



**General Assembly - Paediatric Clinical Trials
sustainability in the framework of the
Paediatric Regulation**

Maria J. Mellado

**Scientific Meeting and General Assembly
The Paediatric theme in the forthcoming
clinical research scenario.**

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European Network of Excellence for Paediatric Clinical Research

PCT SUSTAINIBILITY. AIMS

- To discuss the **challenging matter** of the sustainability of PCT in the **framework of the Paediatric Regulation**
- To **provide expertise** on this with issue based in the experience conducted within the FP7 funded projects
- How to make a PCT **more feasible.**

1. MULTI-STEPS STRATEGY AND PLANNING TO AVOID PATIENT'S RETENTION

- Expertise of previous Networks/ Centres PCT
- Develop a “Go further Guidelines” as an strategy before the start CT by team directive
- Pre-determinate rapid key step's patient's movements in Trial phases.
- Effective Feed back to the promotor, Ethics committee, and Medical Agencies

HOW TO PROMOTE THE PATIENTS RETENTION AT PCT

- After accepted go on CT: innovative follow up: call phone i
- Adolescents: possible reward (money, tablets...) no too big, avoiding participating only by reward.
- Key point: CT Health-benefit, not only academic answer
- Informed consent: confident person with parents and patients involved on minor care (young, critical situations)

2. 'PATIENTS TAILORED APPROACH' INCLUDING CHILDREN, FAMILIES AND ASSOCIATION

- “To achieve a consolidate patients organization in each area”
Only well established in chronical diseases
- Need set up a “Real Conscientious Association”: Easier when a structure are yet implementing: Oncology, HIV...
- Challenge: Push no expert families , new diagnosis, neonates...
- Create: Training Team for CTP in families-children” in each CT: working before starting; specially in adolescents, acute tasks.
- Meet “face to face” Family Association- Regulatory-Industry

2. 'PATIENTS TAILORED APPROACH' INCLUDING CHILDREN, FAMILIES AND ASSOCIATION

- Initiatives as **KIDS** Barcelona/ **Young people UK**
- Involved children/parents on information consent
- Involved children/parents on CT desing: Prior accepting difficults samples or technicals by achieving a real compromise.

3. UNIQUE PROCEDURE AND A UNIQUE ACTA “PACKAGE OF DOCUMENTS’ FOR ECS AND CAS SUBMISSION

- “ CT Unique Acta- Unique Procedure”: Be the rule in PCT proposal by promotor as a condition for CT implementing
- Regulatory bodies supported this plan from a telematics door
- CT promotor develop the procedure in all areas/centres.
- Information to Ethics Committees about Unique CT Procedure for all researching points: Facilitating approvals

4. TRIAL MANAGEMENT ORGANIZATION: SOPS, DATA- DRUG MANAGEMENT, PHARMACOVIGILANCE, MONITORING AND QUALITY ASSURANCE

- “**Transversal Global Trial Management Organization**” established and consolidate on PCT at in draft period ...OBLIED???
- Similar CRO: Important infra-structure requirements
- Including PCT: daily clinical practice as a profession, not doing CT at free time
- Stakeholders’s accepted before CT starting.
- **TGTMO**: Achieve quickly study implementation and provide safety : homogenization monitoring and help researcher less experienced
- **TGTMO**: dissemination before CT set up
- More guaranties for implementing to the countries/centres.

5. DEDICATED PROJECT MANAGER/ TRIAL LEADER

- “**Transversal Global Trial Management Organization**” team head- Procedure safety establishment
- Setting **new tools Group for feasibility**
- Systematic management **CTP training expert group**
- **Implementing across Europe**: solve differences between countries before CT
- **Critical mass expertise** Group useful at ongoing PCT

6. RISK BASED MONITORING APPROACH TO THE PCT

- Planned Data Base recovering PCT risk on events
- Unique available tools (E.g. “Red cup”): free, intuitive DB for recovering together events no predictable CT.
- Part of systematic training Group on PCT
- Type monitoring are conditioned by type of drugs and pathology
- Children population have to monitoring: weight /height curves, sexual development and neurodevelopment

FINALLY: “Apply lesson learned”

- PENTA-ID, PRINTO, pTBnet, RITIP, pTBred
Networking structure
Methodology
Ethics
- Disseminating and also training also PCT
expertise