

# Clinical trials – experience of the pediatric IBD Porto group

# Structure of the pediatric IBD Porto group

**ESPGHAN** – European Society of Pediatric Gastroenterology Hepatology and Nutrition



Gastrointestinal diseases Committee



IBD Interest Group



IBD Porto Working Group

# Clinical Trials

## **GROWTH study**

Growth Relapse and Outcomes With  
THerapy

A multi-center prospective European  
study on new onset disease

# Participants 13(16) centers

- Israel 4
- Italy 3
- Netherlands
- Poland 2
- Finland
- Belgium
- Denmark
- Hungary
- Germany
- Portugal

# Goals

- Primary: Factors predicting disease relapse at disease onset
- Secondary:
  - Factors (aside from treatment) predicting adverse outcomes
  - Factors predicting growth retardation
  - The effect of initial treatment on disease outcomes
  - Antiglycan antibodies and disease presentation

# Flow Chart through year 1

■ Time Therapy	PCDA\CRP	Tanner/BA	Stool		Serologies	Ht\Wt
■ 0	X	X	X	X	X	X
■ 8 w	X		X	X	X	X
■ 12 w	X		X	X	X	X
■ 26 w	X		X		X	X
■ 52 w	X	X		X	X	X
■ 78 w	X				X	X
■ Relapse	X				X	X
■ 8 weeks	X				X	X

# Update April 2010

- 111 patients enrolled
- Investigators
  - Haifa-20
  - Tel Aviv 30
  - Jerusalem-5
  - Budapest -13
  - Krakow-11
  - Warsaw-7
  - Rotterdam-6
  - Antwerp -6
  - Italy (Florence+Naples) -6
  - Porto-5
  - Spain
  - Germany

Ongoing study

# Clinical Trials

Prospective , multicenter, randomized clinical trial  
National (French –speaking Society of Pediatric  
Gastroenterology, GFHGNP)  
11 pediatric IBD sites in France, 1 in Belgium

« Efficacy of maintenance infliximab therapy for pediatric  
CD»

randomized « scheduled every two months »  
versus « on demand »



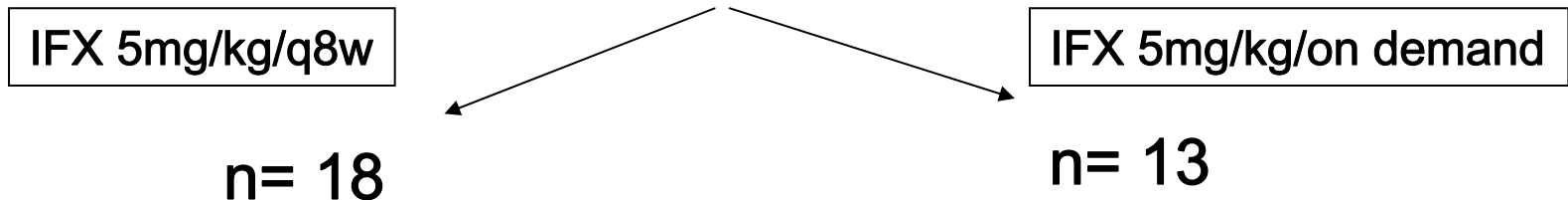
# Efficacy of maintenance therapy GFHGNP prospective study

Inclusion n= 40

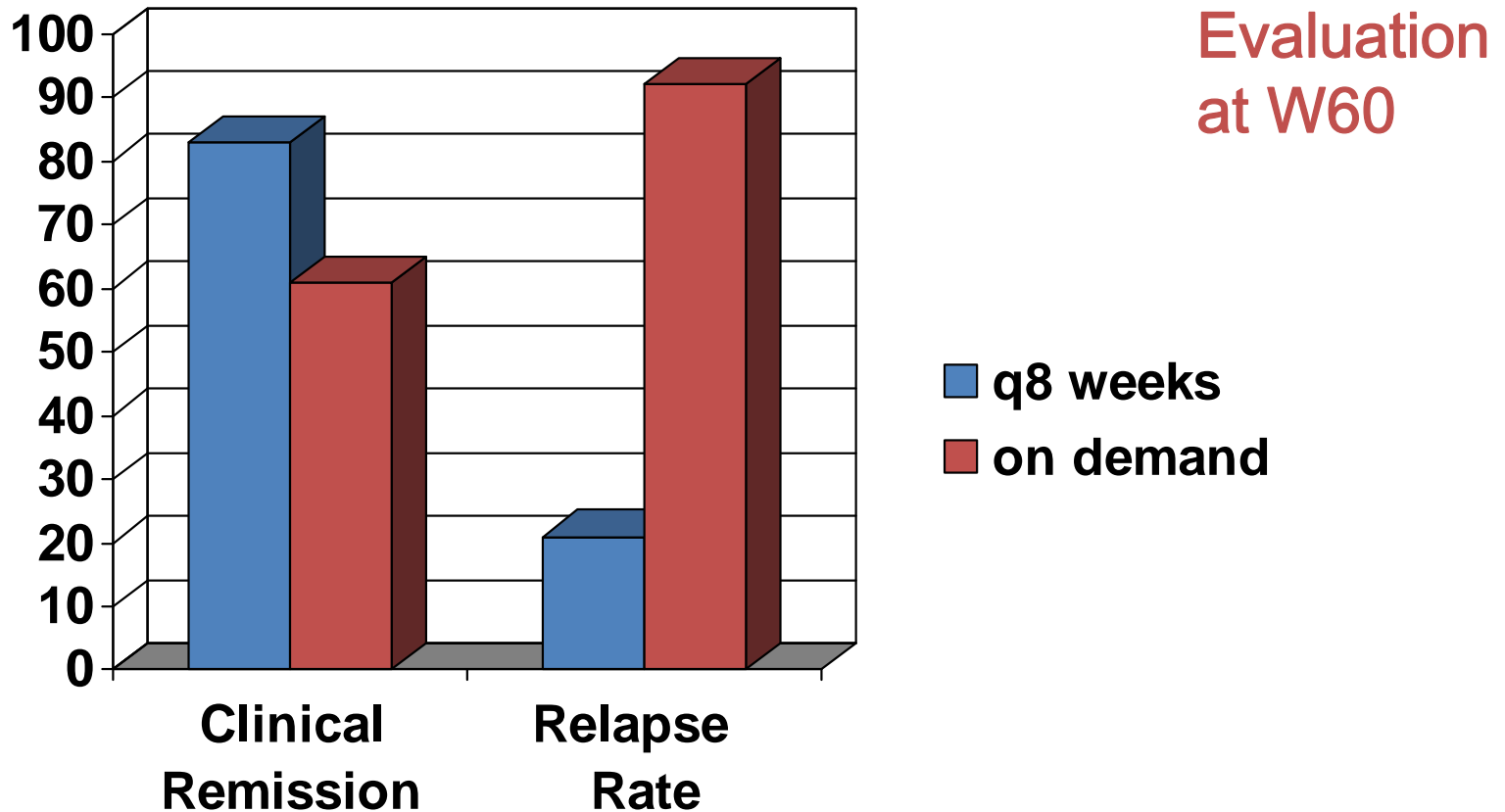
Induction therapy W0, W2, W6  
(IFX 5mg/kg)

Responders n=34 (85%)

Randomisation n=34

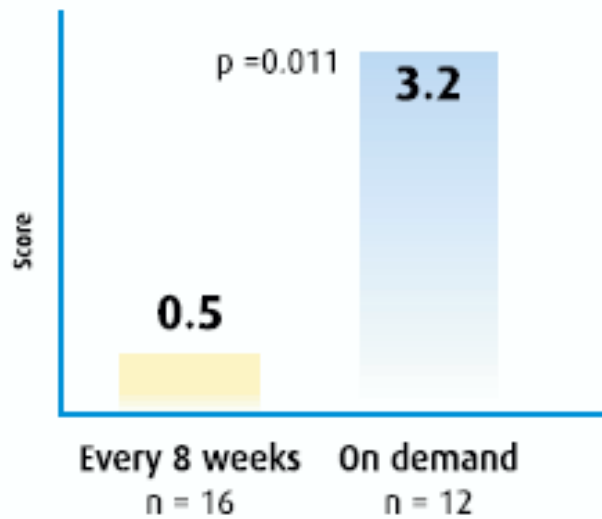


# Efficacy of maintenance therapy

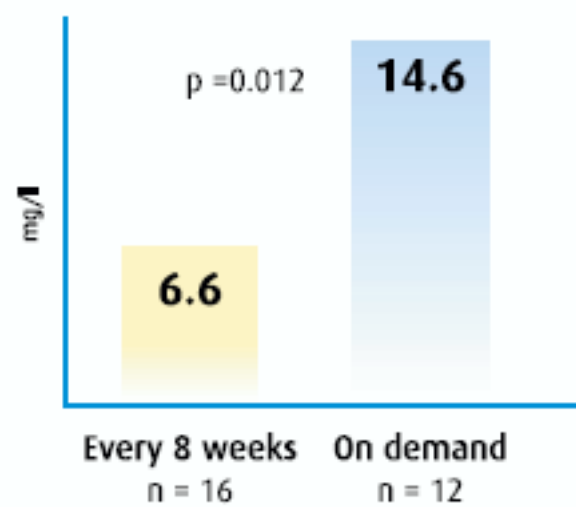


# Evaluation at W60

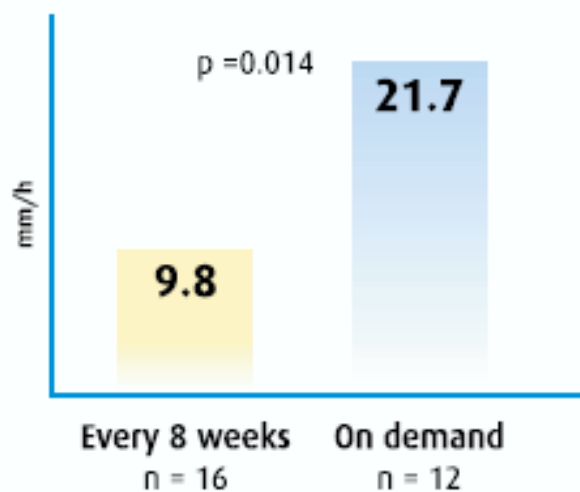
## Harvey Bradshaw median



## CRP median



## ESR median



# Clinical Trials

In France

GETAID – adult IBD



GETAID pédiatrique – pediatric IBD

**Many clinical questions ...**



**major need for clinical  
Trials in the field of  
pediatric IBD**

**next steps...**