ECRIN – European Clinical Research Infrastructure Network

Supporting Clinical Trials Across Borders

ECRIN
EUROPEAN CLINICAL RESEARCH INFRASTRUCTURE NETWORK

Serena Battaglia| June 20th, Brussels

Context

Why ECRIN?

- Need for multinational trials
  - Greater access to patients, medical expertise and appropriate facilities
  - Higher methodological standards
  - Shared costs, tools and procedures
  - Potential for broad implementation of research outcomes
  - Avoidance of duplication of trials
- But several obstacles to multinational trials
  - Infrastructure interoperability, regulation, ethical review, insurance, contracts, management, cost models, funding, languages, etc.

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Context

Why ECRIN?

- ECRIN as a solution
  - Provides support to sponsors in investigator-initiated trials
  - A pathway through Europe's fragmented health and legal systems
  - development of innovative health products
  - exploration of new indications for authorised health products
  - comparative assessment of efficacy and safety of approved healthcare strategies

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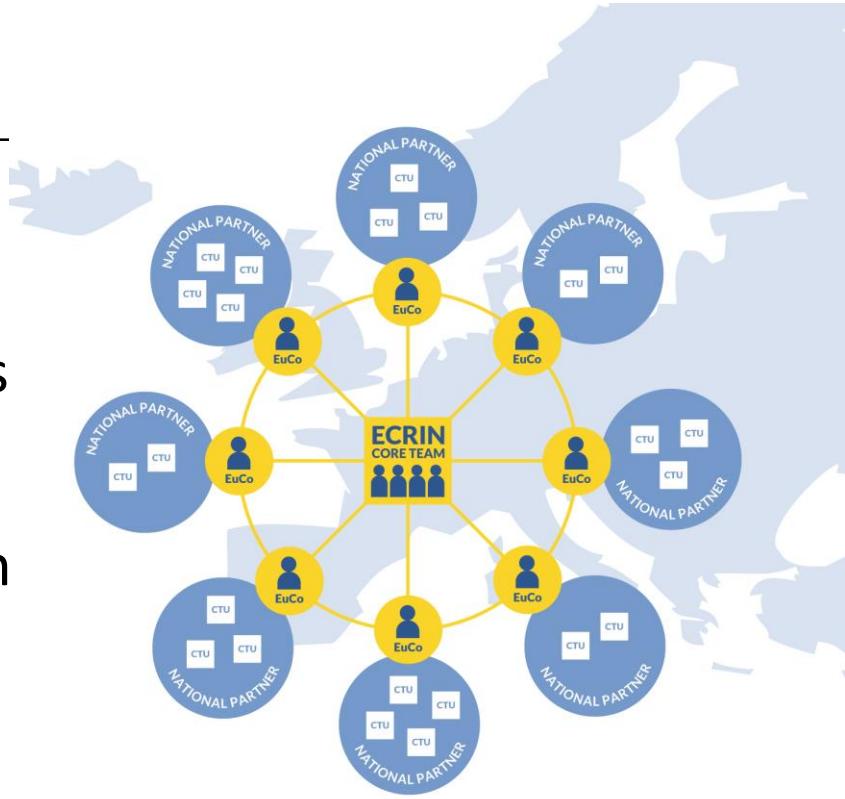
Organisation: Distributed Infrastructure

EuCos, Core Team, National Partners



- **European Correspondents (EuCos)**
  - Implement work in-country in coordination with national partners
- **Core Team**
  - Develops ECRIN's strategy, common tools and procedures
  - Supports EuCos
- **National Partners** (networks of clinical trial units, CTUs)
  - Manage trials in-country and provide services to ECRIN
  - Host EuCos

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Main Activity: Trial Support

Coordinated Support from Preparation to Implementation

1 PREPARATION

ECRIN GIVES ADVICE AND INFORMATION ON:

- Funding sources and applications
- Investigation sites and patient recruitment
- Clinical trial units (location, services)
- Regulatory, ethical and insurance requirements
- Trial methodology
- Cost of trial management services

2 PROTOCOL REVIEW

ECRIN'S SCIENTIFIC BOARD AND EUROPEAN CORRESPONDENTS PROVIDE:

- Scientific and methodological evaluation of the full protocol
- Logistical assessment of project implementation plans

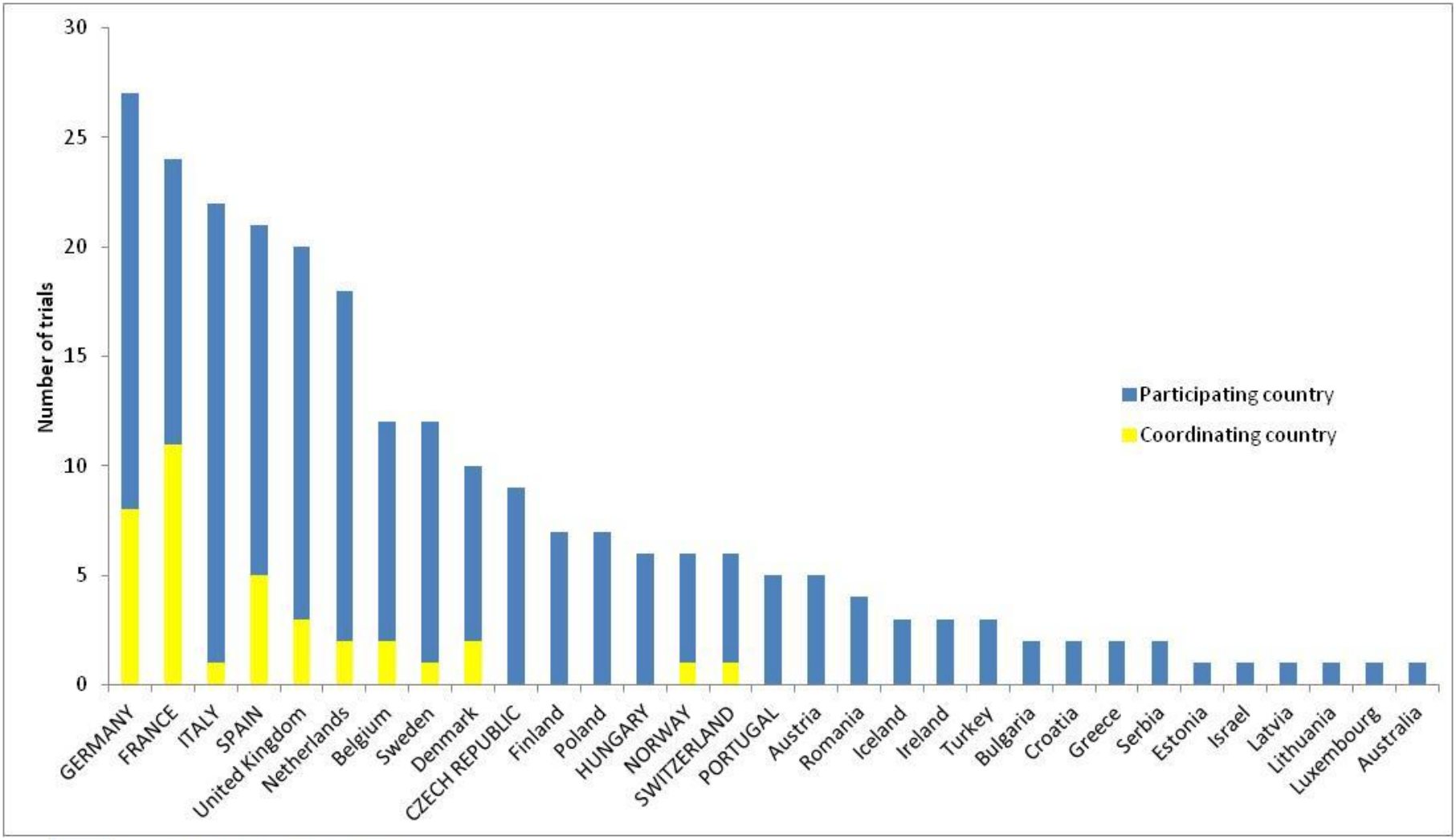
3 TRIAL MANAGEMENT

ECRIN COORDINATES AND SUPPORTS:

- Submissions to competent authorities and ethics committees
- Monitoring
- Adverse event reporting
- Data management
- Health product and biosample management

ECRIN trial portfolio

average 7 countries per trial (eligibility: projects involving at least 2 ECRIN countries)



Support innovative SMEs in the healthcare biotechnology sector *(Call H2020 dedicated SME instrument)*

- Development of clinical trials for the validation of biomarkers and/or medical devices
  - New EU regulation
- New trial design (adaptive design, basket studies)
  - More flexible, efficient and fast clinical trials
  - Targeted therapies
- Data sharing and re-use services
  - Reproducibility of results
  - Reduce the number of clinical trials

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How can ECRIN stimulate innovation in Europe?

- Collaborative approach
  - Overcome challenges and support trials with the greatest public health impact
- Trial design and methodology
  - Reduce the number and the cost of clinical trials
  - Improve the efficacy (faster access to treatments)
- Health policies and clinical guidelines for health professionals
  - Ask "What is the **best treatment option** for this patient/disease?" rather than "Is this particular product effective and safe?"

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Thank you!

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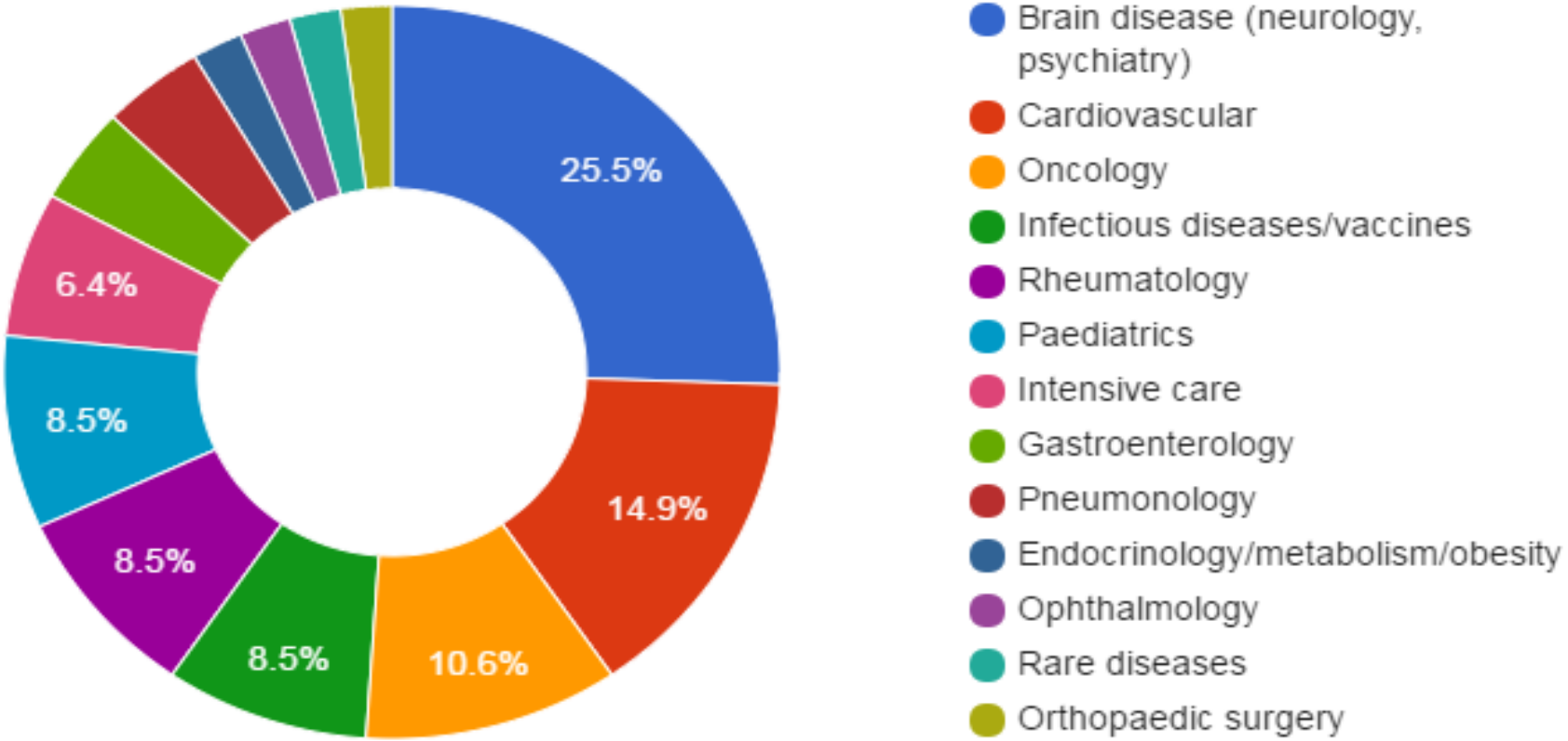
ECRIN trial portfolio

Disease areas



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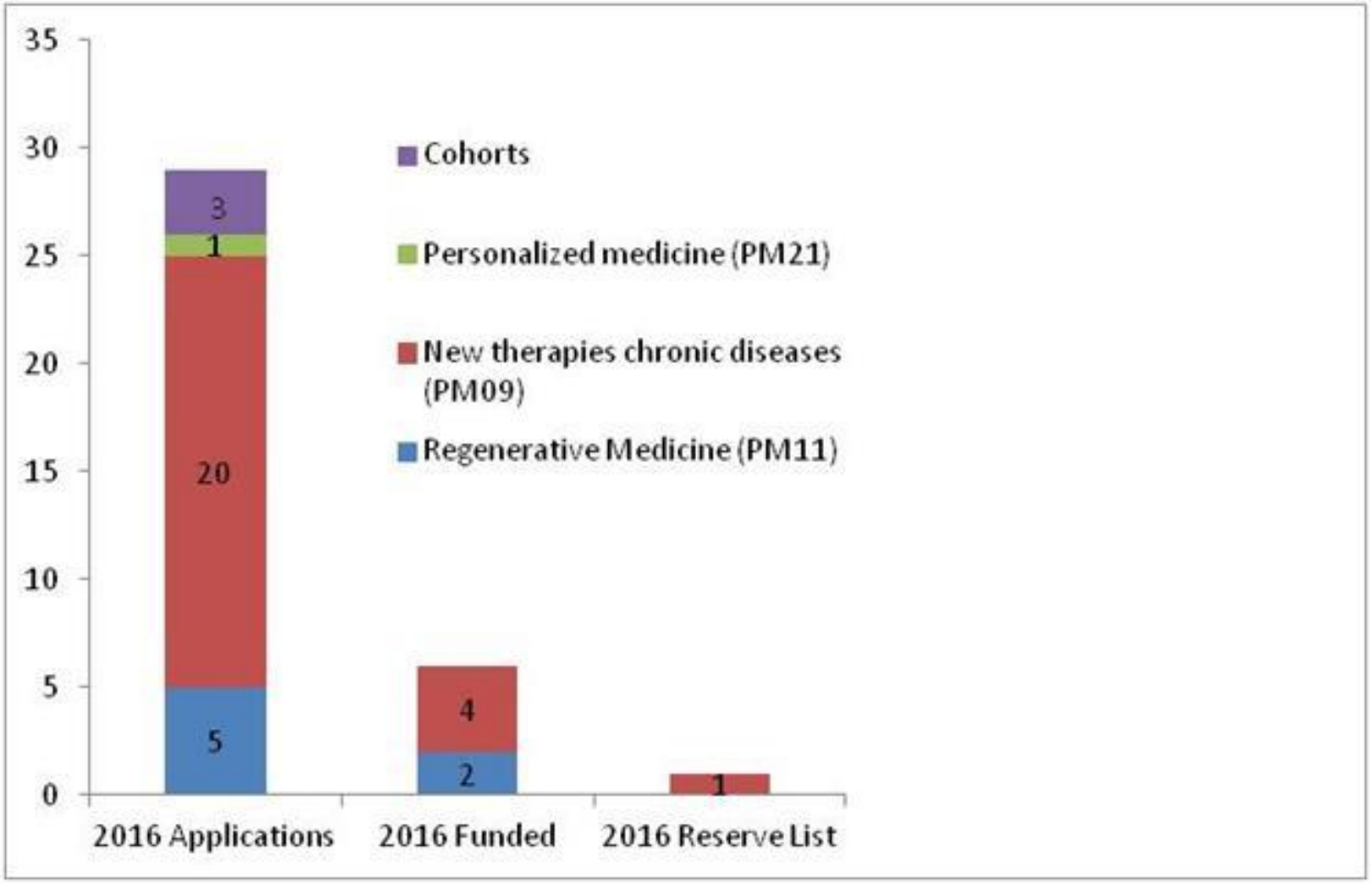
Calls 2016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Cohorts
Personalized medicine (PM21)
New therapies chronic diseases (PM09)
Regenerative Medicine (PM11)
2016 Applications
2016 Funded
2016 Reserve List