Pediatric CIC network: 2000 - 2016

FRANCE

- 2000: 3 centers
- 2005: 8 centers
- 2007: 15 centers - CENGEPS
- 2013: 15 centers - CENGEPS
Aims of Pediatric CICs in France (2000)

- **Develop** paediatric clinical research
- **Interact** with health care professionals and industry
- Participate to improve **trial design** (PK simulation, adapted bayesian design, paediatric tools etc...)
- Participate to **feasability, screening and inclusions, trial conduct**
- Participate to **training** (trial conduct, ethics...)
- Ensure close interactions with industries, specialized networks...
The Paediatric CIC network today

• Ensures the general coordination of high standard research activities and effective communication between sponsors, CIC partners, pediatricians...

• Interacts at an early stage to adapt drug evaluations to children in the different age groups, and optimize drug evaluation: we have experts in pharmacology, methodology, epidemiology, statistics, modelisation in order to optimize trial design ...

• Provide competences required to perform studies in all pediatric area: researchers, paediatricians, reasearch nurses, projet managers, reasearch and lab technicians...

• Harmonie adapted tools – procedures allowing the collaboration between partners

• Train health care professionals to evaluate feasability, ensure trial conduct (screening, inclusions and follow-up)...under GCP, GLP and high ethical standards,

• Coordenate the national organisation of paedatric drug evaluation through interactions with industries
Comment augmenter l’évaluation des médicaments chez l’enfant
CONCILIE DIFFERENT OBJECTIVES

- Scientific Progresses
- Regulatory Requirements
- Costs
- Ethics
Comment augmenter l’évaluation des médicaments chez l’enfant
CONCILE DIFFERENT OBJECTIVES

Experts and Managers within a Network

- Scientific Progresses
- Regulatory Requirements
- Costs
- Ethics
Paediatric Clinical Investigation Center

• 15 Research units in a University hospital Pediatric team - pediatrician, nurses, research and lab technicians - dedicated to research
• Pediatric experts
• Research facilities: beds 24h hospitalisation, research lab, investigations for research ...
Activities: 50% academic, 50% industry trials
75% drug related ...

Pediatricians: experts of different subspecialties

CIC Bordeaux: Pneumology / CRCM (Cystic fibrosis EU network)
CIC Lille: Gastro-entérology
CIC RDébré / Rennes / Tours: Néonatology (Neonatology network)
CIC Marseille: Oncology - Néphrology...
CIC Hopital Robert Debré
## Industry studies

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Both the number of pediatric trials and « early trials (Phases 1 and 2) increases
Industry studies in the different CIC centers

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Funds to support structures are not available / Industry funds are dedicated to sponsor specific drug trials
Network activities

• Ethics – in collaboration with CIC – Bordeaux
• Training: exchanges between centers (Rouen) and within hospital (Neonatology)

• Collaboration with specialised networks / Experts
  Neonatology (FS Neonatology)
  Neurology (RIPPS)
  Nephrology (FS Pediatric Nephrology)
  EU projects: TINN, GRIP, Neovanc
  EmprEMA
PediatriC CIC Network (n=15)
Governning council

- CIC Lyon
- CIC Lille
- CIC Bordeaux
- CIC Robert Debré
- CICR Debré Rennes

- Neurology RIPPS
- Urgences
- CRCM EU CF
- Neonatology
- Nephrology

IMI project...

EU projects
- TINN (3)
- GRIP
- NeoVan

All EU pediatric networks / ECRIN
Points for discussion

A network has to conduct both industry and academic trials:

- Industry trials focus on one drug...drug trials
- We need also an evaluation of therapeutic strategies...

Performances of « academics » are key issues always questioned:

- Optimisation of all delays ... (answer feasibility, optimize screening, increase quality ..)

Interactions with industries can also be improved:
- Design (and reference arm...), delay between first contact (through CROs..), feasibility and real start, quality of interactions with industry « partners » ...., real evaluation of costs (not only on patients’ costs...)

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Why a paediatric French « STRUCTURAL » network?

There are many major scientific, practical and ethical issues in relation to studying medicines in children:

- limited number of patients with comparable diseases in each site.
- need for adapted formulations
- need for suitable methodological approaches for clinical trials
- limited number of trained investigators with expertise in neonatal clinical trials (inadequate critical mass of investigators in any single European country)
- centralisation of information
- set up transversal procedures and avoid duplication of tasks
- need to optimize recruitment
- major ethical issues
- Interaction with “SPECIALIZED networks....
- Interactions with regulators
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CIC Pédiatrique – Hopital Robert Debré