

ECRIN: Supporting Clinical Trials Across Borders

EURORDIS Meeting
Castelldefels,
Barcelona, Spain
June 5 - 9, 2017



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Agenda

Why do we need clinical trials?

Overview of ECRIN

Why do we need to involve patients?

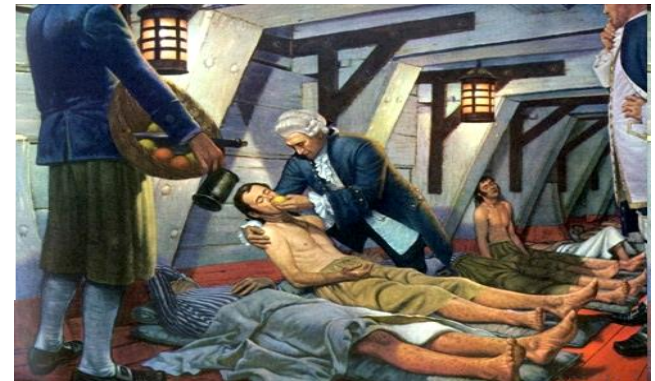
What is a clinical trial?

- Any **research** study that prospectively assigns human participants or groups of humans to one or more health-related interventions to **evaluate/compare** the effects on health outcomes (*“Which is the best intervention?”*)
- **Interventions** include but are not restricted to **drugs, cells and other biological products, surgical procedures, radiological procedures, devices, behavioural treatments, process-of-care changes, preventive care, etc** (*“Intervention= how do we treat the disease?”*)



The following are the experiments.
On the 20th of *May* 1747, I took twelve
patients in the scurvy, on board the *Salisbury*
at sea. Their cases were as similar as I could
have

- 2 got oranges and lemons
- 2 got cider
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Then, why do we need clinical trials?

- **Gold standard** to demonstrate the value of an intervention (*value: is it efficacious? Is it safe?*)
- **We need a method to test** efficacy and safety, **consistently** (*good science*)

Problem with interventions not tested with a validated scientific method: not sure about efficacy and **safety**

- **We need to advance in knowledge acquisition:** research and *research in research* (*new methods of testing interventions; new approaches; facilitate the conduction of collaborative multinational clinical trials*)



What do we need to conduct a clinical trial?

- **An innovative hypothesis to be tested**
- **Funding**
- **Recruitment of patients into the clinical trial** (*more difficult in rare diseases, need to involve specialized clinical centres*)
- **Support to investigators:** regulatory requirements, trial management, preparation of the clinical trial, quality assurance, etc.
- **Increasingly more frequent:** the patient perspective

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ECRIN

Overview

A non-profit organisation with:

- **Mission:** support the conduct of multinational clinical trials across Europe
- **Diverse support areas for investigators in investigator-initiated trials :** regulatory requirements, trial management, preparation, protocol evaluation, quality assurance, etc.
- **Interconnection function:** A pathway through Europe's fragmented health and legal systems

Main Activity: Trial Support

Coordinated Support from Preparation to Implementation

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

Interconnection function

- We collaborate with diverse partners in Europe and beyond to address the key bottlenecks to multinational clinical trials
- We fill a gap in the European clinical research landscape
- Through our collaborative approach, we aim to support trials that have the greatest public health impact
- We can work across a wide range of clinical trial areas (e.g., medicines, medical devices, nutrition, surgical procedures)
- We respect the highest ethical and methodological standards

Interconnection: 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)



Foundation for
Biomedical Research and Innovation



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Scientific Evaluation / Protocol Review

- Independent Scientific Board includes patient representative(s)
- Criteria for selection of scientific projects includes patient perspective

10. Involvement of pertinent patient organisation (if available) or patient representatives in the protocol design.

- Rules for transparency:
 - Register the trial in a public register before inclusion of the first participant (e.g. www.clinicaltrials.gov)
 - Publish results irrespective of findings
 - Make raw anonymised data sets available to the scientific community upon request to the sponsor or principal investigator one year after the trial is completed (last follow up of the last patient) or, for registration trials, when registration is completed or the development is discontinued

Scientific evaluation (example)

- **One patient representative involved in the evaluation of the call**



Paediatric Clinical Research
Infrastructure Network

CALL FOR PROJECTS

PedCRIN call for multinational clinical studies in children and neonates

Supporting multinational extension of paediatric clinical studies funded in the coordinating country

Deadline for applications: 2nd May, 2017 at 17.00 CET

Active participation in research

- Patient associations as beneficiaries of multinational clinical trials:

LIVERHOPE (*European Liver patient Association, ELPA*)

HIVACAR (*European AIDS Treatment Group, EATG*)

-Design of the clinical trial

-Selection of clinical outcomes that they feel will be more relevant to change their life (PROs, patient reported outcomes)

-Communication and dissemination (e.g. webpage)

-Participation in decisions of the clinical trial, governing bodies

«The voice of the patient»

International collaboration

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Clinical Research
Initiative for Global Health

PATIENT INVOLVEMENT

Leader: National Institutes of Health (NIH)

Objectives:

To foster patient involvement as trial participants, and also in trial design, in the definition of outcome measures, in Ethics Committees, and in establishing research priorities.

Description of the work:

CRIGH

[Overview](#)[Infrastructure & Funding](#)[Global Core Competencies](#)

Communication

Promote public awareness of the challenges raised by clinical research

Stimulate debates between representatives of **European patients associations**, clinical scientists, scientific agencies, sponsors, ethics committees, competent authorities, medical journal editors, citizens

2015 in Norway 21 May on Transparency

2016 In Czech Republic 20 May on Clinical trials in the era of personalised medicine

2017 in Portugal 19 May on Data sharing and re-use: attitudes and practices in multinational clinical research

INTERNATIONAL CLINICAL TRIALS DAY (ICTD)



ICTD celebrates the anniversary of the world's first clinical trial, led by Scottish physician James Lind starting 20 May 1747 on sailors with scurvy.

**Celebrated
internationally
on May 20th
every year**

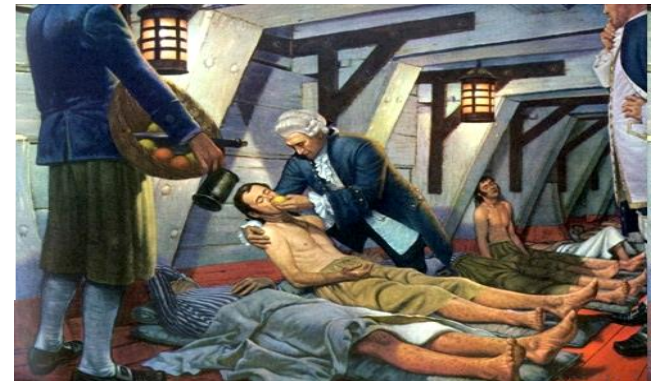
ECRIN, a European organisation that supports multinational clinical trials, is proud to host an annual conference in honour of ICTD.

Celebrated by ECRIN since 2005



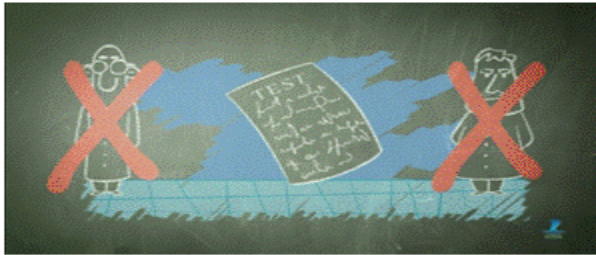
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Communication

« How to explain clinical trials? » (<http://www.ecranproject.eu/>)



Thank you!

Any questions?