Agenda

About ECRIN

Overview of ECRIN Activities

Increasing value
ECRIN

Overview

- A non-profit organisation with the legal status of European Research Infrastructure Consortium (ERIC)

- **Mission:** support the conduct of multinational clinical trials across Europe

- **Coordinated services from preparation to implementation**

- **9 Member and Observer Countries:** Czech Republic, France, Germany, Hungary, Italy, Norway, Portugal, Spain, Switzerland (additional countries about to join)
History At A Glance

- **2004:** ECRIN created; began 1st project (EU Framework Program 6, FP6) on strategy development involving six countries
- **2006:** 2nd project (FP6) on tools development with 12 countries; listed on European Strategy Forum on Research Infrastructures (ESFRI) roadmap
- **2008:** 3rd project (FP7) with 14 countries to develop ECRIN’s business plan and legal status
- **2012:** 4th project (FP7), ECRIN Integrating Activity (ECRIN-IA), with 23 countries to structure national scientific partners and build their capacity to manage multinational trials
- **2013:** Awarded ERIC status
- **2016:** Listed as an “ESFRI Landmark” on the updated ESFRI Roadmap
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
ECRIN - Organisation

National Scientific Partners

- Czech Republic: CZECRIN – Czech Clinical Research Infrastructure Network
- France: F-CRIN – French Clinical Research Infrastructure Network
- Germany: KKSN – Netzwerk der Koordinierungszentren für Klinische Studien
- Hungary: HECRIN–Hungarian Clinical Research Infrastructure Network
- Italy: Istituto Superiore di Sanita (ISS), Rome
- Norway: NorCRIN – Norwegian Clinical Research Infrastructure
- Portugal: PtCRIN–Portuguese Clinical Research Infrastructure Network
- Spain: SCReN –Spanish Clinical Research Network
- Switzerland: Swiss Clinical Trial Organisation (SCTO)
Additional Partners

Collaborating Across Borders for Greater Impact

- Collaboration with specialised centres and disease-networks in Europe and worldwide
- Affiliate/international partners include:
  - Therapeutic Innovation Australia Ltd (TIA)
  - Korea National Enterprise for Clinical Trials (KoNECT)
  - European Vision Institute Clinical Research Network (EVICR.net) (Portugal)
  - National Center for Advancing Translational Sciences (NCATS) at the National Institutes of Health (NIH) (USA)
  - Oswaldo Cruz Foundation (FIOCRUZ) (Brazil)
  - Foundation for Biomedical Research and Innovation (FBRI) (Japan)
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Diverse Activities to Facilitate Multinational Clinical Research

- Support for multinational trial preparation, protocol review and management
- Development of tools
- Quality assurance and data centre certification
- Participation in capacity building projects
Main Activity: Trial Coordinated Support

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 Campus for Regulatory & Ethical Requirements

- 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
Tools to Facilitate Multinational Trials (2/2)

ECRIN Provides Tools to Measure Outcome & Assess Risk

Medical Device Outcome Measure Database

- Identifies relevant outcomes for specific medical devices.
  Information on:
  - Product names
  - Risk class
  - Disease
  - Body system
  - Intervention type, device category
  - Source publication

Risk-Based Monitoring Toolbox

- Enables researchers to create appropriate risk-based strategies
  - Choose risk assessment, monitoring adaptation, or study conduct tools to find related tool names, institutions where they are used, links, and feedback
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Increasing value
How to improve?

- Questions relevant to clinicians, patients
- Appropriate design and methods
- Accessible full publication
- Unbiased and usable report
ECRIN Scientific Board

- To assess/improve relevance and quality of projects to be supported by a publicly funded infrastructure
- Aimed at ensuring
  - Transparency: registration, publication, data sharing, disclosure
  - Real and relevant questions: trial hypotheses
  - Reliable answers: trial methodology

- ECRIN on board: early methodological support
- **Transparency**

- **Methodology**
Hydroxyethyl Starch 130/0.4 versus Ringer’s Acetate in Severe Sepsis
Anders Perner, M.D., Ph.D., Nicolai Haase, M.D., Anne B. Guttmann, M.D., Ph.D., Jyrki Tenhunen, M.D., Ph.D., Gudmundur Klemenzson, M.D., Anders Aneman, M.D., Ph.D., Kristian R. Madsen, M.D., Morten H. Møller, M.D., Ph.D., Jeanie M. Eligir, M.D., Lone M. Poulsen, M.D., Asger Bendtsen, M.D., M.P.H., Robert Winding, M.D., Morten Steensen, M.D., Pawel Berezowski, M.D., Ph.D., Peter Sae-Jensen, M.D., Morten Børløk, 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., Helle H. Andersen, M.D., Lars B. Holst, M.D., Katrin Thomar, M.D., Anne-Lene Kjeldgaard, M.D., Maria L. Fabritius, M.D., Frederik Mondrup, M.D., Frank C. Pott, M.D., D.M.Sc., Thea P. Møller, M.D., Per Winkel, M.D., D.M.Sc., and Jørn Wetterslev, M.D., Ph.D., for the 6S Trial Group and the Scandinavian Critical Care Trials Group.*

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-Tawil2, Maja Jahnmatz,1,4 Jakob Bergström1, Margaretha Ljungan,1 Anna Törner1, Lena Wehlin1, Annie Van Broeckhoven6, Fons Bosman6, Anne-Sophie Debrée5,6,7,8, Nathalie Mielenz6,7,8, Camille Locht5,6,7,8
1Swedish Institute for Communicable Disease Control, Solna, Sweden, 2Karolinska Trial Alliance, Karolinska University Hospital, Stockholm, Sweden, 3Department of Microbiology, Tumor and Cell Biology, Karolinska Institute, Stockholm, Sweden, 4Disease Biologics, Bioinvent, Zaventem, Belgium, 5Immun, Lille, France, 6National Center for Scientific Research, Lille, France, 7Université Lille Nord de France, Lille, France, 8Center for Infection and Immunity of Lille, Institut Pasteur de Lille, Lille, France

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., M.D.Sc., Jannicke Horn, M.D., Ph.D., Jan Hovdenes, M.D., Ph.D., Jesper Kjaergaard, M.D., M.D.Sc., Michael Kuiper, M.D., Thor Tommaso Pellis, M.D., Pascal Stammel, M.D., Michael Wanscher, M.D., Ph.D., Mathijs Wise, M.D., D.Phil., Anders Aneman, M.D., Ph.D., Nawaf Al-Sabahi, M.D., Søren Boesgaard, M.D., M.Sc., John Bro-Jepsesen, M.D., Iole Brunetti, M.D., Jan Frederik Bugge, M.D., Ph.D., Christopher D. Hongton, M.D., Nicole P. Juffermans, M.D., Ph.D., Matty Koopmans, M.R., N.Sc., Lars Køber, M.D., M.D.Sc., Jarund Langergaard, M.D., Ph.D., Louise Lili, O.T., Jacob Elfer Møller, M.D., M.D.Sc., Malin Sundgren, M.D., Ph.D., Christian Rylander, M.D., Ph.D., Ondrej Smid, M.D., Ph.D., Per Winkel, M.D., D.M.Sc., and Hans Frimberg, M.D., Ph.D., for the TTM Trial Investigators*

RESEARCH
Cerebral near infrared spectroscopy oximetry in extremely preterm infants: phase II randomised clinical trial
Simon Hyltén-Cosell research fellow1, Adeline Polleru associate professor2, Thomas Åkerlöf research fellow1, Topun Austin consultant neonatologist3, Frank van Baaij professor of Neonatology4, Maron Benders consultant neonatologist3, Olivier Clarke professor2, Eugene Dempsey professor2, Axel R Pranz assistant professor2, Monica Pumagati consultant neonatologist3, Christian Giudet head of Department1, Berit Gravaas trial manager1, Cornelia Hagmann consultant neonatologist4, Petra Lennern consultant neonatologist4, Wim van Geulen managing director1, Gerhard Pichler associate professor2, Anne Mette Piirgraukne consultant neonatologist1, Joanne Kirner senior researcher1, Martin Wolf professor1, Gorm Griesen associate professor2, Laura Sanchez consultant neonatologist3, Per Winkel senior researcher5, Martin Wolf professor1, Gorm Griesen associate professor2.
Quality Assurance & Data Centre Certification
Promoting Quality Inside and Outside the Organisation

- ECRIN has an internal quality management system
- Promotes quality externally through, for example, the Data Centre Certification programme:
  - CTUs in Europe that can provide safe, secure, compliant and efficient management of clinical research data
Individual patient-level CT data sharing

- Strong move towards data sharing of IPD from clinical trials
- Strong impact and benefit expected from secondary analyses of IPD
- Several policies/recommendations for access to IPD developed and several repositories available for sharing of IPD
- CORBEL/ECRIN has provided up to date, detailed, broad in scope and applicable recommendations supporting the implementation of access to IPD from clinical trial
- Next steps are piloting the recommendations within ECRIN trials, discussing the recommendations in the international context and supporting the implementation of the recommendations
Research for innovative methods to improve the process of clinical research comprehensively

What is Research on Research?

Research on Research is an emerging new scientific discipline that aims to identify and minimise persistent threats to medical research quality.

Why should we develop Research on Research?

Tens of billions of Euros are spent each year on studies that are redundant, flawed in their design, never published or poorly reported. Further, given current research practices, research claims are more likely to be false than true. The public is the main victim of this waste. If clinical research is not adequately planned, conducted and reported, clinicians are prevented from using effective health interventions in practice and researchers from adequately prioritising future research questions. This situation ultimately has a detrimental impact on patient care. Therefore, reducing waste and increasing value of research represents a major societal challenge.

What is our aim?

Our aim is to create, in Europe, an innovative and ambitious multidisciplinary intersectoral joint doctoral training programme, dedicated to Methods in Research on Research (MiRoR) in the field of clinical research.
Thank you!

Any questions?