



TEDDY Collaborative Group
*“Regulatory procedures
for paediatric clinical trials”*

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IN 2010

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European Network of Excellence
for Paediatric Clinical Research

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TEDDY Initiatives



Survey for assessment of
expertise and services for
paediatric clinical research in
Europe



TEDDY Inventory of procedures
for obtaining Paediatric Clinical
Trials approvals



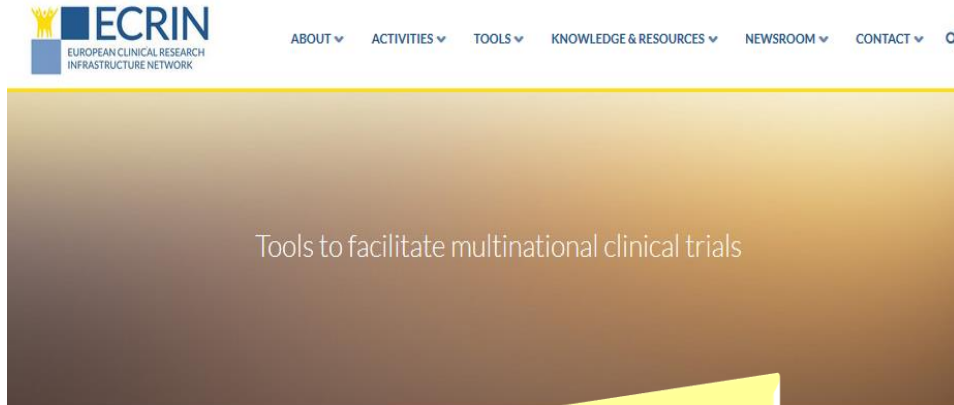
European Paediatric Medicines
Database (EPMD)



TEDDY Ethics Committees
Surveys

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



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

TOOLS OVERVIEW

ECRIN develops...
Europe including...
• Databases...
• A resource...
• A risk-based...
• A medical d...
• Data certifi...
high-quality...
management services

Need for immediate update of tools and databases developed for adult trials

TOOLS

Overview

Regulatory & Ethical Tools

> Centre Locators

> Risk-Based Monitoring Toolbox

> Outcome measures

ECRIN REGULATORY AND ETHICAL TOOL: THE CAMPUS DATABASE



ABOUT ▾ ACTIVITIES ▾ TOOLS ▾ KNOWLEDGE & RESOURCES ▾ NEWSROOM ▾ CONTACT ▾ Q

Tools to facilitate multinational clinical trials

REGULATORY AND ETHICAL TOOLS

ECRIN CAMPUS for Regulatory and Ethical Requirements

ECRIN CAMPUS is a central resource for information about clinical trial regulatory and ethical requirements covering 22 European countries and multiple study types such as clinical drug trials, clinical investigations of medical devices, combination drug-device studies and nutritional studies. Use CAMPUS to locate country-specific competent authorities and ethics committees, consult the summary of requirements for each country, compare country information, and browse related documents (e.g., regulations and guidelines). All information from the Treat-NMD Regulatory Affairs Database and Medical Device Toolkits (see below) is included in CAMPUS.

[ACCESS CAMPUS](#)

TOOLS

> Overview

> **Regulatory & Ethical Tools**

> Centre Locators

> Risk-Based Monitoring
Toolbox

> Outcome measures

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



**NO FOCUS ON THE
PAEDIATRIC CONTEXT**

MERGE OF INFORMATION

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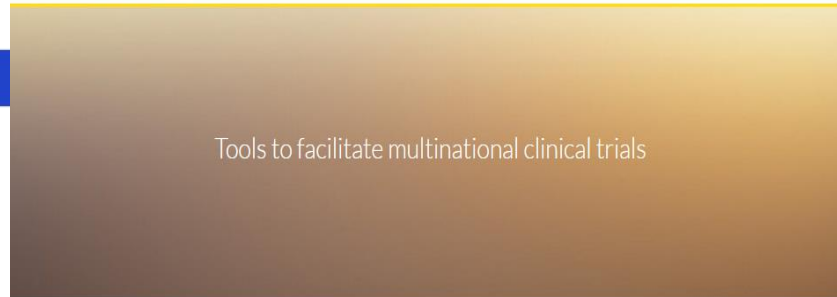


New tab: "Paediatric studies – specific requirements"



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TEDDY Initiatives

Survey for assessment of expertise and services for paediatric clinical research in Europe

TEDDY Inventory of procedures for obtaining Paediatric Clinical Trials approvals

European Paediatric Medicines Database (EPMD)

TEDDY Ethics Committees Surveys

REGULATORY AND ETHICAL TOOLS

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TOOLS

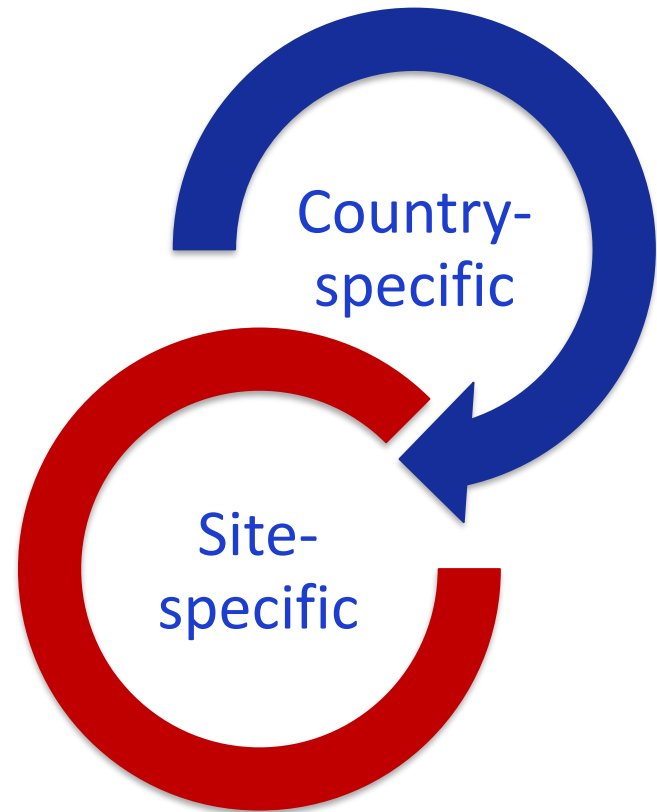
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- > Outcome measures



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



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)

• ...

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



NEXT STEPS

February 2018

Set up the CG

March/April 2018

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
- ...



STEP 1 – SET UP THE CG



People who have expressed interest in participating in the CG activities

