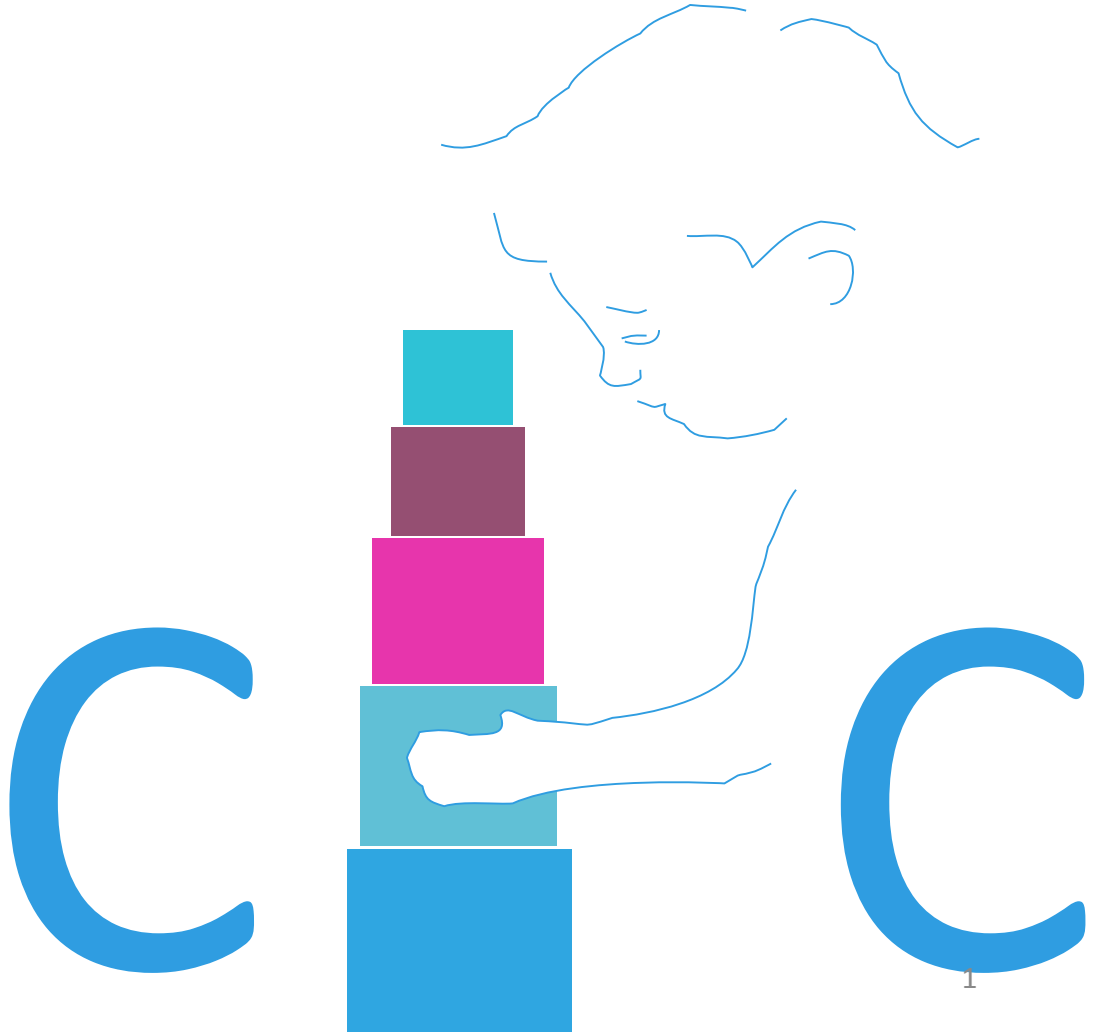
Pediatric CIC network : 2000 - 2016

FRANCE

2000 : 3 centers
2005 : 8 centers
2007 : 15 centers - CENGEPS
2013 : 15 centers - ~~CENGEPS~~
….



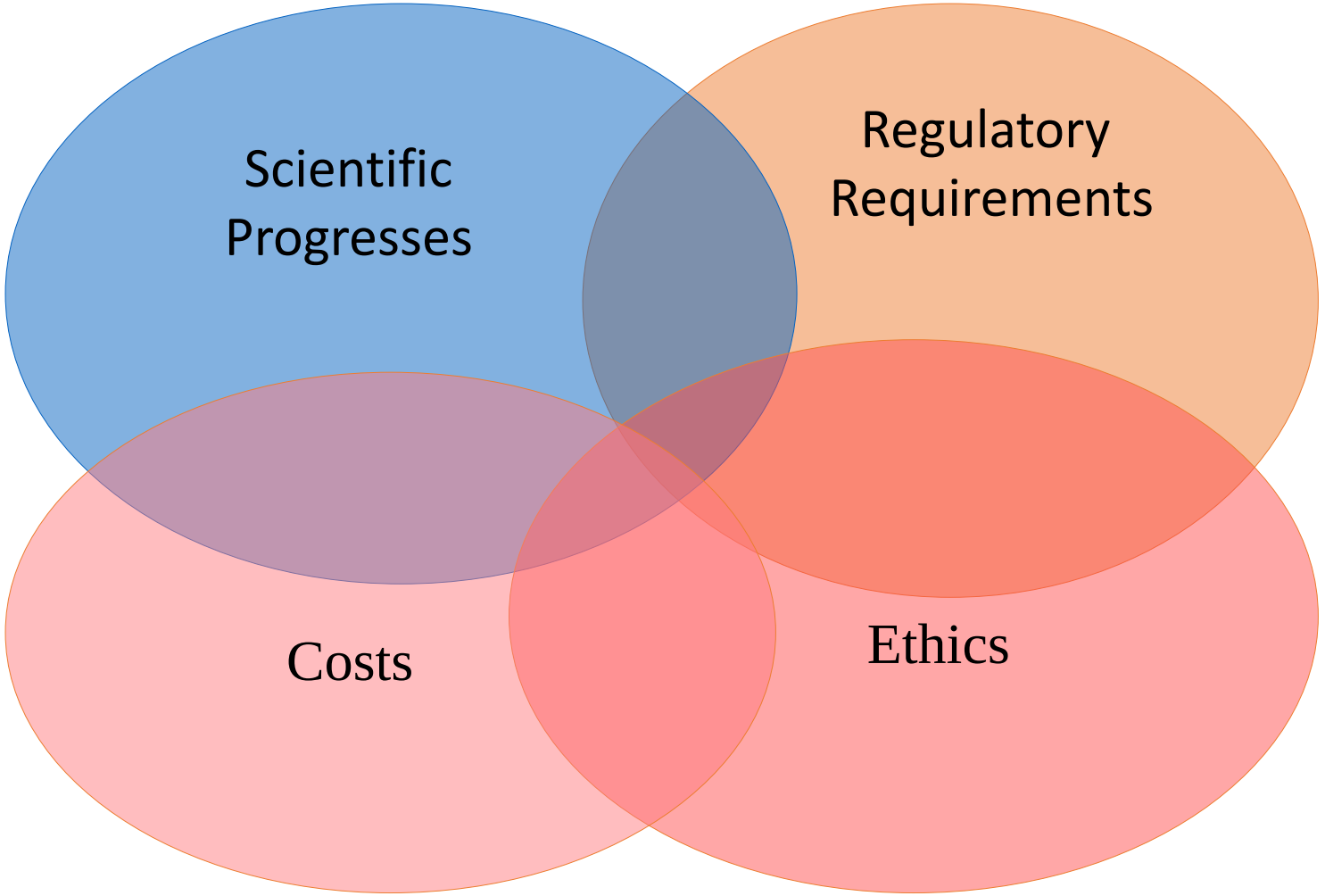
Aims of Pediatric CICs in France (2000)

- **Develop** paediatric clinical research
- **Interact** with health care professionals and industry
- Participate to improve **trial design** (PK similation, adapted bayesian design, paediatric tools etc…)
- Participate to **feasabiliy, 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, reaserch 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,
- **Coordonate the national organisation of paedatric drug evaluation through interactions with industries**

Comment augmenter l'évaluation des médicaments chez l'enfant
CONCILE DIFFERENT OBJECTIVES



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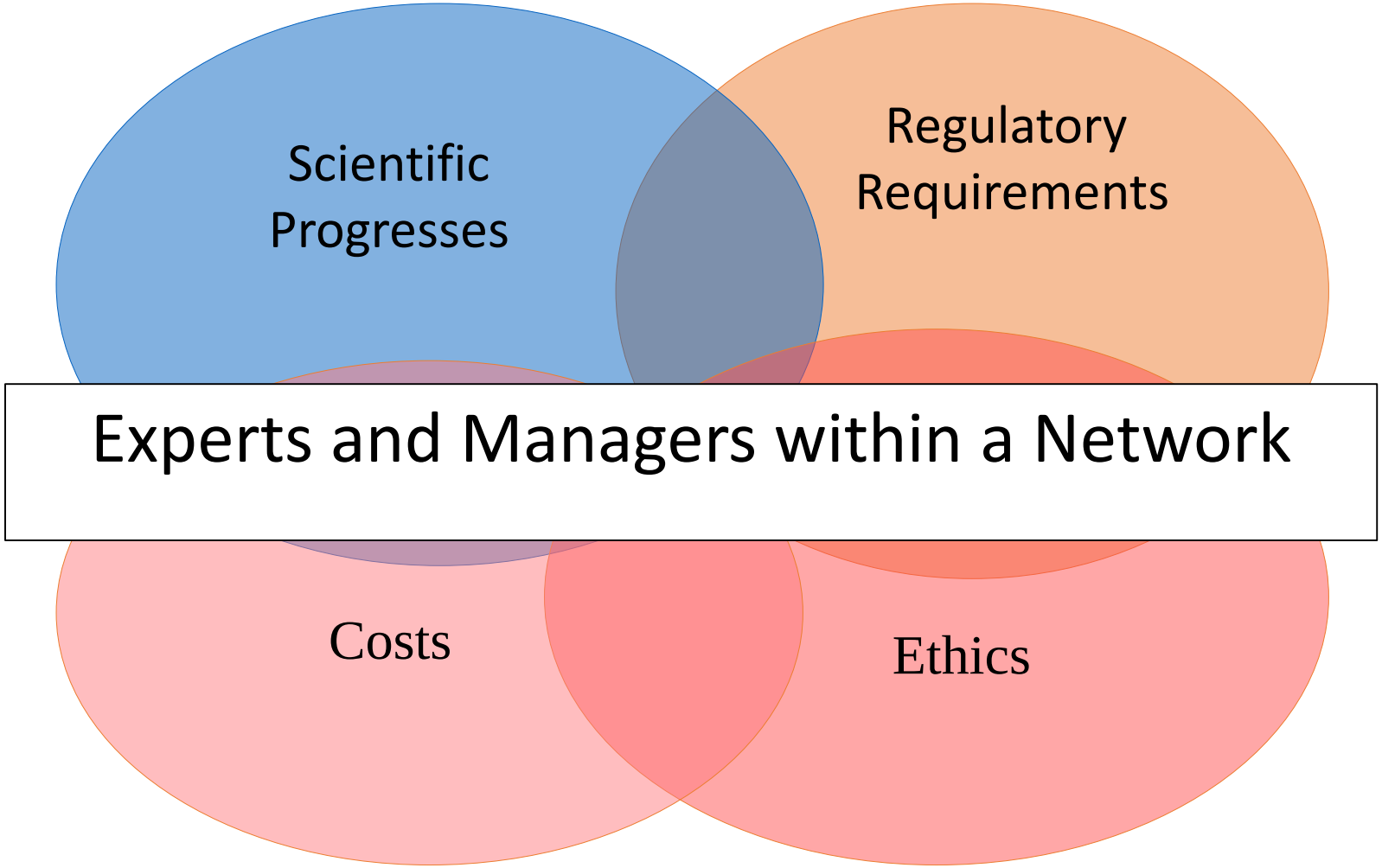


Paediatric Clinical Investigation Center

- 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 RDebré / Rennes / Tours : Néonatology (Neonatology network)

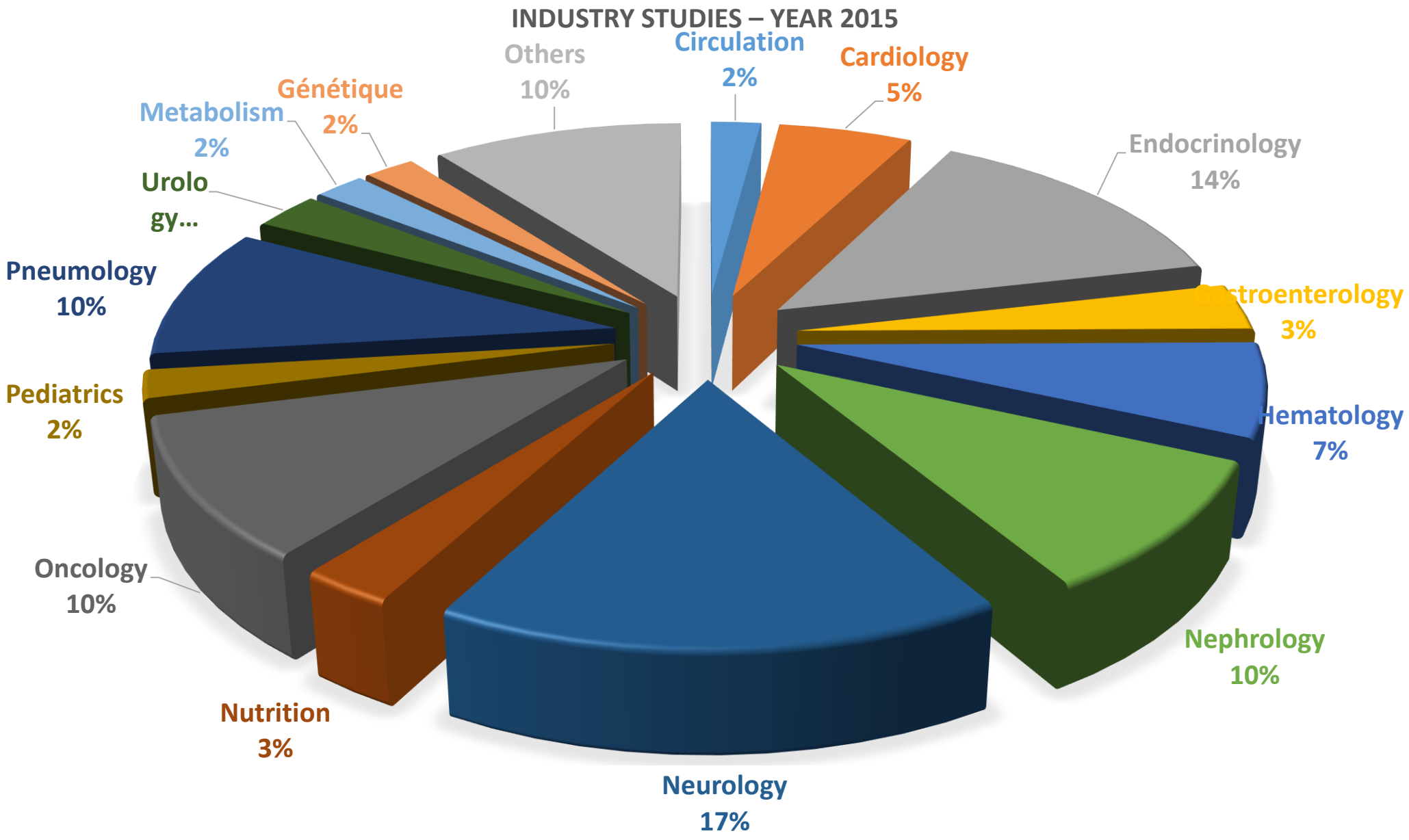
CIC Marseille : Oncology - Néphrology…

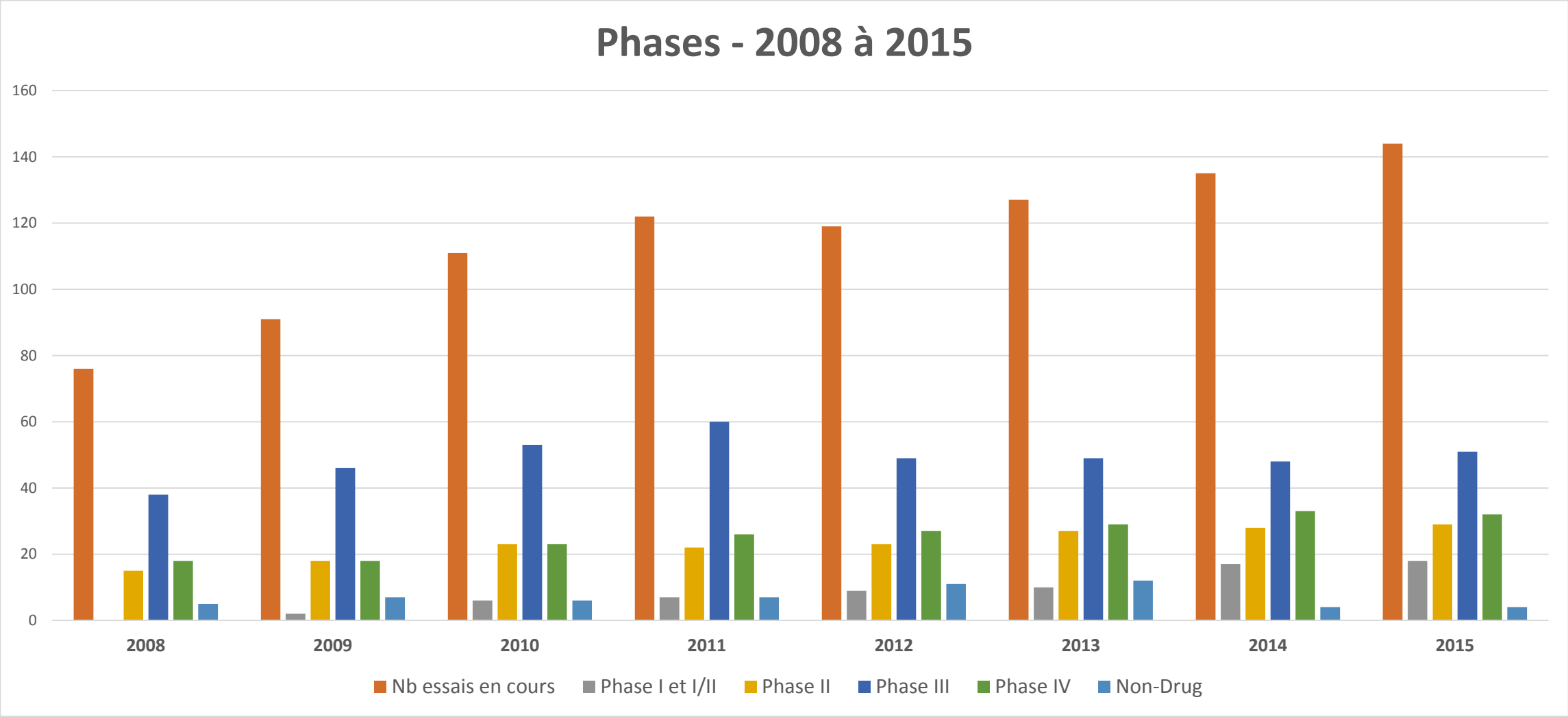
CIC Hopital Robert Debré

IMG_0290

Industry studies

Drug trials	2008	2009	2010	2011	2012	2013	2014	2015
New studies	32	29	35	39	31	36	36	41
Active studies	**76**	**91**	**111**	**122**	**119**	**127**	**135**	**144**
Studies closed	12	18	27	30	23	29	30	21


INDUSTRY STUDIES – YEAR 2015
Others 10%
Circulation 2%
Cardiology 5%
Endocrinology 14%
Génétique 2%
Metabolism 2%
Urolo gy…
Pneumology 10%
troenterology 3%
Pediatrics 2%
Hematology 7%
Oncology 10%
Nephrology 10%
Nutrition 3%
Neurology 17%



Both the number of pediatric trials and« early trials (Phases 1 and 2) increases

Industry studies in the different CIC centers

Centres	2011	2012	2013	2014	2015
1*	**28**	**34**	**37**	**49**	**41**
2	/	/	2	2	5
3	9	6	4	5	3
4	2	2	1	0	2
5	5	6	9	11	7
6*	**20**	**22**	**26**	**34**	**31**
7*	**29**	**25**	**28**	**29**	**24**
8*	**12**	**14**	**17**	**19**	**20**
9	3	6	9	11	14
10	9	10	10	9	6
11	0	0	0	1	1
12*	**20**	**22**	**26**	**26**	**41**
13	12	9	9	13	9
14*	**32**	**31**	**33**	**42**	**54**
15	5	6	6	8	7

….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

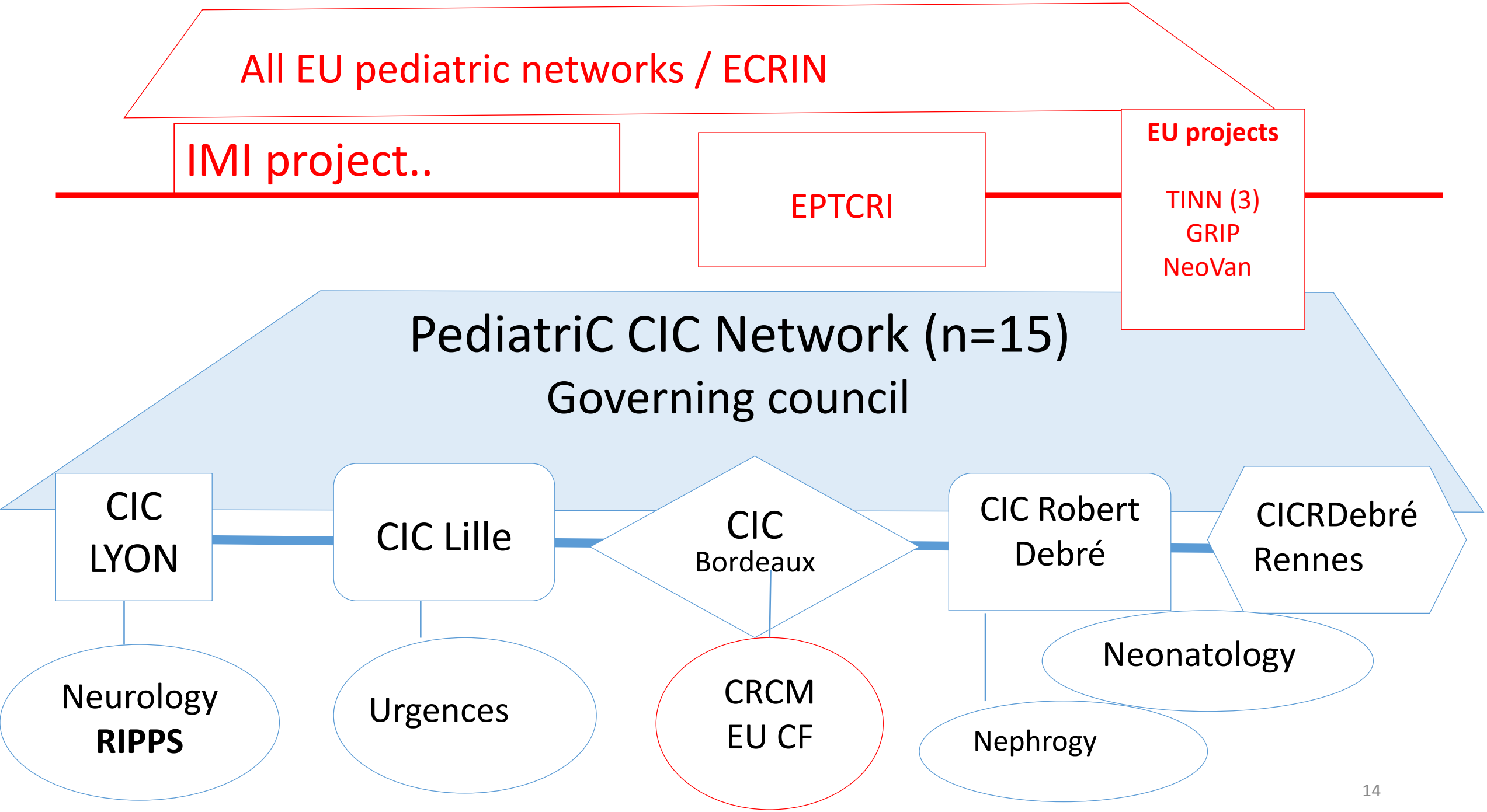
  Neonatalogy (FS Neonatology)

  Neurology (RIPPS)

  Nephrology (FS Pediatric Nephrology)

  EU projects : TINN, **GRIP**, Neovanc

  EmprEMA


All EU pediatric networks / ECRIN
IMI project..
EPTCRI
EU projects
TINN (3)
GRIP
NeoVan
PediatriC CIC Network (n=15)
Governing council
CIC LYON
CIC Lille
CIC Bordeaux
CIC Robert Debré
CICRDebré Rennes
Neurology RIPPS
Urgences
CRCM EU CF
Neonatology
Nephrogy

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 questionned :

Optimisation of all delays … (answer feasability , optimize screening, increase quality ..)

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

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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Registries

+++ Mobile research teams +++

CIC Pédiatrique – Hopital Robert Debré