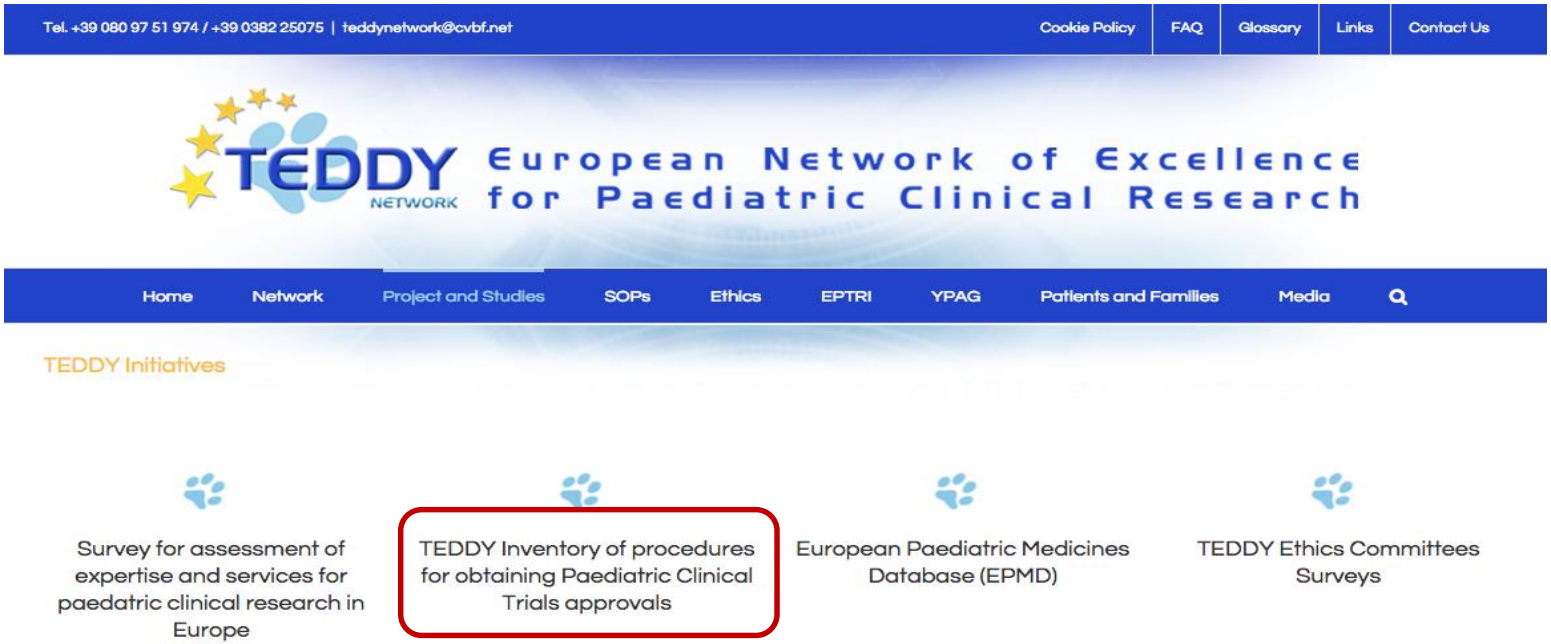
TEDDY Collaborative Group

# *"Regulatory procedures for paediatric clinical trials"*

Cristina Manfredi

# IN 2010

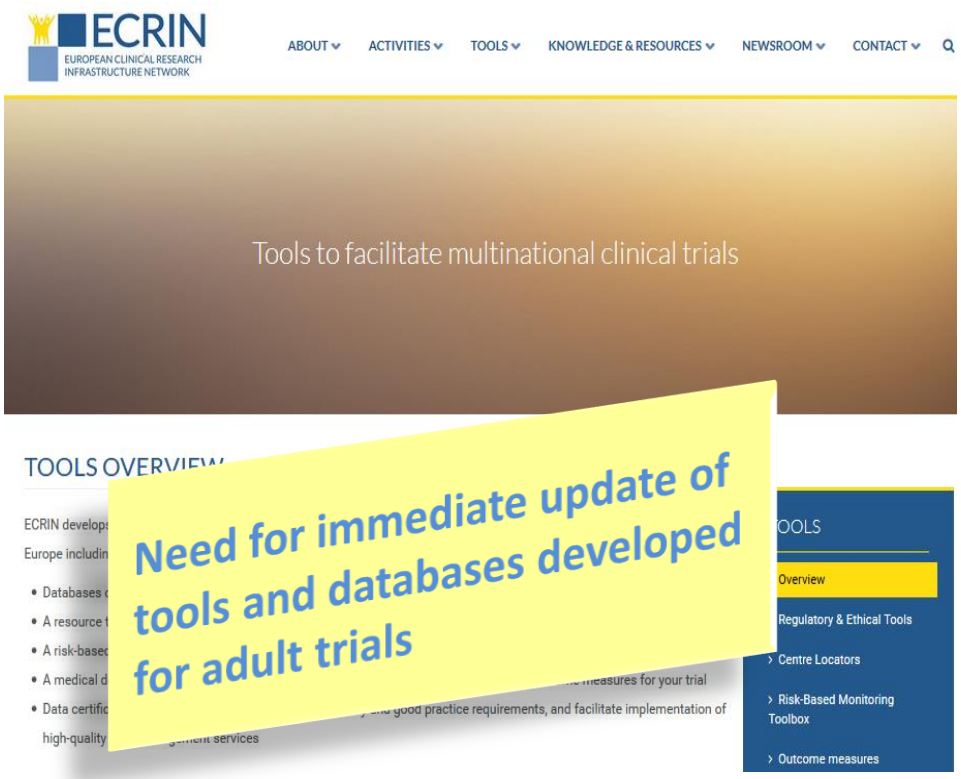



**A database containing information on the relevant local requirements and procedures to carry out the Clinical Trial Application in European and non-European Countries**

- **Laws** governing clinical trials
- Ad hoc **provisions** for **paediatric** trials
- Details on the **ethics committees** / national **competent authority**
- **Type** of application (paper or electronic) / existence of a **national website**
- **Procedures** for compiling the EU CTA form (e.g. from EudraCT or from the national database)
- **Documents** to be submitted

# PedCRIN

# IN 2017




***ACTORS INVOLVED***:

- ECRIN
- Founding partners of the European Paediatric Clinical Trial Research Infrastructure (EPCTRI)

***AIM***:

- to **develop capacity for the management of multinational paediatric clinical trials,** extending ECRIN's business model and upgrading its services

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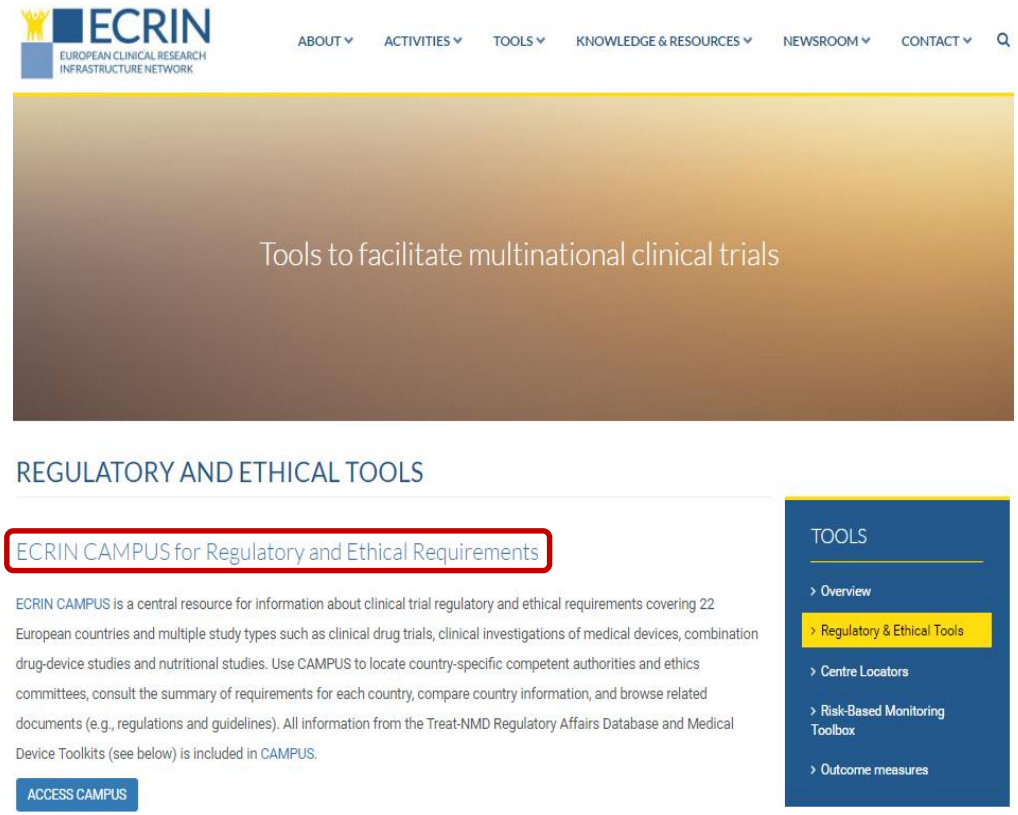
## PAEDIATRIC CLINICAL RESEARCH INFRASTRUCTURE NETWORK

# ECRIN REGULATORY AND ETHICAL TOOL: THE CAMPUS DATABASE




- **Online database**
- **Country-specific information** for studies on:
  - medical devices,
  - medicinal products for human use, and
  - nutrition studies
- **22 European countries**

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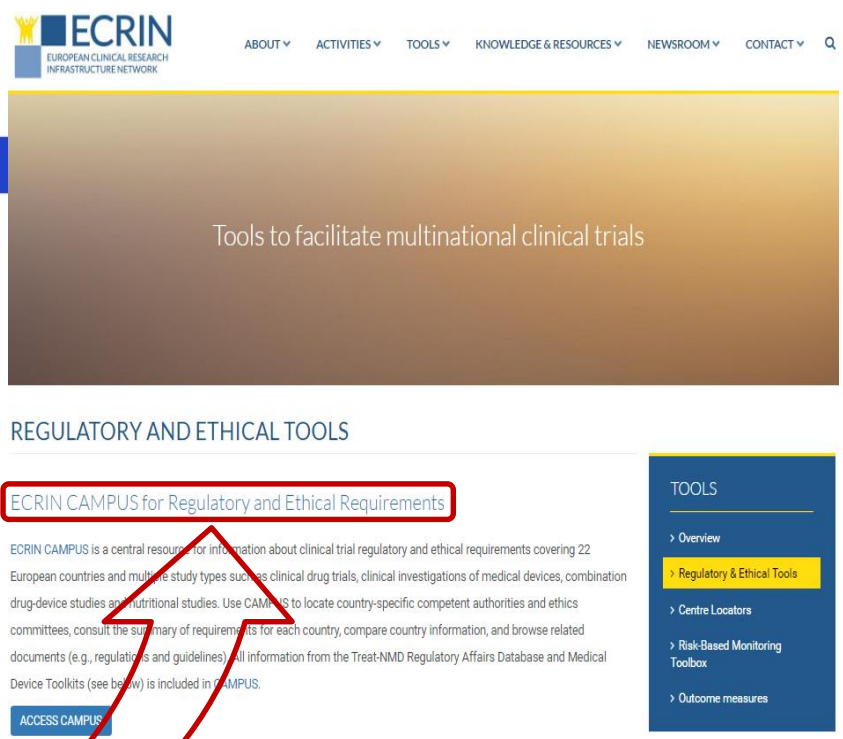
**NO FOCUS ON THE PAEDIATRIC CONTEXT**

# MERGE OF INFORMATION


**New tab: "*Paediatric studies – specific requirements*"**

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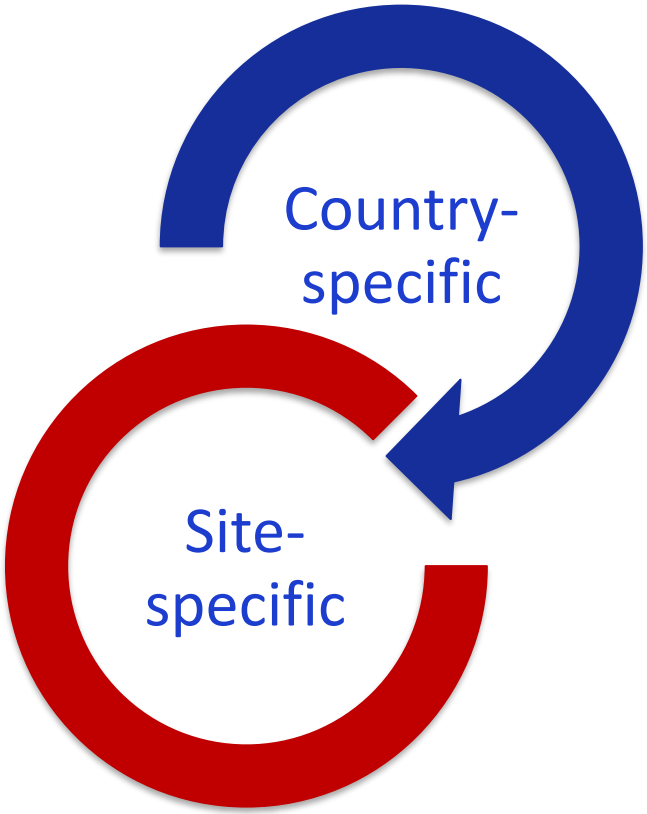
**Ad hoc provisions for paediatric trials**

# SO, WHY THIS COLLABORATIVE GROUP?

- To support TEDDY Partners and other Sponsors in complying with regulatory requirements
- Focus:
  - CTs approval and authorisation
  - Pharmacovigilance activities during clinical trials

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# CTA REQUIREMENTS

- Details on the national competent authority / ethics committee(s)
- Type of application required (e.g., paper or electronic,  national website)
- Procedures for compiling the EU CTA form (e.g., EudraCT / national database)
- Documents to be submitted
- Contracts/agreements with site (e.g., availability of template, procedure to follow)
- …

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# PHARMACOVIGILANCE REQUIREMENTS

- SAEs/SARs
- SUSARs
- DSURs
- Other periodic reports
- Any additional requirements

**WHO** → Sponsor/CRO/delegate
**WHEN** → Timelines
**WHERE** → Mode of submission
**WHAT** → Format, language

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# NEXT STEPS

February 2018

March/April 2018

Set up the CG

Agree on the action plan

Start the data collection!

- information to be collected
- data collection modalities and validation
- timeframes for infos update
- where to store the infos
- how to provide access
- …


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# STEP 1 – SET UP THE CG


People who have expressed interest in participating in the CG activities

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