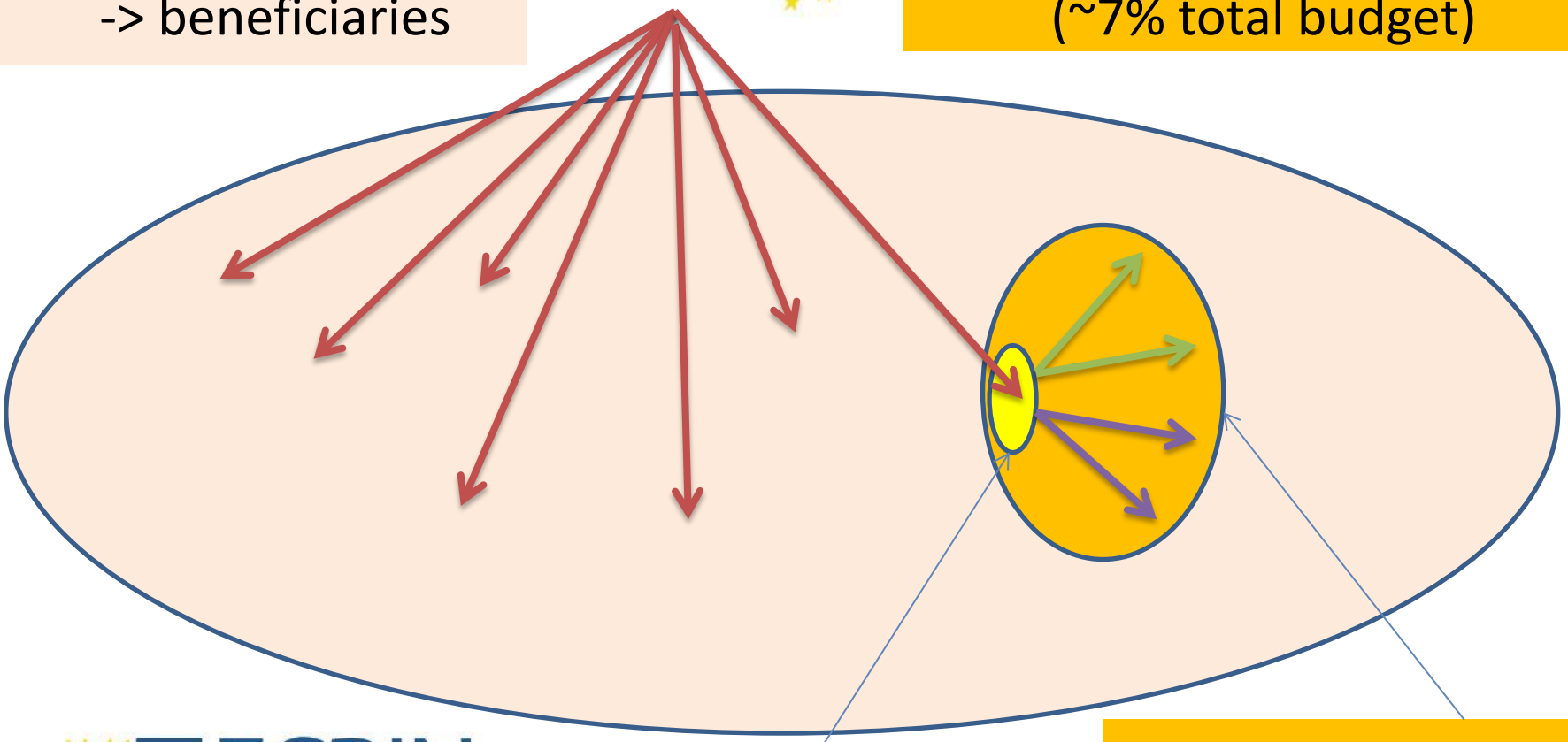
- 4 clinical trials

Funding ECRIN services in H2020 trials

H2020 clinical trial budget ~6M€, 4 years -> beneficiaries

HORIZON 2020
LE PROGRAMME DE RECHERCHE ET D'INNOVATION DE L'UNION EUROPÉENNE

ECRIN trial management services ~400k€ (100k€/y) (~7% total budget)



ECRIN
EUROPEAN CLINICAL RESEARCH INFRASTRUCTURE NETWORK

ECRIN core team budget ~40k€ (10k€/y)

ECRIN partners as subcontractors or third parties, ~360k€ (90k€/y)

ECRIN 2017 budget outlines : total €5.515M

Contribution of Members and Observers : €1.925M

- to European Correspondents €0.75M
- to core team €1.175M

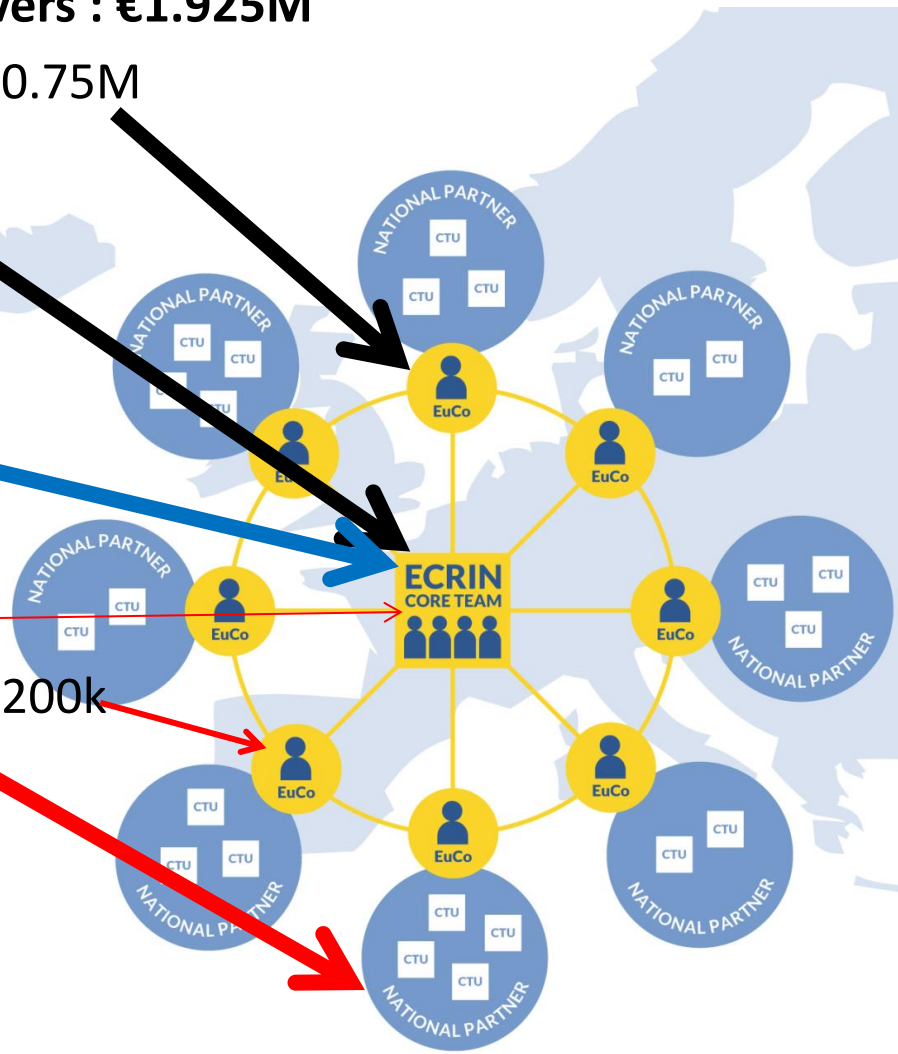
Capacity building projects : €0.565M

- to core team

Clinical trials : €3.025M

- to core team €100k
- to European Correspondents €200k
- to national partners €2.722M

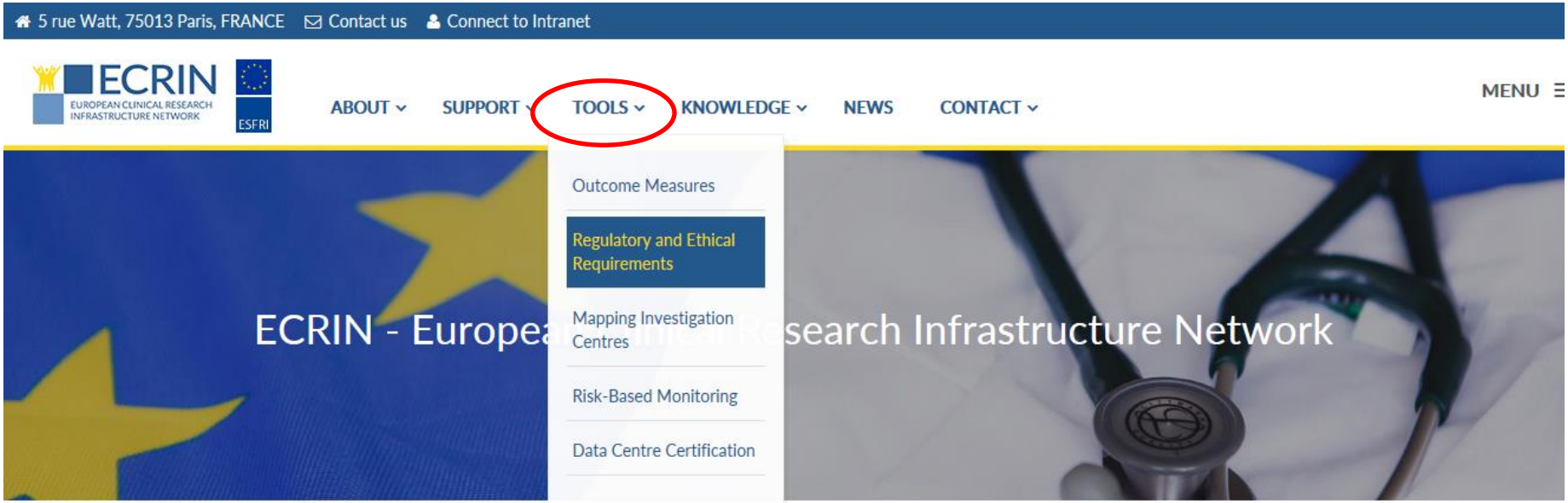
➢ **~€40M to countries involved**



ECRIN
EUROPEAN CLINICAL RESEARCH INFRASTRUCTURE NETWORK

Tools for multinational trials

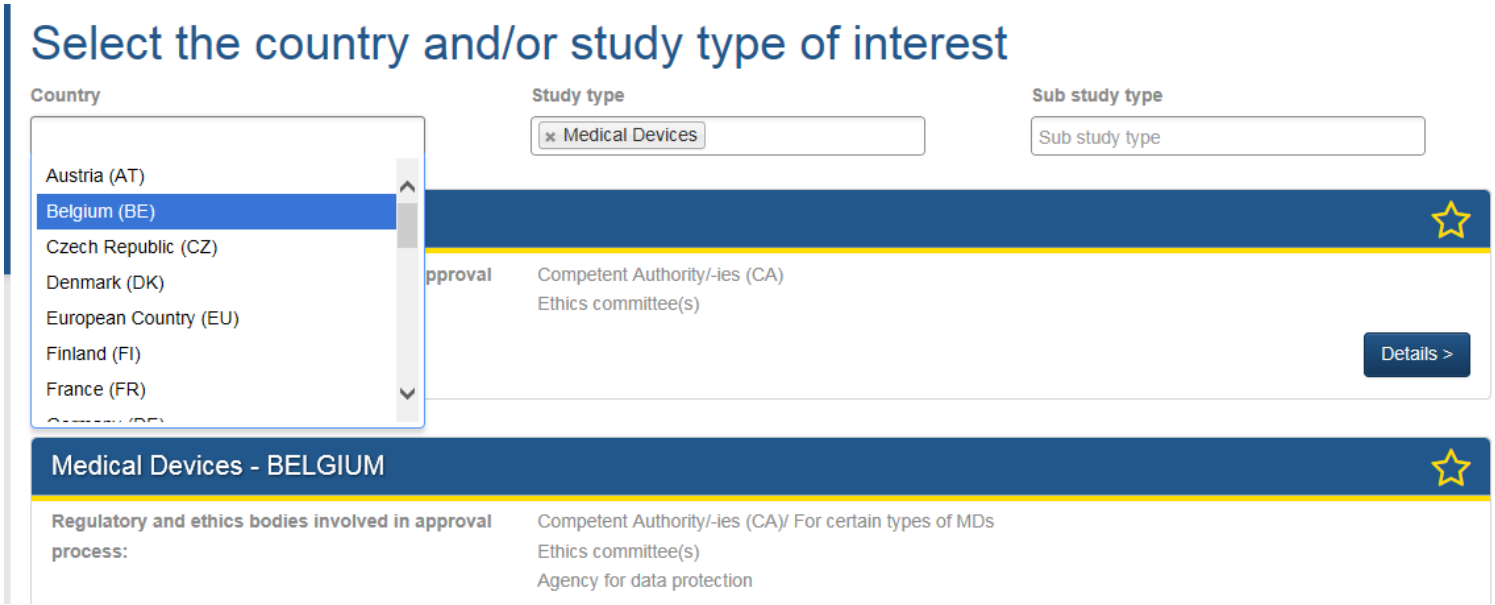
ECRIN tools to facilitate multinational trials (*www.ecrin.org*)



- Quality management
- Data centre certification
- Regulatory and ethical database
- Methodology guidelines
- Outcome measure database
- Risk-based monitoring toolbox
- Mapping of investigation sites
- Training
- Communication

ECRIN
EUROPEAN CLINICAL RESEARCH INFRASTRUCTURE NETWORK

ECRIN Regulatory and Ethical database



Central resource covering 22+ European countries and multiple study types.

Use to: Locate country-specific competent authorities and ethics committees

Consult summary of requirements in each country

Browse related documents

ECRIN
EUROPEAN CLINICAL RESEARCH INFRASTRUCTURE NETWORK

Risk based monitoring toolbox

- Enables researchers to create appropriate risk-based strategies

Training and Other On-Site Activities

As stated by Baigent et al (Baigent et al. 2008), "on-site monitoring should be ... regarded as "mentoring", providing opportunities for training and supporting study staff". In this section, two papers describing on-site activities beyond SDV are reviewed.

Topic	Validation	Reference
Site Monitoring Process Using Peer Reviewers to Improve Staff Training, Site Performance, Data Collection and GCP Compliance Procedure for annual site visits performed by an experienced team, with detailed description of proposed on-site activities	Implementation in a large multicentre trial is described, demonstrating a decrease of findings with ongoing site visits.	Lane et al. 2011
Clinical Trial Educator (CTE) Program – to accelerate enrolment Program involving regular site visits by specifically trained personnel in order to train and educate investigators and site staff with respect to recruitment challenges.	Non-randomised evaluation of the programme in a large-scale trial showed significantly better recruitment rates in sites visited by a CTE,	Kendall et al. 2012) Central Monitoring

Central Monitoring

ECRIN data center certification

Certification criteria (129 requirements, V 3.1 available on www.ecrin.org)

Data Management Standards (48)

DM01 CDMAs - Design and Development (7)

DM02 CDMAs - Validation (6)

DM03 CDMAs - Change management (7)

DM04 Data Entry and Processing (7)

DM05 Managing Data Quality (12)

DM06 Delivery and Coding of Data for Analysis (9)

Ohmann et al. Trials 2011, 12:85
http://www.trialsjournal.com/content/12/1/85

TRIALS

RESEARCH Open Access

Standard requirements for GCP-compliant data management in multinational clinical trials

Christian Ohmann[1*†], Wolfgang Kuchinke[1†], Steve Canham[2†], Jens Lauritsen[3], Nader Salas[4], Carmen Schade-Brittinger[5], Michael Wittenberg[5], Gladys McPherson[6], John McCourt[7], Francois Gueyffier[8], Andrea Lorimer[9] and Ferràn Torres[10] for the ECRIN Working Group on Data Centres

IT Standards (42)

IT01 Management of Servers (5)

IT02 Physical Security (5)

IT03 Logical Security (7)

IT04 Logical Access (7)

IT05 Business Continuity (6)

IT06 General System Validation (9)

IT07 Local Software Development (3)

General Standards (39)

GE01 Centre Staff Training and Support (4)

GE02 Site Management, Training & Support (9)

GE03 Treatment Allocation (9)

GE04 Transferring Data (6)

GE05 Receiving and Uploading Bulk Data (6)

GE06 Long Term Data Storage (5)

Experience of ECRIN data center certification, and perspectives

Contemporary Clinical Trials Communications 5 (2017) 153–159

Contents lists available at ScienceDirect

Contemporary Clinical Trials Communications

journal homepage: www.elsevier.com/locate/conctc

Raising standards in clinical research – The impact of the ECRIN data centre certification programme, 2011–2016

C. Ohmann [a,*], S. Canham [b], J. Demotes [c], G. Chêne [d], J. Lauritsen [e], H. Martins [f], R.V. Mendes [g], E.B. Nicolis [h], A. Svobodnik [i], F. Torres [j]

https://authors.elsevier.com/sd/article/S2451865416300825

ECRIN
EUROPEAN CLINICAL RESEARCH INFRASTRUCTURE NETWORK

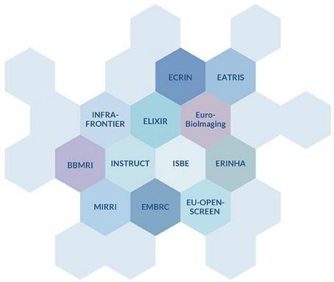
Capacity projects

- ***ECRIN-IA***
- CORBEL
- PRO4VIP
- RI-Train
- ***PedCRIN***
- TRANSVAC
- RISCAPE
- EOSC pilot

- EMTRAIN
- MiRoR
- TESA II
- CRIGH

ECRIN
EUROPEAN CLINICAL RESEARCH INFRASTRUCTURE NETWORK

ESFRI-roadmap Biological and Medical Science Research Infrastructures



BMS RIs

BIOLOGICAL AND MEDICAL SCIENCES RESEARCH INFRASTRUCTURES

ECRIN | clinical trials
EATRIS | translational research
EuroBioImaging | cellular and medical imaging
ELIXIR | bioinformatics
BBMRI | biobanks
INSTRUCT | structural biology
INFRAFRONTIER | mouse models
ISBE | systems biology
ERINHA | high-security laboratories
MIRRI | microbial collections
EMBRC | marine biology
EU-OPENSCREEN | chemical libraries and screening

CORBEL

erinha — European Research Infrastructure on Highly Pathogenic Agents

MIRRI — MICROBIAL RESOURCE RESEARCH INFRASTRUCTURE

ECRIN — EUROPEAN CLINICAL RESEARCH INFRASTRUCTURE NETWORK

BBMRI-ERIC — Biobanking and BioMolecular resources Research Infrastructure

HORIZON 2020 — LE PROGRAMME DE RECHERCHE ET D'INNOVATION DE L'UNION EUROPÉENNE

EURO-BIOIMAGING

Clinical research

Translational research

Biomarkers

eatris — European infrastructure for translational medicine

elixir

Drug discovery/ development

EU-OPENSCREEN — Chemical Keys for Life's Locks

instruct Integrating Biology

ISBE — Infrastructure for Systems Biology Europe

Target identification

INFRAFRONTIER — mouse disease models

EMBRC EUROPEAN MARINE BIOLOGICAL RESOURCE CENTRE

CORBEL cluster project

ECRIN

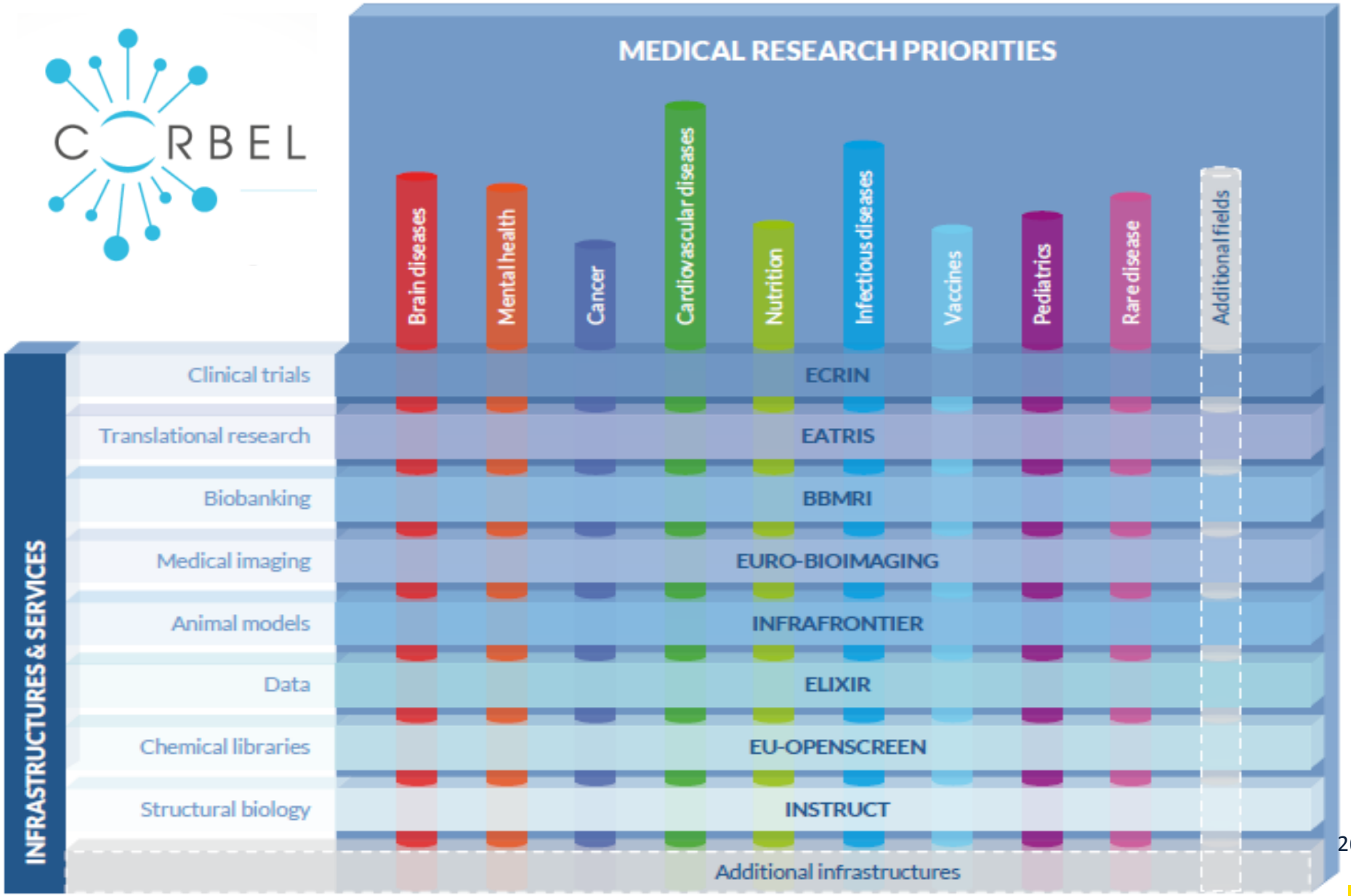
- Leader WP3 (health use cases)

involved in

- Communication
- Access Quality management
- ELSI
- Innovation
- Training

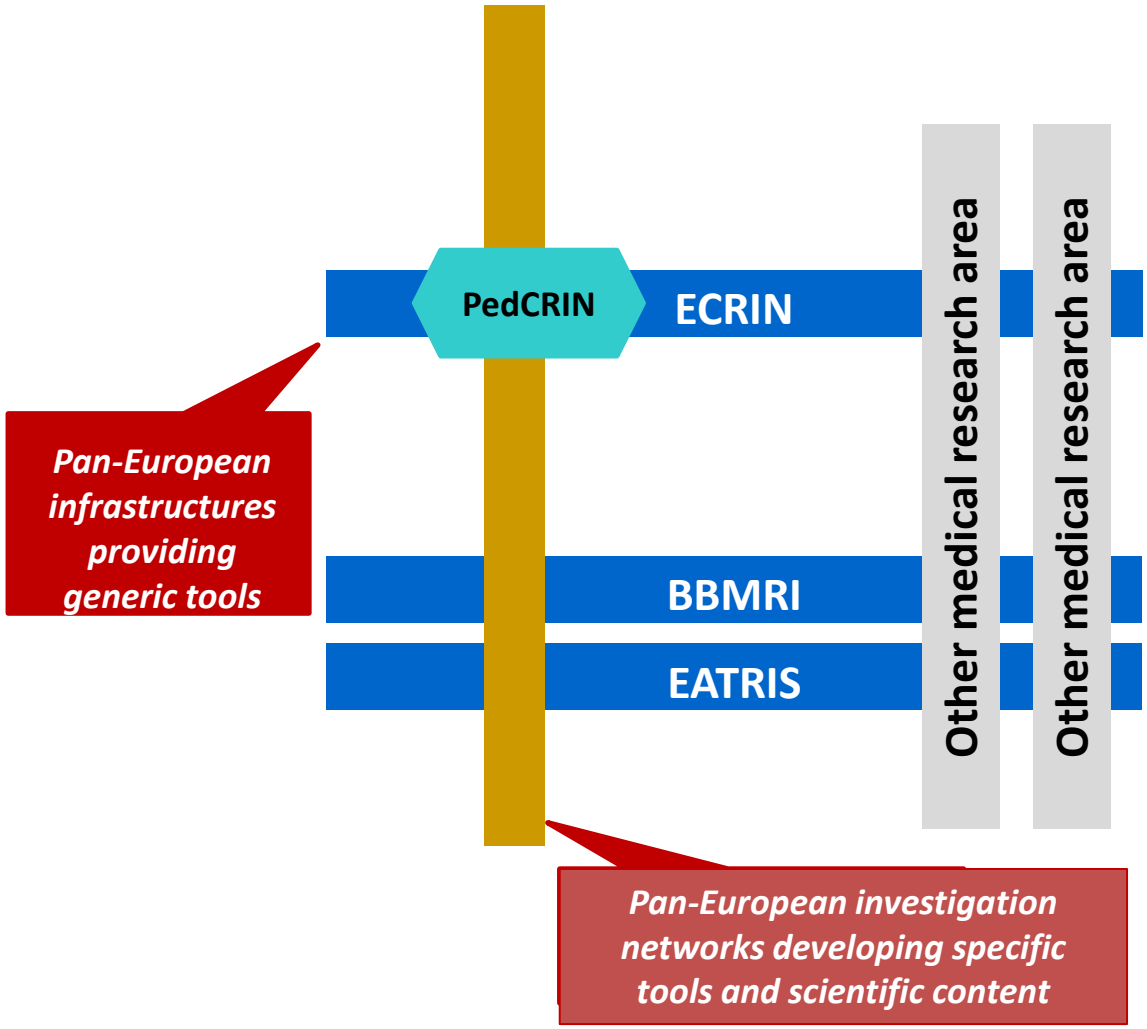
ECRIN
EUROPEAN CLINICAL RESEARCH INFRASTRUCTURE NETWORK

Medical Infrastructures / Users Forum



PedCRIN consortium and objectives

- ECRIN and linked third parties: trial management capacity
- EPCTRI partners: investigation capacity
- BBMRI and EATRIS as partners

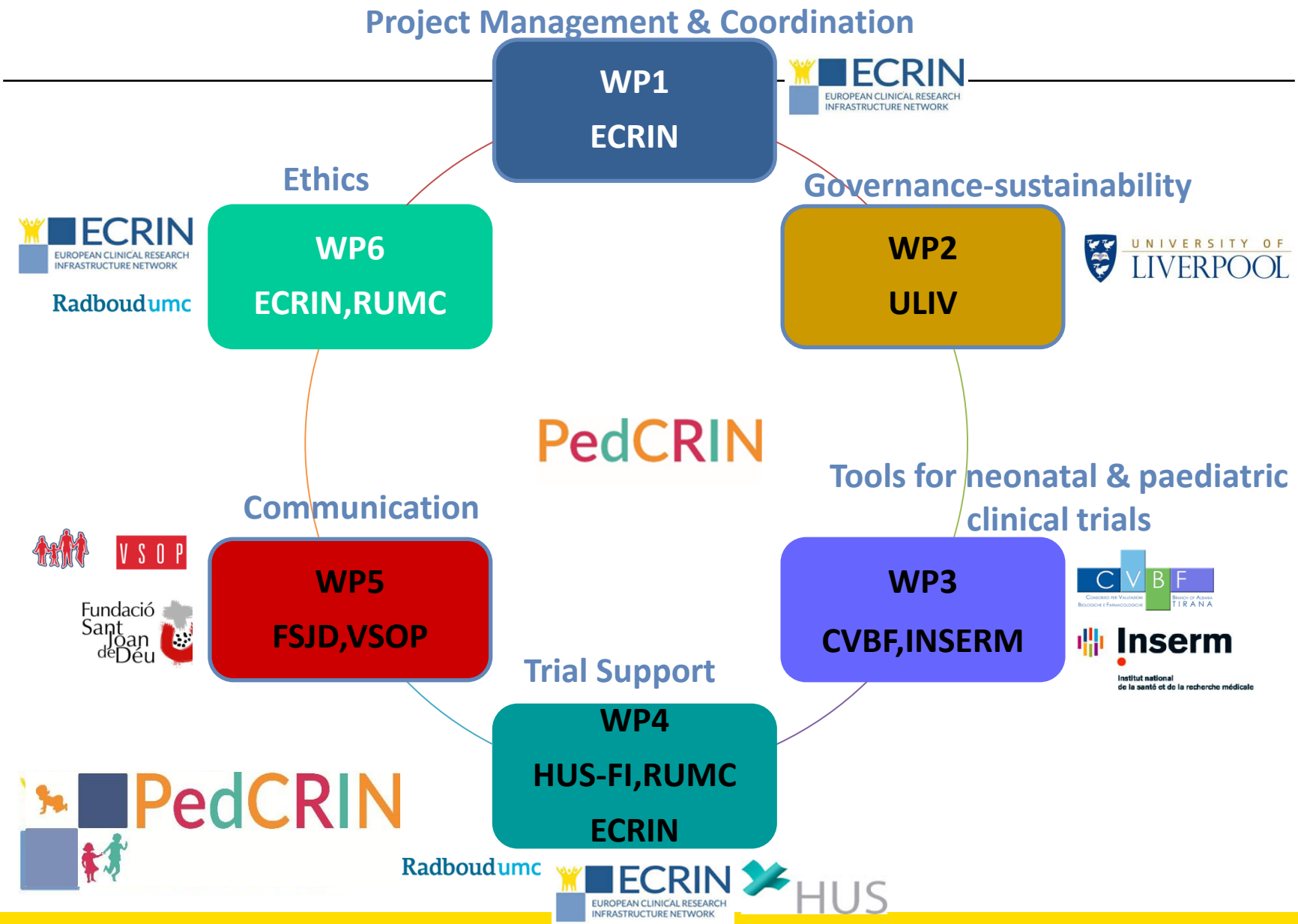


- Budget 3.3M€
- Duration 36/48 months

PedCRIN partners

ECRIN & linked third parties	*EPCTRI partners*
ECRIN	AT : OKIDS
CH: SCTO	CH : SCTO
CZ : CZECRIN	EE : UTartu
DE : KKSN	ES : FSJD
ES : SCReN	FI : HUS
FR : F-CRIN	FR : INSERM
HU : HECRIN	GR : AUTH
IT : ISS	IRL : NCRC
NO : NorCRIN	IT : CVBF
PT : PtCRIN	NL : RUMC, VSOP
BBMRI	NO : HUS
EATRIS	SW : KI
	UK : ULIV

PedCRIN activities



International partnerships

- **Bilateral cooperation :** Australia, Korea, USA, Brazil, Japan

- **Multilateral cooperation : CRIGH**
  - Clinical Research Initiative for Global Health
  - Secretariat NIH + ECRIN (OECD and WHO partners)
- **6 projects**
  - Infrastructure and funding
  - Global core competencies
  - Research ethics
  - Patient involvement
  - Comparative effectiveness research
  - Regulatory awareness

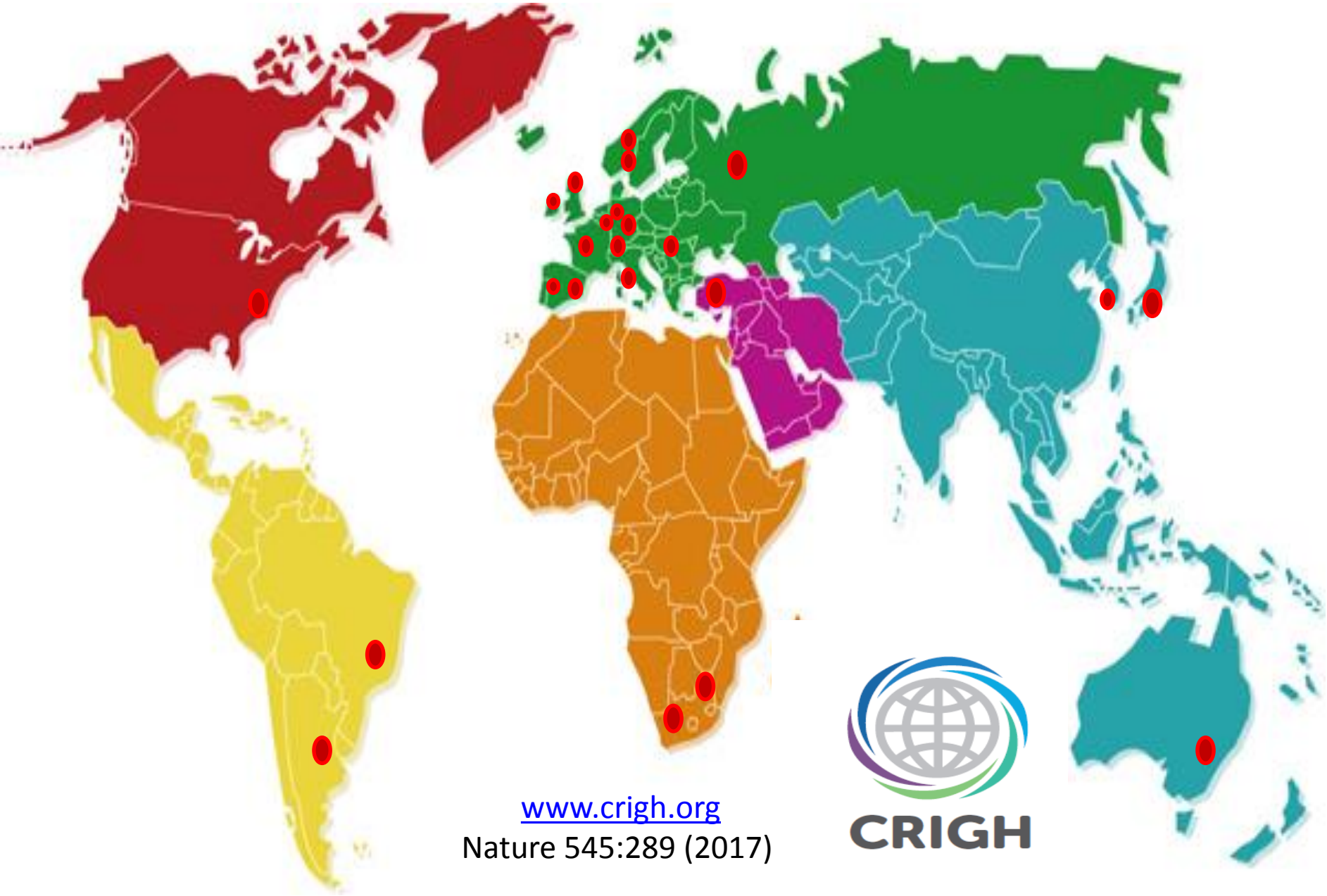
CRIGH

ECRIN
EUROPEAN CLINICAL RESEARCH INFRASTRUCTURE NETWORK

OECD Recommendation on the Governance of Clinical Trials

OECD

Clinical Research Initiative for Global Health



www.crigh.org

Nature 545:289 (2017)

CRIGH

Added value of ECRIN Membership

- **Scientific impact - structuring effects**
  - national standards impact on common tools
  - availability of, and access to common tools
  - quality standards, quality services (ECRIN data centre certification)
  - strengthening of national clinical trial infrastructure, attractiveness for industry and academic trials
  - participation in H2020 structuring projects (CORBEL, etc)
  - training of investigators and support staff / multinational trials

ECRIN
EUROPEAN CLINICAL RESEARCH INFRASTRUCTURE NETWORK

Added value of ECRIN Membership

- **Scientific impact - operational support to clinical trials**
  - access to patients and to medical expertise, unlocking the national scientific potential
  - facilitating national participation in H2020 and IMI-funded projects and supporting the applications
  - supporting trial design, methodology, logistics and management
  - facilitating the involvement of national investigators in multinational clinical trials initiated by European investigators

ECRIN
EUROPEAN CLINICAL RESEARCH INFRASTRUCTURE NETWORK

Added value of ECRIN Membership

Socio-economic impact on health and on economy

- health innovation from national SMEs
  - medical device, biotherapy
- evidence-based medical decision
  - patients and healthcare system
- fostering H2020 - IMI funding

ECRIN
EUROPEAN CLINICAL RESEARCH INFRASTRUCTURE NETWORK

Conditions for ECRIN Membership

- National network of clinical trial units as „Scientific Partner“
  - Capacity to manage trials in any disease area
  - Framework contract with ECRIN
  - senior delegate as Member of the „Network Committee“
- National hub
  - hosting ECRIN European Correspondent (EuCo), ECRIN employee

- Commitment of Government : Member, or Observer (3 years max)
- Contribution stratified / GDP and GDP per capita :
- Local contribution (in-kind or in-cash, for Members and Observers) : €50k (GDP per capita <€20k)
- Core contribution (in cash, for Members) : €20k (GDP <€200bn)

ECRIN
EUROPEAN CLINICAL RESEARCH INFRASTRUCTURE NETWORK