

# Barriers to Pediatric Clinical Trials: Patient/Caregiver Perspective

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# Foundation's Research on Clinical Trial Participation



## Goals:

- Understand attitudes, knowledge, and beliefs regarding participation in an IBD clinical trial
- Create resources to increase awareness, education, and support of clinical trials
- Support enrollment and retention in IBD clinical trials



## Methodology:

- Conduct focus groups with:
  - Adult patients
  - Pediatric patients
  - Caregivers of pediatric patients
  - Providers
- Conjoint analysis to survey:
  - Adult patients
  - Caregivers of pediatric patients
  - To understand trade-offs

## Focus Group Timeline

Spring 2016 –  
36 adult  
patients

- Atlanta, GA
- Los Angeles, CA
- Washington D.C.
- New York, NY

Fall 2016 –  
23 adult  
patients

- Boise, Idaho
- Miami, Florida
- Greenwich,  
Connecticut

Fall 2017 –  
11 adult GIs

- Portland, Oregon
- Cleveland, Ohio

Winter 2018 –  
22 caregivers  
and pediatric  
patients (11 each)

- Ann Arbor,  
Michigan
- Dallas, Texas

# Focus Group Findings (Adult patients)

## Adult attitudes towards clinical trials

Acknowledge promising nature of trials in finding new treatments

Desire for more clinical trials to focus on cure vs. new treatment options only

Still hesitant to enroll, assume last resort only

## Adult motivations for participation

Advance the science

Achieve remission more quickly

Access free medication

# Focus Group Findings (Pediatric/Caregivers)

## Pediatric attitudes towards clinical trials

Altruistic towards participation

Neutral descriptors; “new medicine,” “test,” “help others”

Motivated to advance science

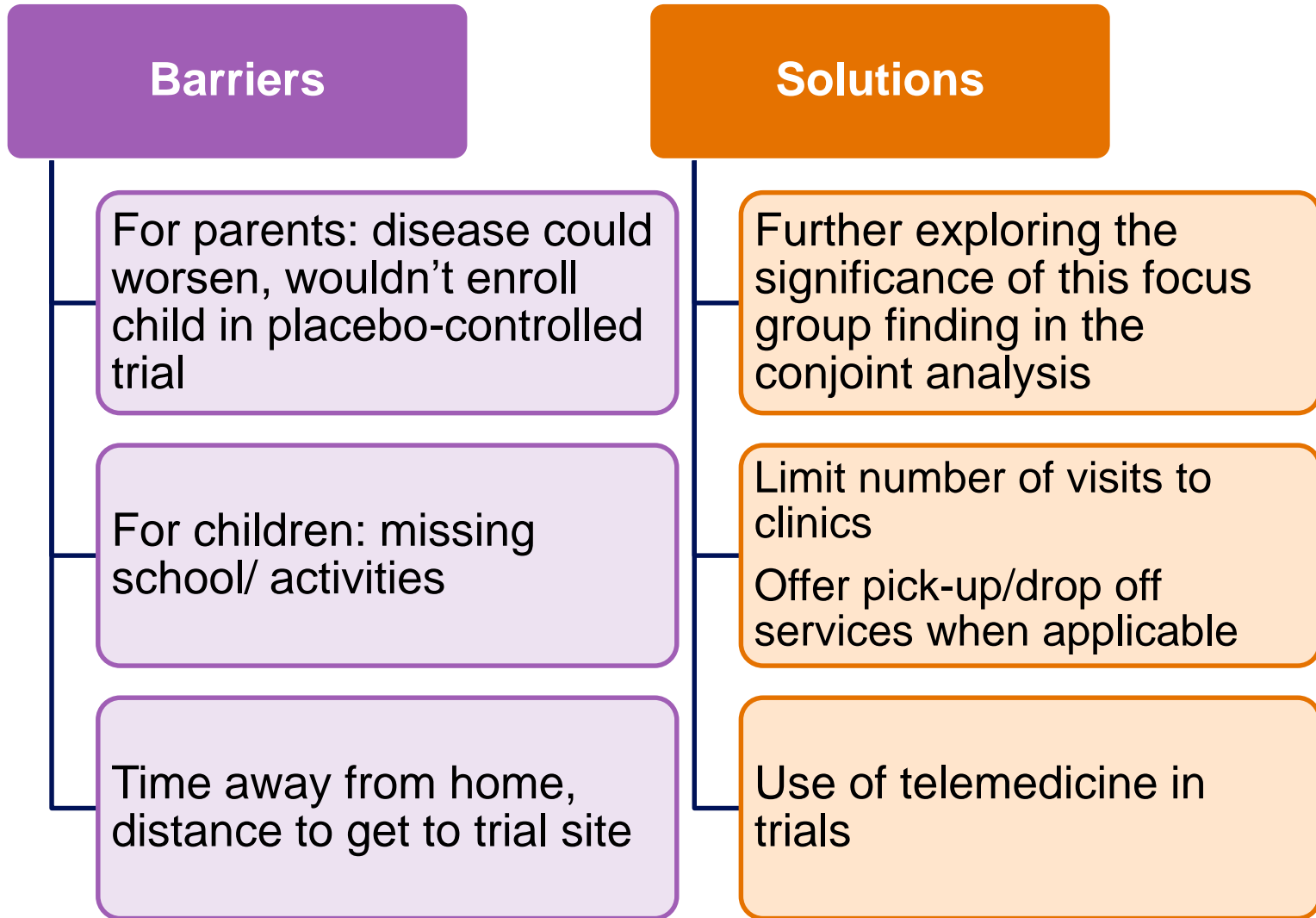
## Caregiver perceptions of clinical trials

Fearful and uncertain towards child’s participation

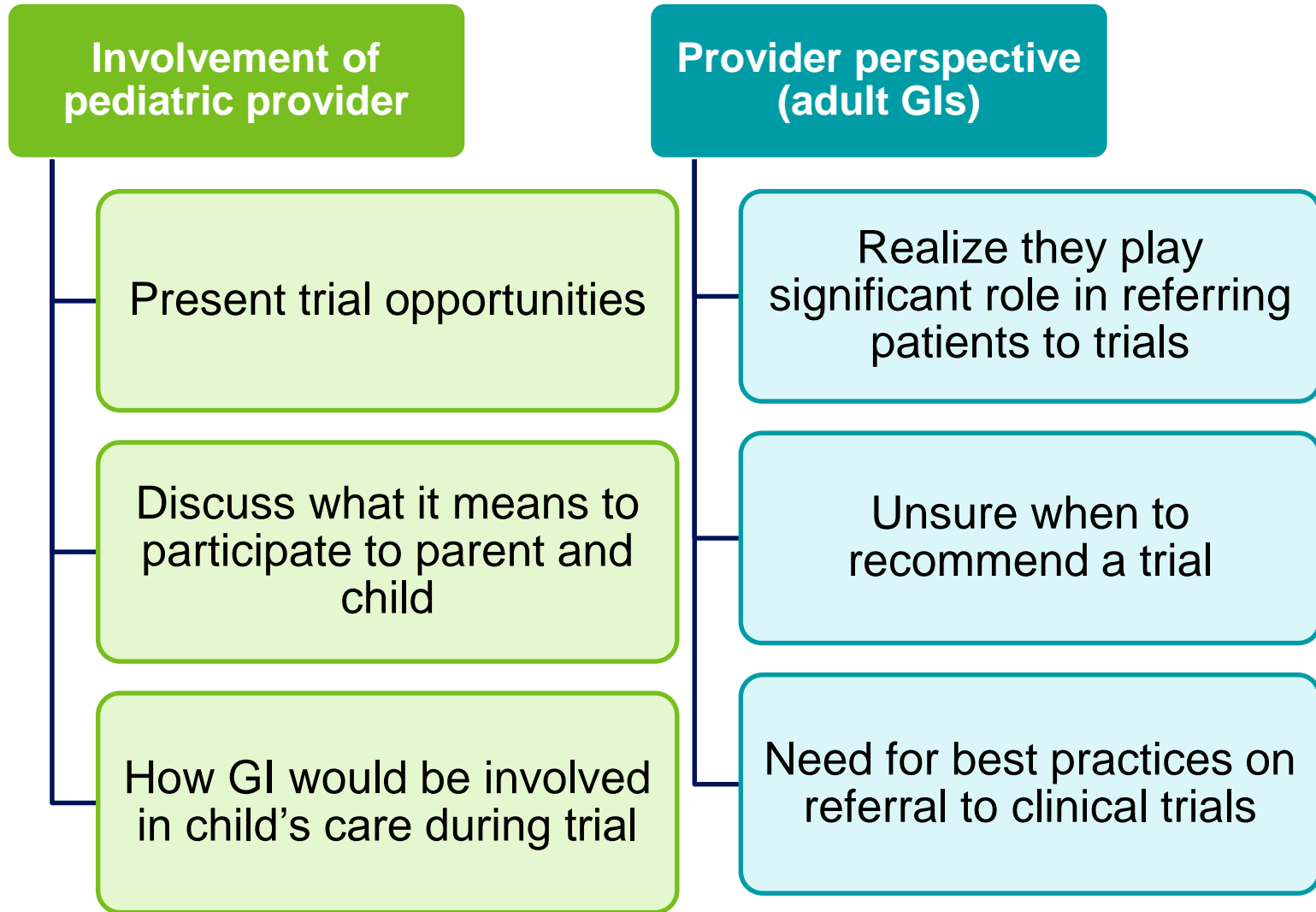
Negative descriptors; “scary,” “uncertainty,” “too risky,” “guinea pig,” “fear”

Struggle with decision to enroll their child

# Focus Group Findings



# Focus Group Findings (Provider Support in Participation)



# Focus Group Findings

*Key takeaways:*

## Patient/ Caregiver Motivation

- Personal benefit
- Altruism

## No GI Support

- Clinical trials not mentioned
- Not integrated in routine care

## GI Referral

- Would provide reassurance
- More comfortable participating





## Conjoint Analysis: Patient Trade-offs

- Verify findings of the focus groups utilizing choice-based conjoint surveys
  - Partnering with RTI International
- Determine:
  - Which attributes of clinical trials patients value most
  - Predict the probability of enrollment in proposed clinical trials
- Focus on adult patients and caregivers of pediatric patients

# Conjoint Analysis: Patient Trade-offs

*Attributes being examined:*



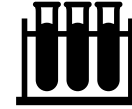
## Doctor Involvement

- Conducting trial
- Not conducting, but request reports from trial
- Not involved at all



## Placebo Rate

- 0, 2, 3, 5 out of 10 participants will receive placebo



## Number of colonoscopies or flex sigs

- 2, 3, 4 procedures/year



## Time spent per month during study

- 3, 6, 12, 24 hours/month



## Open label extension

- Yes or no





## Monetary compensation

- \$0, \$300, \$750, \$2000 over life of trial

# Sample Question from Conjoint Analysis Survey

Last time. Imagine your child has an opportunity to participate in one of two clinical trials to treat his or her **Ulcerative colitis**. The table below details each trial.

	Trial A	Trial B
Your child's GI doctor's involvement in the trial	The trial is conducted at an IBD Center, and your GI doctor gets a detailed report of each visit	The trial is conducted with your child's primary GI doctor's involvement
The chance of your child receiving a placebo when participating in the trial	 2 out of 10 participants will receive placebo	 5 out of 10 participants will receive placebo
The number of procedures per year (such as colonoscopies, CT scans, MRI scans)	2 procedures per year	6 procedures per year
The time commitment you will have to make to participate in the trial (e.g., traveling, answering questions, participating in procedures)	6 hours per month	24 hours per month
Will your child be able to continue the treatment after the trial has ended (i.e., will there be an open-label extension)?	No	Yes
Your monetary compensation (in addition to travel cost reimbursements)	\$300 over life of trial	\$2,000 over life of trial

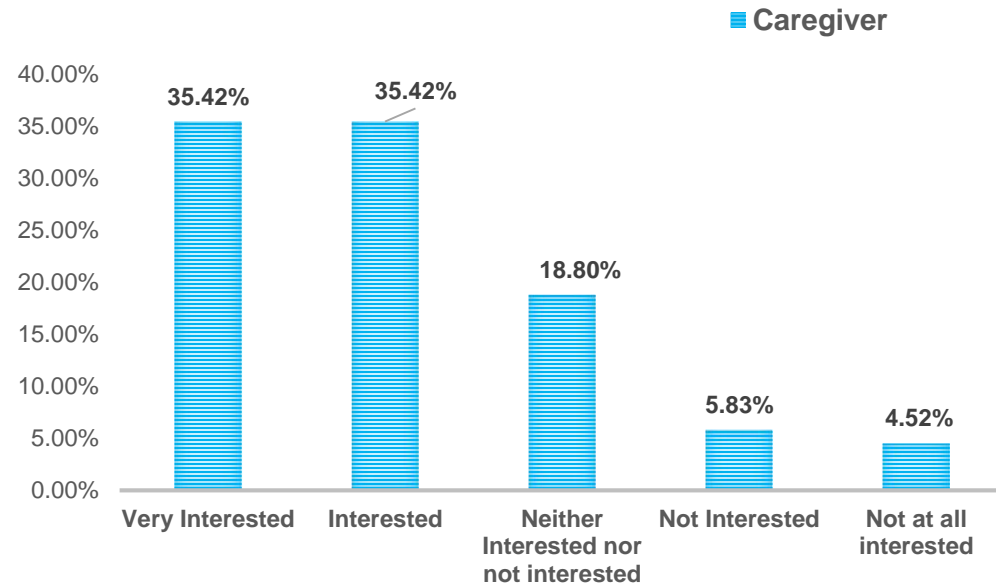
Given the two options in the table, which trial would you choose for your child to participate in for **1 year?**

# Preliminary Findings: Caregivers

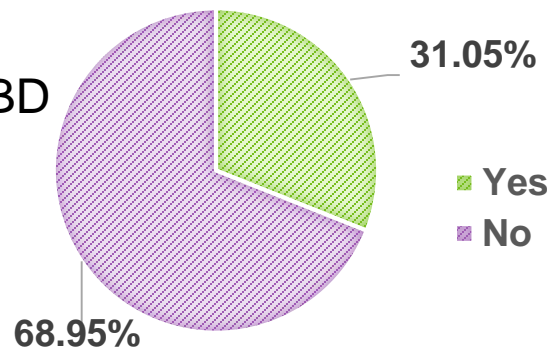
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Demographics	Caregiver
Race (% Nonwhite)	16.91%
Gender (% Female)	61.08%
Household Income (% ≤ 75k)	50.94%
Education (% Some College or more)	92.77%
Insurance Status (% W/O Health Insurance)	9.22%

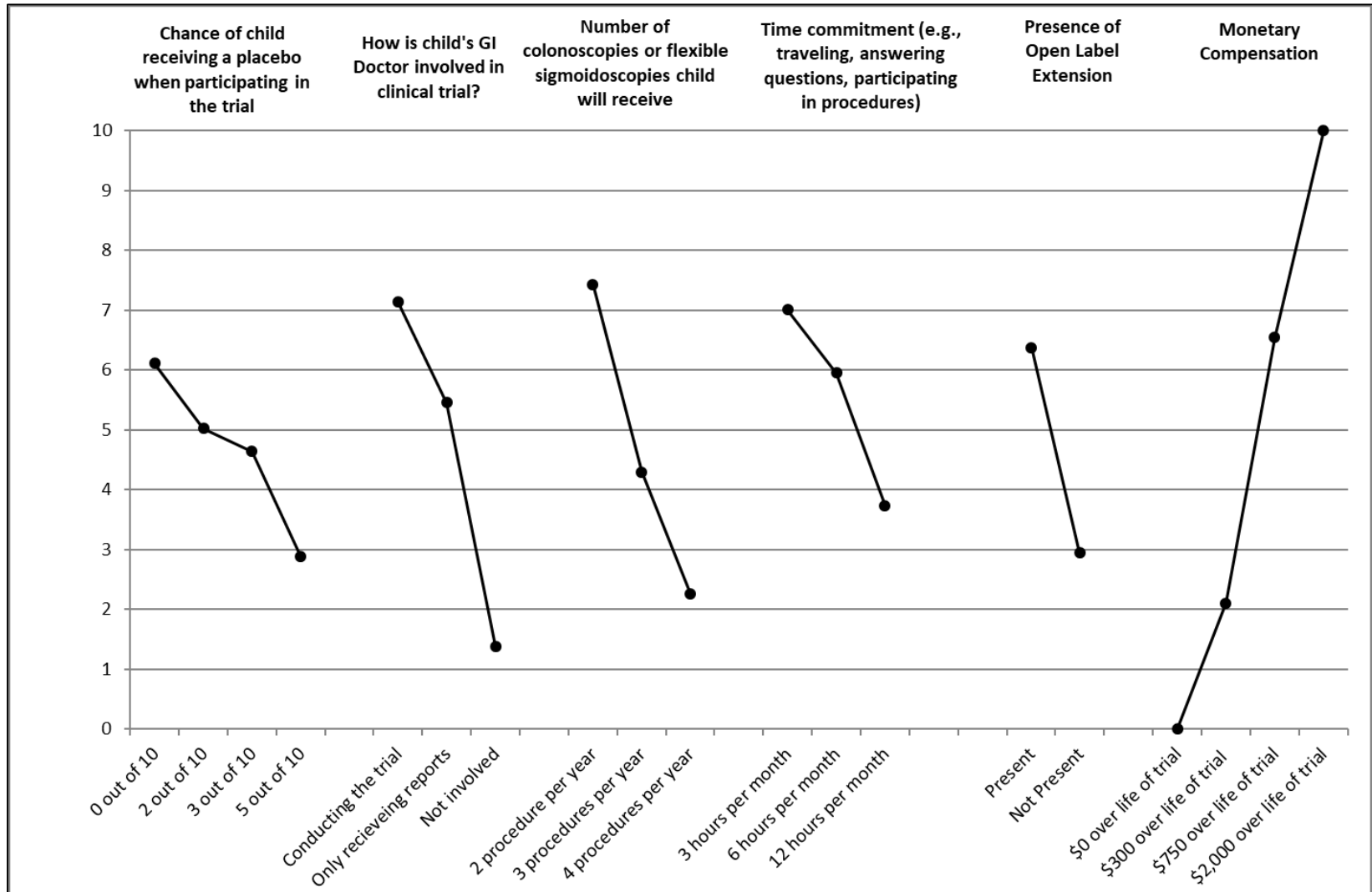
Interest of patient participating in IBD clinical trial



Past Participation in IBD clinical trial?



# Preliminary Findings: Satisfaction Scores by Trial Attribute



## Next Steps

- Publish findings from focus groups and conjoint analysis
- Translate findings into publicly available enrollment predictor calculator



### Study Participation Calculator

Enter the attributes for your study below. The result will update when a selection is changed.

Who needs to provide consent for the trial?

Patient

What portion of patients will receive a placebo treatment?

3 out of 10 participants will receive placebo

How is the patient's Gastrointestinal doctor involved in the trial?

They are conducting the trial

How many colonoscopies or flexible sigmoidoscopies will the patient receive during the trial?

3 procedures per year

How many hours will the patient spend each month participating in the trial (e.g., traveling, answering questions, participating in procedures)?

6 hours per month

Will the treatment being considered have an open label extension?

Yes

How much money will the patient receive for participating in the trial?

\$0 over life of trial

Based on your study's attributes, we estimate the percentage of patients willing to participate in your study would be: **82%**

**Thank You**

Questions?