

# ECRIN support H2020 and Multinational Clinical trials

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# AGENDA

- **ABOUT ECRIN**
- **INVOLVEMENT OF ECRIN IN H2020**
  - Figures
  - Success Story
  - Difficulties to build up a multinational project
  - New initiative: ECRIN On Board!

# ABOUT ECRIN

- **MISSION** – To support the conduct of independent, multinational trials
  
- **ACTIVITES** – ECRIN's work comprises multiple strands of activity:
  - provides guidance, consulting and operations management for multinational clinical trials on **a not-for-profit basis**. This work is facilitated by European Correspondents
  
  - Openly accessible tools for key trial features (regulations, ethical requirements, outcome measures, and trials unit locations for medicines, medical devices and nutrition, and risk-adapted monitoring strategies)
  
  - Interaction with disease-related investigation networks and other distributed research infrastructures
  
  - ...

# ABOUT ECRIN

- **ORGANISATION** – Connecting research facilities

## **ECRIN – a distributed research infrastructure**

- with **ERIC legal status** since November 29th, 2013 (awarded by the European Commission)

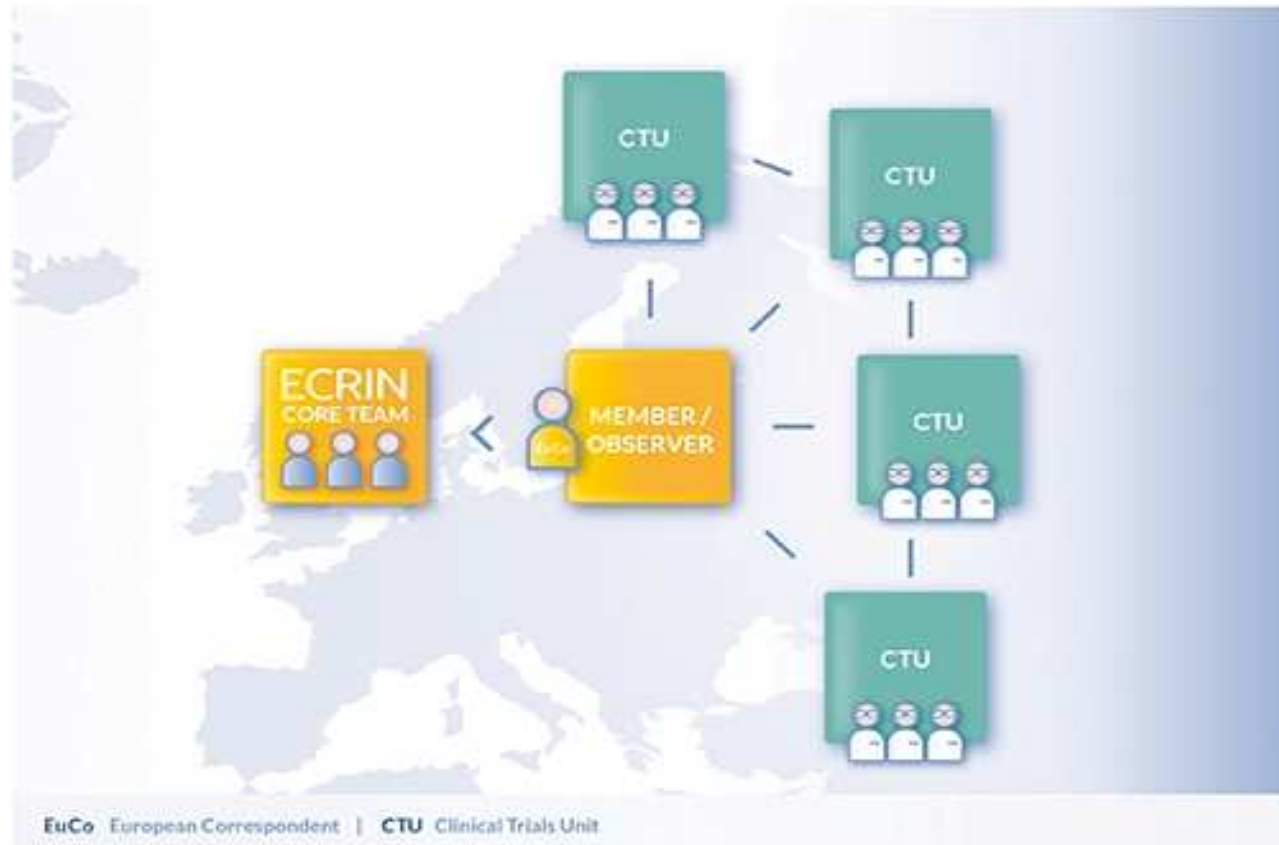


PIC Number

- is a public, not-for-profit research organisation that is **sustainably funded** by the contributions of its Member and Observer Countries.
- that connects research facilities at multiple sites in countries across Europe and provides services for clinical research

# ABOUT ECRIN

- **ORGANISATION** – Connecting research facilities  
ECRIN currently has a membership of 8 countries

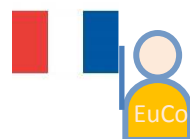


# ABOUT ECRIN

- **European Correspondents** – based in each Country



- link the national clinical research network to the ECRIN core team and other countries.
- their deep knowledge of the national research landscape ensures efficient management of multinational trials.
- Contact Point in the country ... **All the contact details available on our website:** <http://www.ecrin.org/fr>

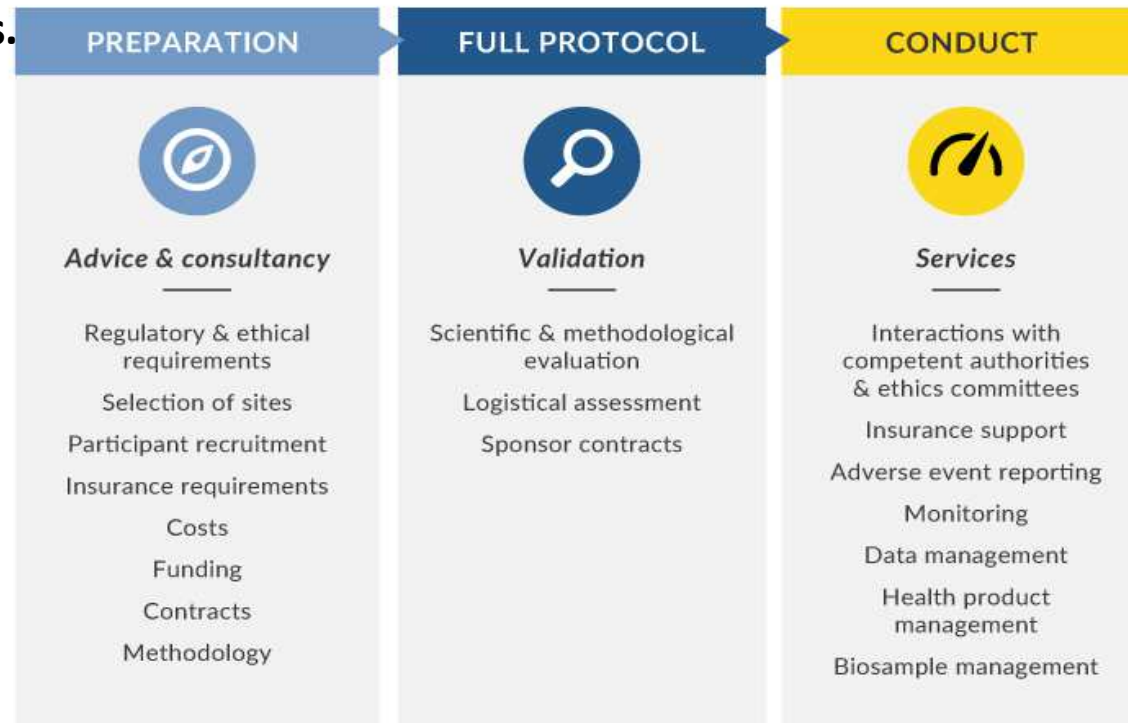


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# ABOUT ECRIN

- **TRIAL MANAGEMENT OPERATIONS** - Supporting your trial across borders

through local ECRIN European Correspondents with the contribution of their national partners, easily **overcoming any obstacles that occur due to working in different country systems.**



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## Calls 2014-2015

### •2014

- 32 proposals sent with ECRIN as a Partner
- **4 projects funded** and 2 on waiting list (finally not funded)

### •2015

- 20 proposals sent with ECRIN as a Partner
- **4 projects funded**



**Involvement in 21 proposals / 3 funded projects (2014-2015):**

- 2 coordinated by French teams: FAIR-PARK II, MEDIT-

- 1 coordinated by Irish team (with a French PI): ADIPOA-2

## Example: FAIR-PARK II

- **PHC-13-2014:** New therapies for chronic non-communicable disease
- **Coordinated by Pr David DEVOS, CHRU Lille**
- **Budget :** 5,998 M€
- **Duration:** 5 years
- **16 partners:** 8 clinical Partners (1/country – Coord National), ECRIN, Patient association, Pharma company, Inserm-Transfert ...
- **1 multinational trial:**
  - PI: Pr Devos (CHRUL– France)
  - 8 countries (FR, CZ, DE, NL, UK, ES, PT, AT)
  - 4 ancillary studies

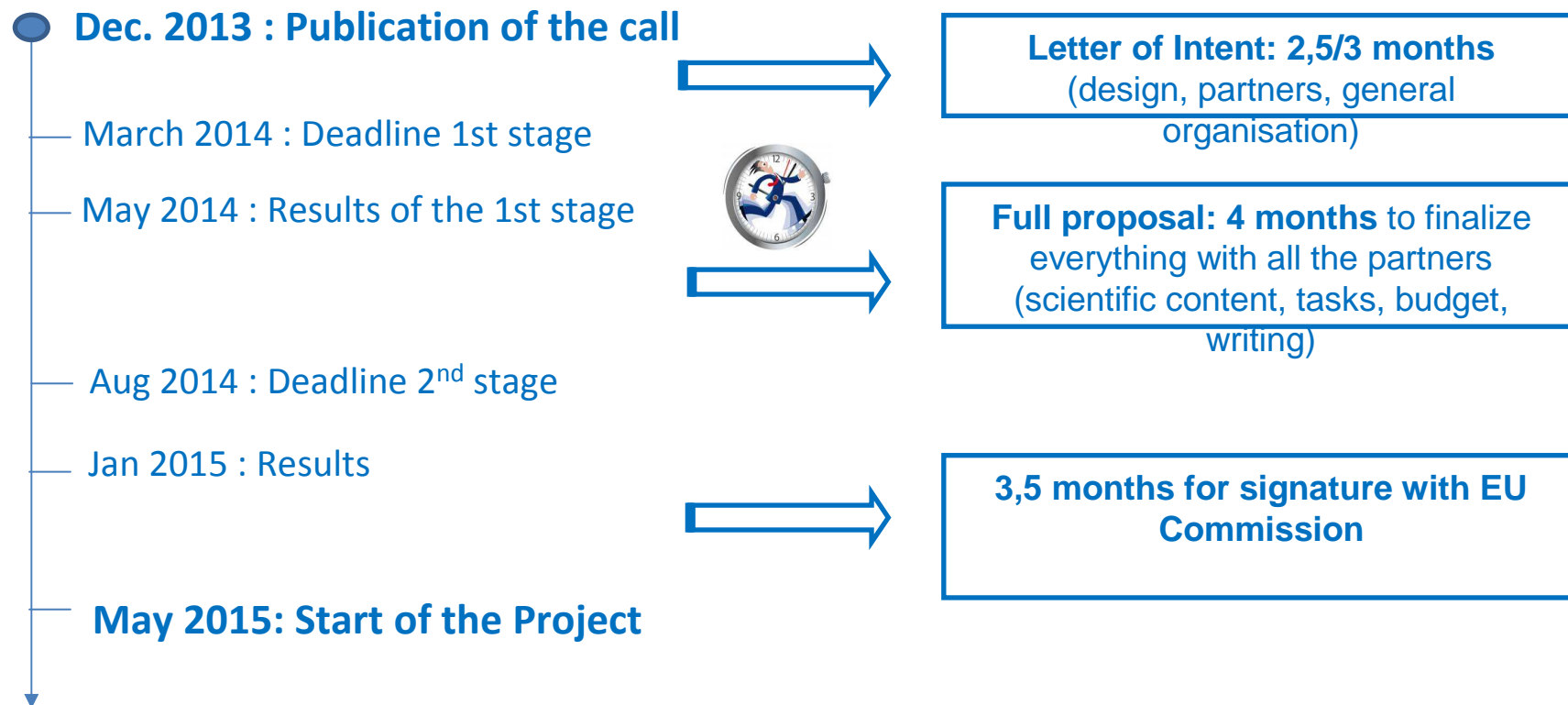


*This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 633190*



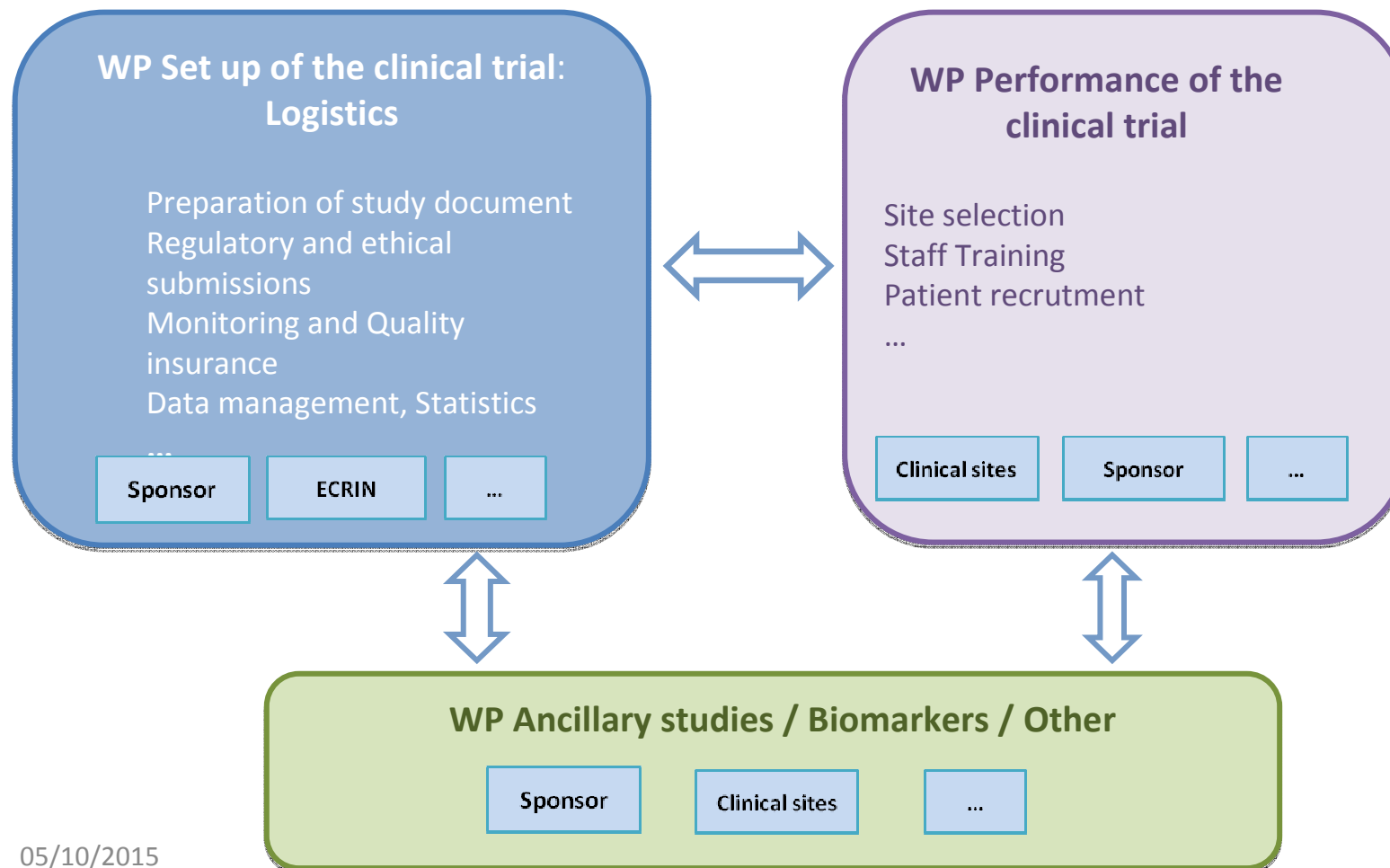


- **TIMELINES:** from the call to the start of the project (2 stages)





- ORGANISATION OF THE TRIAL: 3 Clinical WorkPackages (6 in the project)





- **ORGANISATION OF THE TRIAL** - Strength of this project beyond scientific aspects
  - Coordinator fully supported by his institution (administrative and financial support)
  - **Design of the trial:** open discussion with all the partners
  - **Feasibility of the trial:** country/country
  - WP Performance of the trial: **European Network of clinical sites (+++) → KOL involved in a same project**
  - Involvement of 8 countries with a **good balance of tasks distribution and WP leadership**

# DIFFICULTIES TO BUILD UP A MULTINATIONAL PROJECT

- (NOT EXHAUSTIVE AND BASED ON MY PERSONAL EXPERIENCE!)
  - Lack of support to the Coordinator (**Institution / Sponsor**)
  - Network of European clinical partners: takes time to build up a EU network but **it's absolutely necessary**
  - Clinical partners **not really supportive**
  - Lack of communication between partners and thus clinical trial not well defined
  - The trial is the main aspect of the project **but ethics, health-economy, ...** are also evaluated and part of the project
  - Budget: cost evaluation

# DIFFICULTIES TO BUILD UP A MULTINATIONAL PROJECT

## ▪ NOT TO OVERLOOK

### • TIME

- Preparation of the dossier takes time for the Coordinator and for all the Partners (Delegation ...)
- When you will plan the tasks: don't be too optimistic

### • COMMUNICATION:

- Regular TCs (+++) with European Partners
- Physical meeting (if possible)

### • COLLABORATIVE PROJECT!



- The “ECRIN-On-Board” initiative offers support to multinational, clinical research projects preparing a H2020 application for the SC1 2016 call:
  - early collaborative involvement of ECRIN in the H2020 application process
  - provides free support to project development through:
    - Independent consulting on methodology during protocol development
    - Consulting on logistical and operational aspects of the clinical trial with a focus on the international nature
    - Advice on clinical aspects of the H2020 application: work package architecture, impact
    - (however ECRIN will not draft the application)





# NO WORRIES ...

... YOU WILL OVERCOME THE  
OBSTACLES!

