

# What are the factors influencing parental apprehension about consenting children to participate in pediatric observational studies? A survey conducted in France with In fine PHARMA®, a pharmacist network

Sohéla EL KEBIR<sup>1</sup>, Yann BOURHIS<sup>1</sup>, Rahaf HUSSEIN<sup>2</sup> R., Remi GAUCHOUX<sup>1</sup>  
<sup>1</sup>REGISTRAT-MAPI, Lyon, France and <sup>2</sup>Université de Bourgogne, Dijon, France

## Background

- Conducting pediatric studies is complex and the most significant barrier is infant enrollment by parental consent
- This obstacle is currently found both for healthy and sick infants
- The reason for the parents' refusal to consent is not obvious and may be due to multiple factors

## Objectives

The objective of this survey was to identify the factors influencing parents' decisions to refuse infant participation in pediatric studies

## Methods

- This observational, transversal study was carried out by French pharmacists randomly selected among the 2,090 pharmacies of the In fine PHARMA® network, representative of French pharmacies in terms of geographic location and sales
- Parents presenting to participating pharmacies were eligible
- Data was collected through questionnaires fulfilled by participating parents

## Results

- 21 pharmacists agreed to participate and enrolled 105 participating parents. Among them, 78 (74%) filled out a questionnaire
- Participating families had an average of 2.3 children, 81% were living in an urban environment, and 51% of the infants were males
- Most of the parents (97%) had never enrolled their children in a study
- Main deterrents to parental consent were: they viewed pediatric studies as risky, they did not want their infant to be treated as an experimental animal, their infant was not ill, the information provided by the physician was too confusing and/or complicated
- Parents may have been willing to have their child participate in a study only if the study was evaluating a new drug, their child's participation would further medical research, their child suffered from a severe illness, and they had great confidence in their Health Care Provider (HCP)
- 60% of the parents expressed their willingness to have further information

Table 1. Infants' characteristics (N=78)

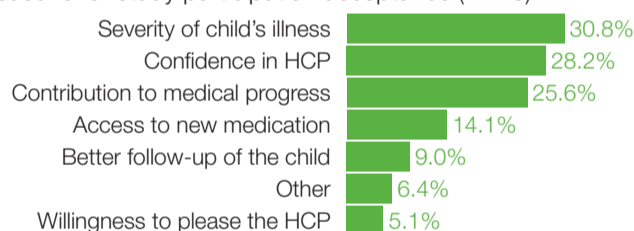
	N	%
<b>Age (years)</b>		
Mean: 8.3		
< 2	16	20.5
2–5	14	18.0
6–9	15	19.2
10–14	18	23.1
15–18	15	19.2
<b>Gender</b>		
Male	40	51.3
Female	38	48.7
<b>Number of children with chronic disease</b>		
	5	6.4

Table 2. Parents' characteristics (N=78)

	N	%
<b>Completion of the questionnaire</b>		
Father	24	30.8
Mother	54	69.2
<b>Level of education</b>		
Primary school	2	2.5
High school	30	38.5
College	46	59.0
<b>Living environment</b>		
Rural	15	19.2
Urban	63	80.8
<b>Experience in study participation</b>		
Yes	2	2.6
No	76	97.4

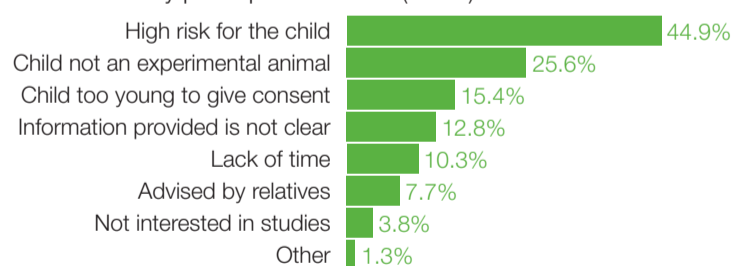
Graph 1.

Reasons for study participation acceptance (N=78)



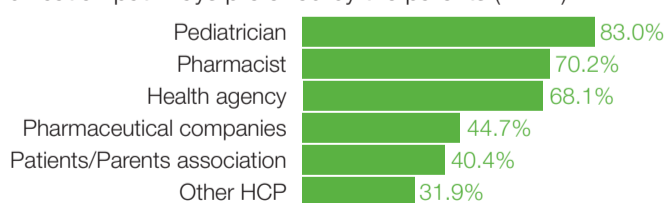
Graph 2.

Reasons for study participation refusal (N=78)



Graph 3.

Communication pathways preferred by the parents (N=47)



## Conclusions

The results of this survey show that the factors negatively influencing parents' decisions to consent were the perceived risk presented by the studies, the lack of interest to medical research if their child was not ill, and the lack of information about studies.