ECRIN,
the European infrastructure
for multinational clinical research

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EUROPEAN CLINICAL RESEARCH INFRASTRUCTURE NETWORK

EMA, EU-Innovation Office Network workshop

London, November 16th, 2018

Jacques Demotes

ECRIN : supporting multinational clinical trials

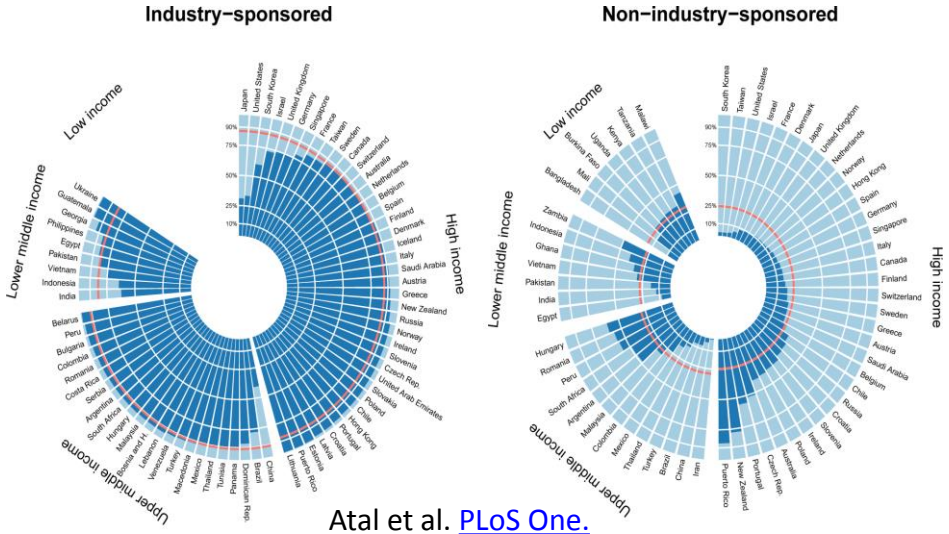
eunethta

Registration trials

Repurposing trials

Comparative effectiveness

Personalized medicine



Atal et al. PLoS One. 2015:e0145122.

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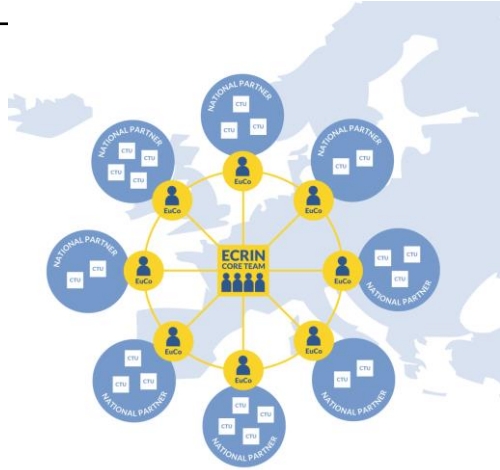
Access to patients and to medical expertise

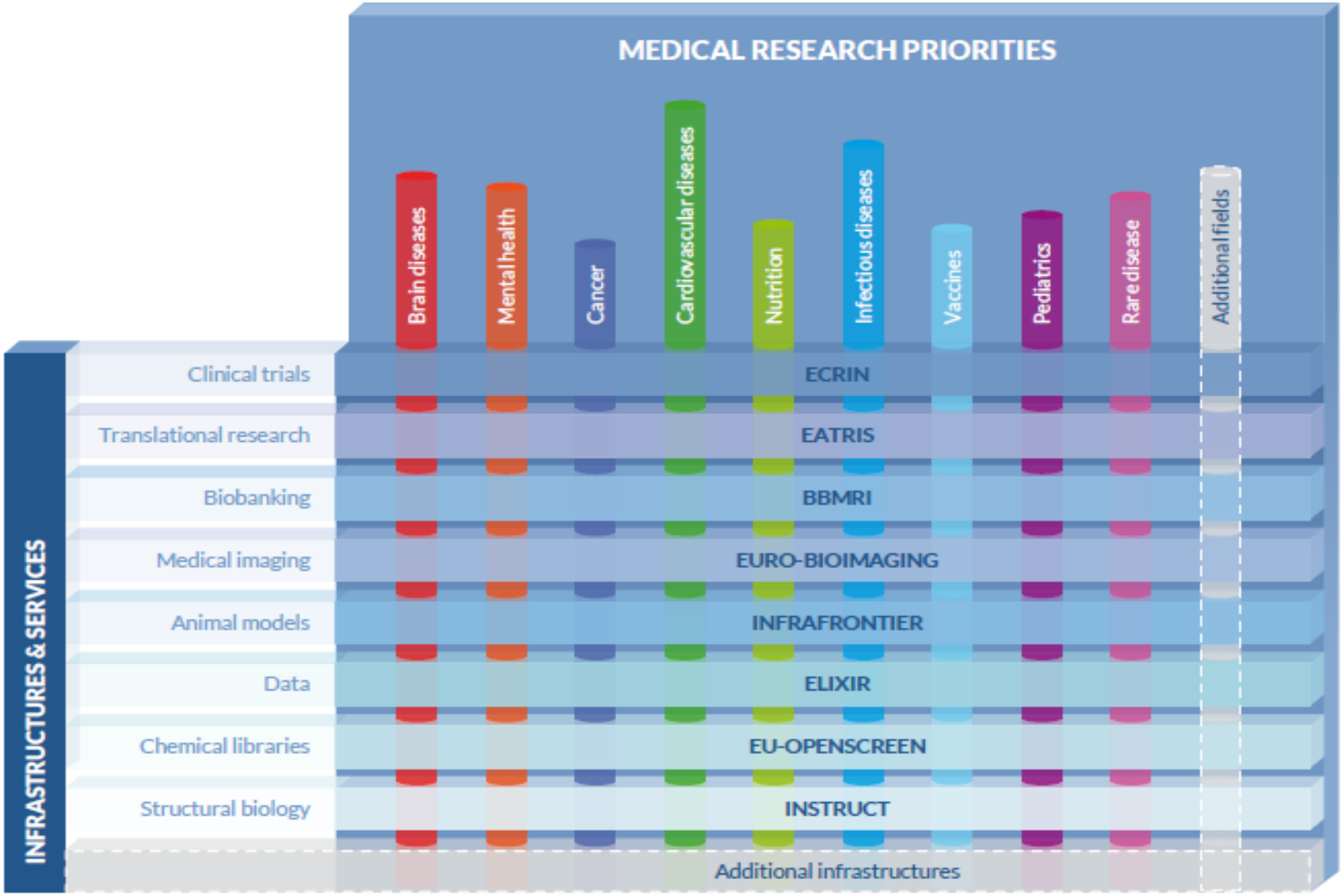
Unlock scientific potential

Promote quality harmonisation interoperability

Share tools and procedures



Research infrastructures vs. investigation networks



50 multinational trials supported by ECRIN

Operational services and tools to support trial management

ECRIN operational support	ECRIN tools
1 – Support to planning / design / funding	✓ *guidance on methodology / design*
2 – Protocol peer review, risk assessment	
3 - ECRIN operational services	
➢ ***Distributed services***	
✓ *regulatory-ethics approvals*	✓ *regulatory / ethics database ('Campus')*
✓ *study monitoring*	✓ *risk-based monitoring toolkit*
➢ ***Central services***	
✓ *pharmacovigilance*	
✓ *data management*	✓ *data centre certification*
	✓ *data sharing*

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

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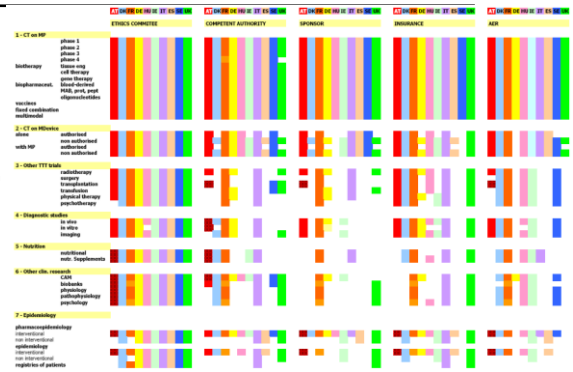
Challenges and key opportunities for changes

1 - Funding multinational trials

2 - Governance of clinical studies

- *EU Regulations Medicines (2014/536) and Devices (2017/745)*
- *Diversity in clinical research not covered by EU Regulations*
- *Diverse insurance policies in the MS*



3 - Data protection vs. data sharing / reuse

- *research data (interventional, observational)*
- *health data, EHR*

4 - Patient-centred outcome measures

5 - Patient stratification studies

- *methodological standards*
- *multimodal data management*
- *AI algorithms*

BMJ Open **Sharing and reuse of individual participant data from clinical trials: principles and recommendations**

Christian Ohmann,[1] Rita Banzi,[2] Steve Canham,[3] Serena Battaglia,[4] Mihaela Matei,[4] Christopher Ariyo,[5] Lauren Becnel,[6] Barbara Bierer,[7] Sarion Bowers,[8] Luca Clivio,[2] Monica Dias,[9] Christiane Druml,[10] Hélène Faure,[11] Martin Fenner,[12] Jose Galvez,[13] Davina Ghersi,[14] Christian Gluud,[15] Trish Groves,[16] Paul Houston,[6] Ghassan Karam,[17] Dipak Kalra,[18] Rachel L Knowles,[19] Karmela Krleža-Jerić,[20] Christine Kubiak,[4] Wolfgang Kuchinke,[21] Rebecca Kush,[22,23] Ari Lukkarinen,[5] Pedro Silverio Marques,[24] Andrew Newbigging,[25,26] Jennifer O'Callaghan,[27] Philippe Ravaud,[28] Irene Schlünder,[29] Daniel Shanahan,[11,30] Helmut Sitter,[31] Dylan Spalding,[32] Catrin Tudur-Smith,[33] Peter van Reusel,[6] Evert-Ben van Veen,[34,35] Gerben Rienk Visser,[36] Julia Wilson,[8] Jacques Demotes-Mainard[4]

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Highlights in the track record of working in regulatory science

1 - FP7 ICREL project

2 - OECD Council Recommendation on the Governance of Clinical Trials

CRIGH

www.crigh.org

Nature 545:289 (2017)

3 - Development of regulatory and ethical database ('ECRIN Campus')

4 - Development of ECRIN risk-based monitoring toolbox

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Together we can promote regulatory science: share experience, discuss, learn, and work with you

1 – Regulatory awareness : upgrade Campus databases, e.g.

- paediatric trials, vaccine trials
- Regulation 2014/536 and 2017/745
- develop expertise on drug-device trials (project)
- global extension

2 – Transnational data sharing / reuse : CORBEL / EOSC-Life including

- sharing and reuse of research data : trials, cohorts, registries
- sharing and reuse of health data : EHR, EDC, health databases
- pilot on federation of hospital data warehouses (*project*)

3 – Methodology for patient stratification studies

- stratification/validation cohorts, and interventional trials (*project*)

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Thank you for your attention and
your involvement

For further information and collaboration contact us

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