



Adherence to study drugs in clinical trials

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Adherence: A few Facts

Cost of Care per Patient not related to adherence

CF patients report high adherence

Actual adherence much lower

Study drugs are counted post return by patient

In most cases adherence can be calculated accurately

Method 1

All studies carried out at the Hadassah CF Center over the last 5 years were analyzed:

Study Name	label	mode	length months	# visits	# enrolled patients
A	open	per os Capsule	12	14	10
B	placebo	per os Tab	2	7	4
C	vs Tobi	inh	2.5	9	4
D	placebo	inh	3	6	7
E	placebo	inh	2	7	7
F	placebo	per os Powder	12	12	32
G	open	per os Powder	24	20	28
H	placebo	inh	2.5	5	21
I	vs Tobi	inh	6	8	5

Method 2

Actual adherence compared with:

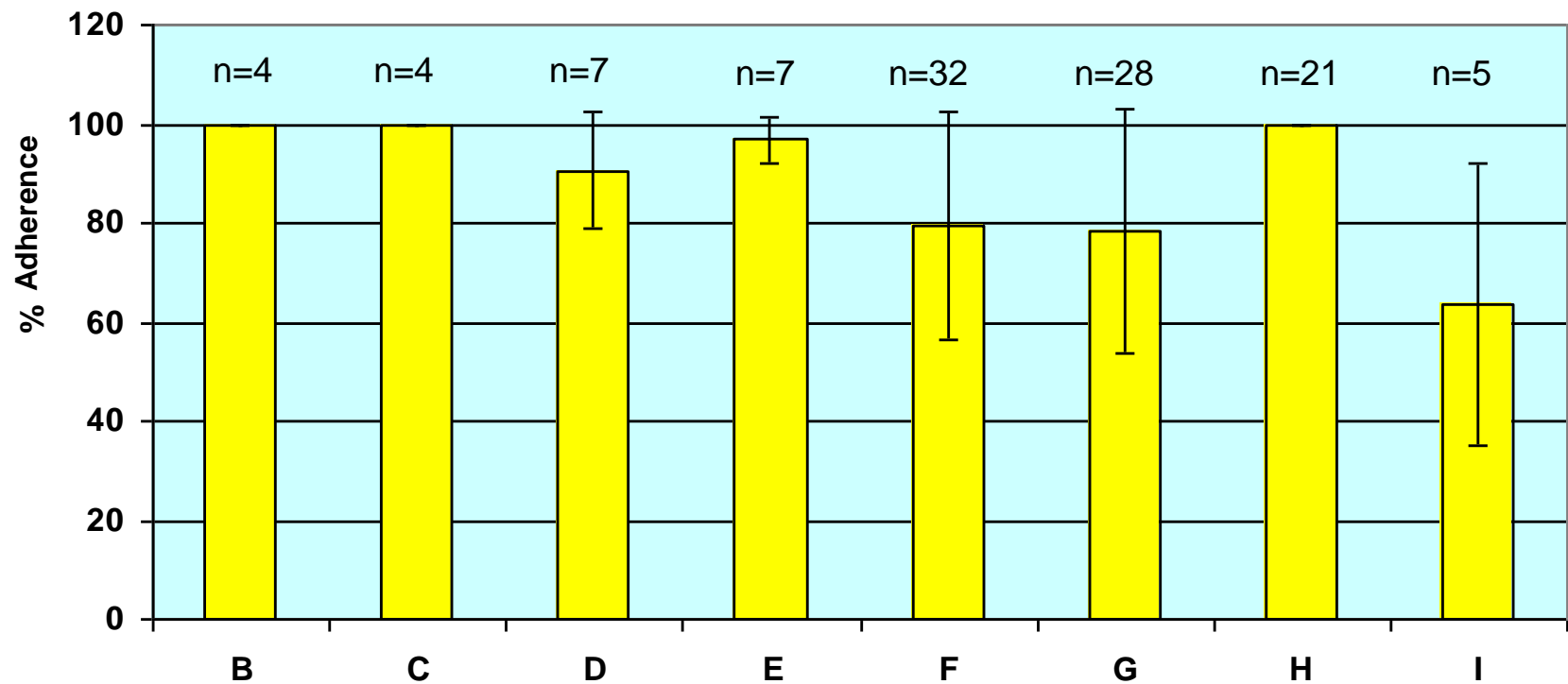
- **Drug administration mode**
- **Study length**
- **Number of visits**

Anonymous Questionnaire:

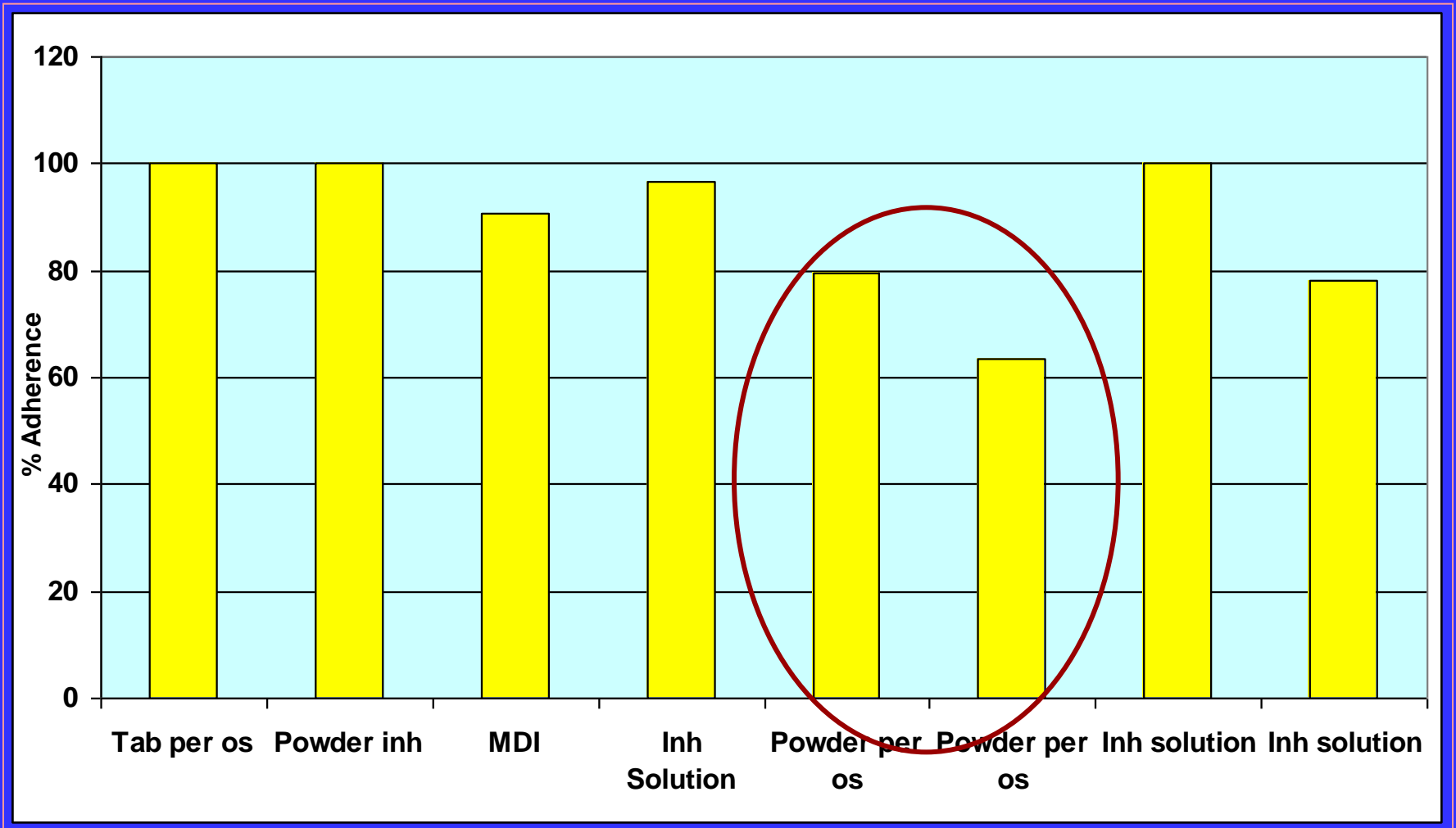
- **Patient population of last 2 studies**
- **2-parts: study specific; general adherence**

Mean adherence for different studies

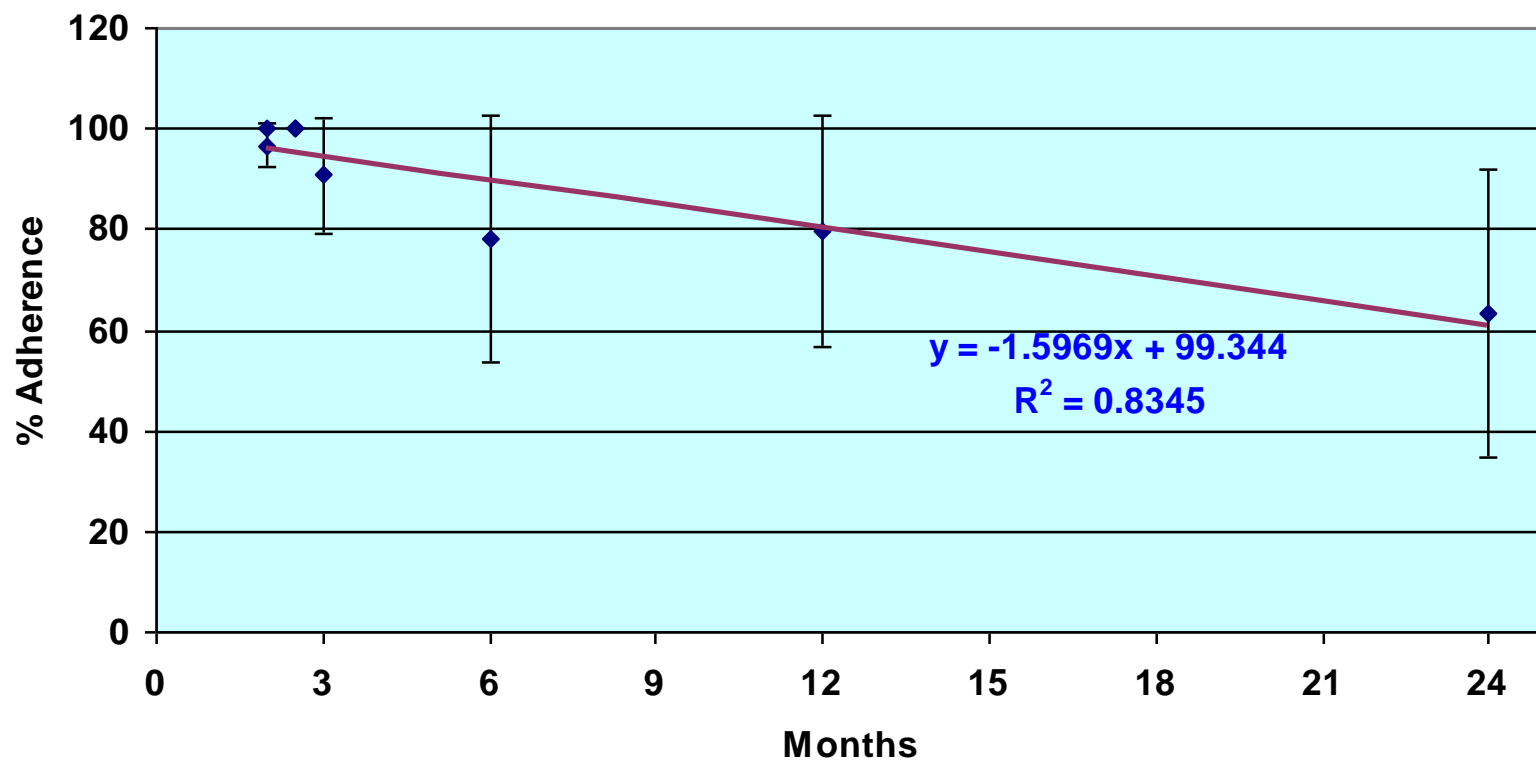
Adherence



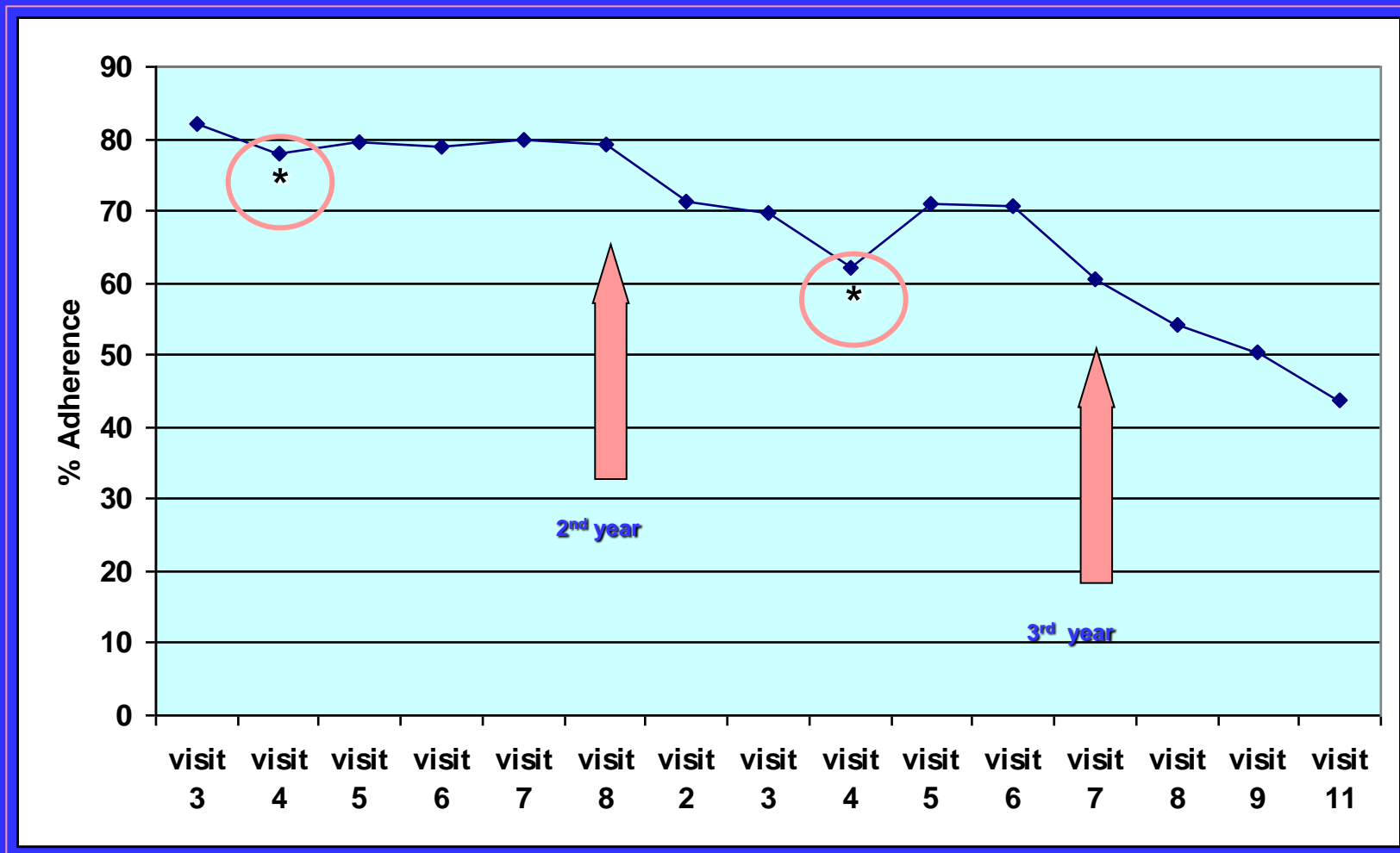
Mode vs Adherence



Study length vs Adherence 1



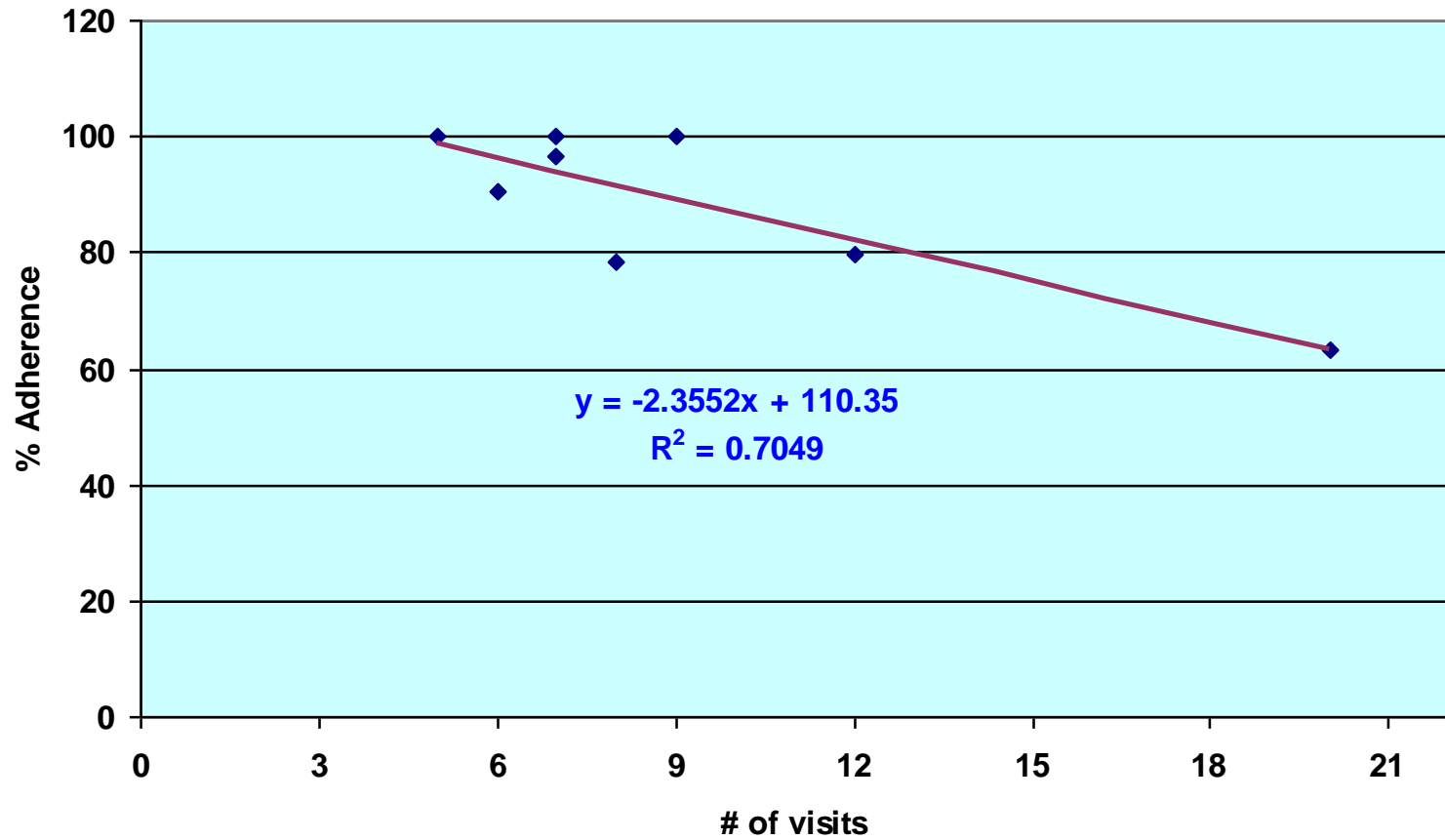
Study length vs Adherence 2



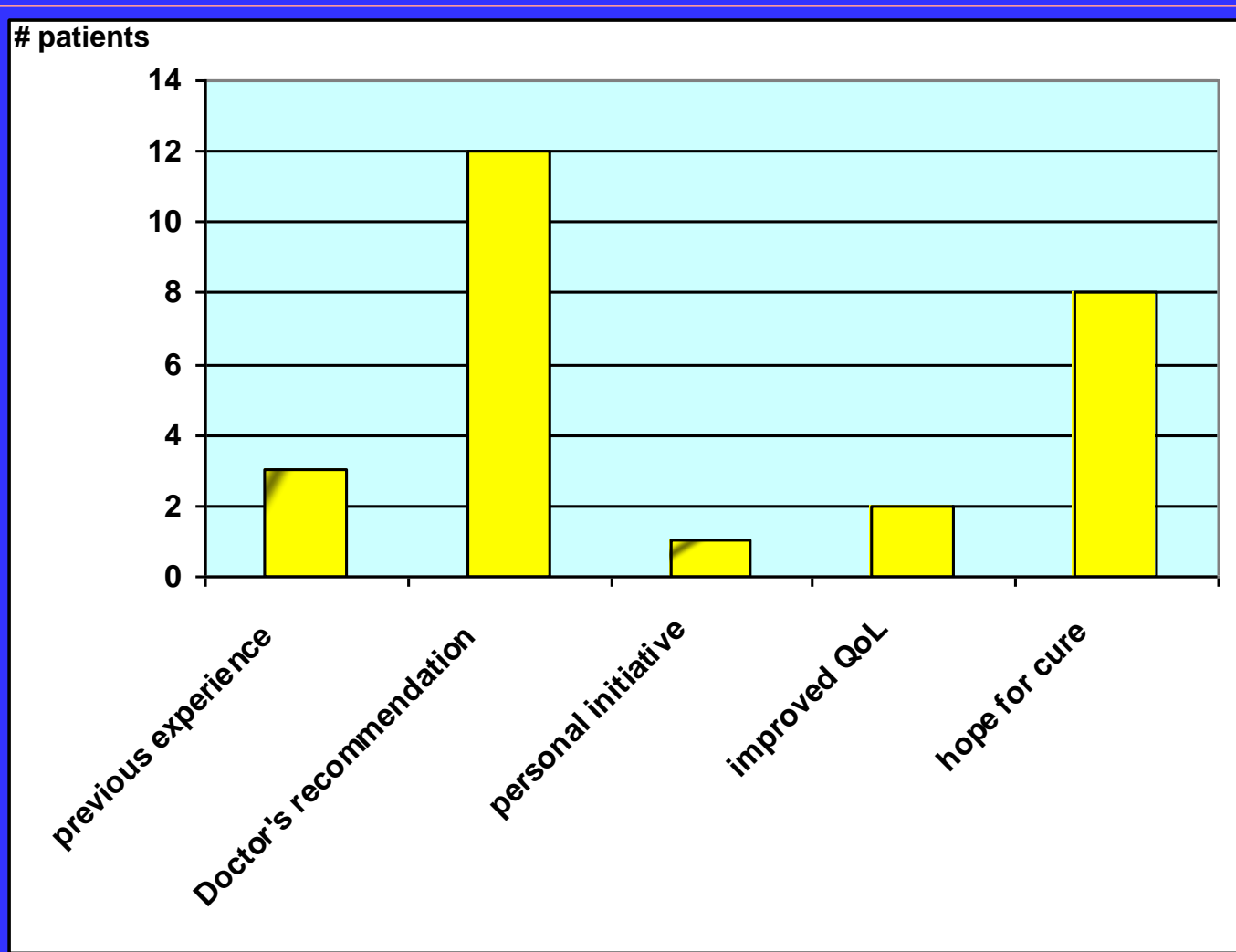
* Visit 4, 1st year: 1 = Jan, 4 = Feb; 8 = Mar-Apr; 4 = May; 7 = June-Jul; 2 = Sep; 2 = Oct; 1 = Nov; 2 = Dec

* Visit 4, 2nd year: 2 = Jan; 5 = Mar; 3 = May; 13 = June- Aug; 3 = Nov

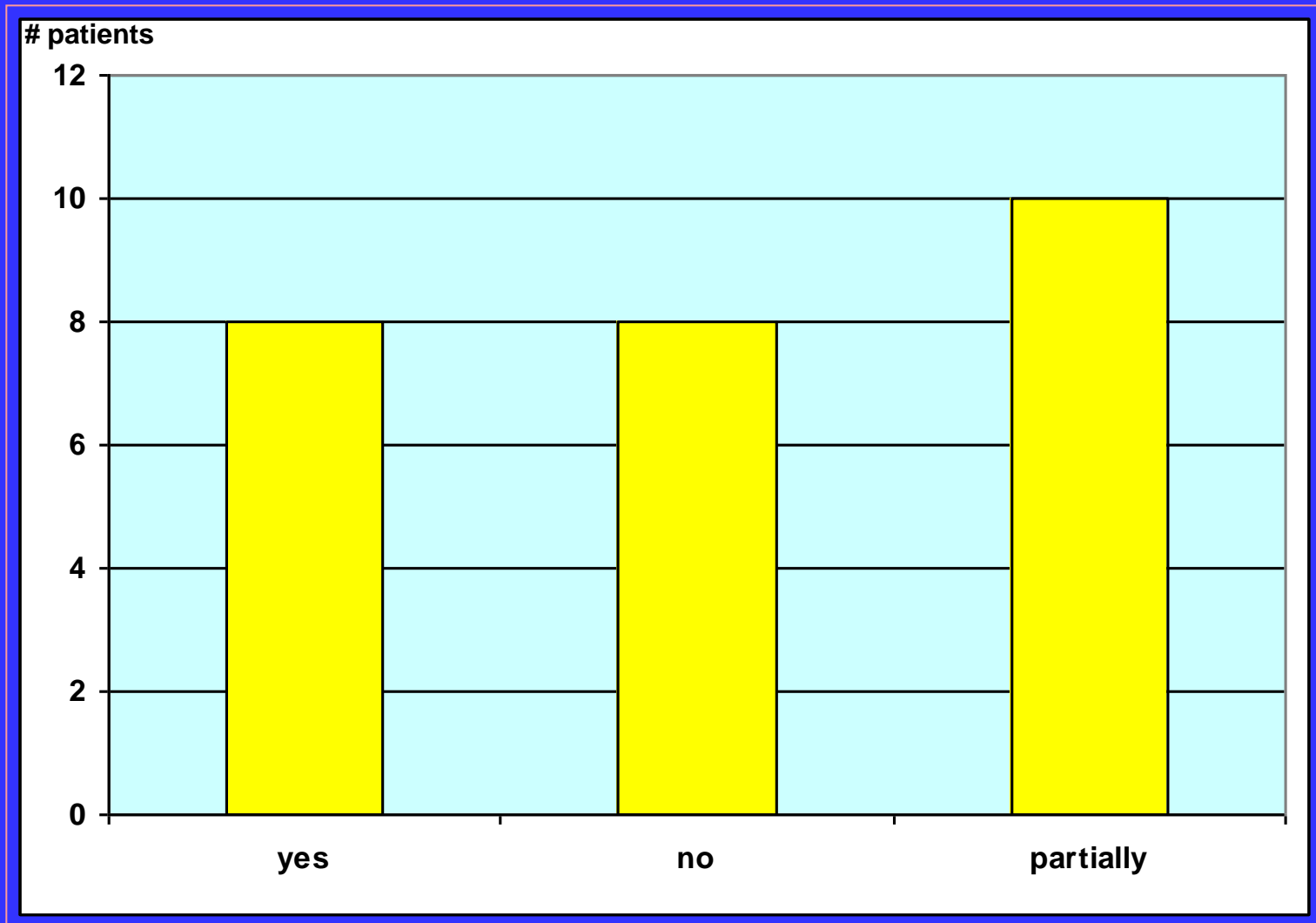
Visits vs Adherence



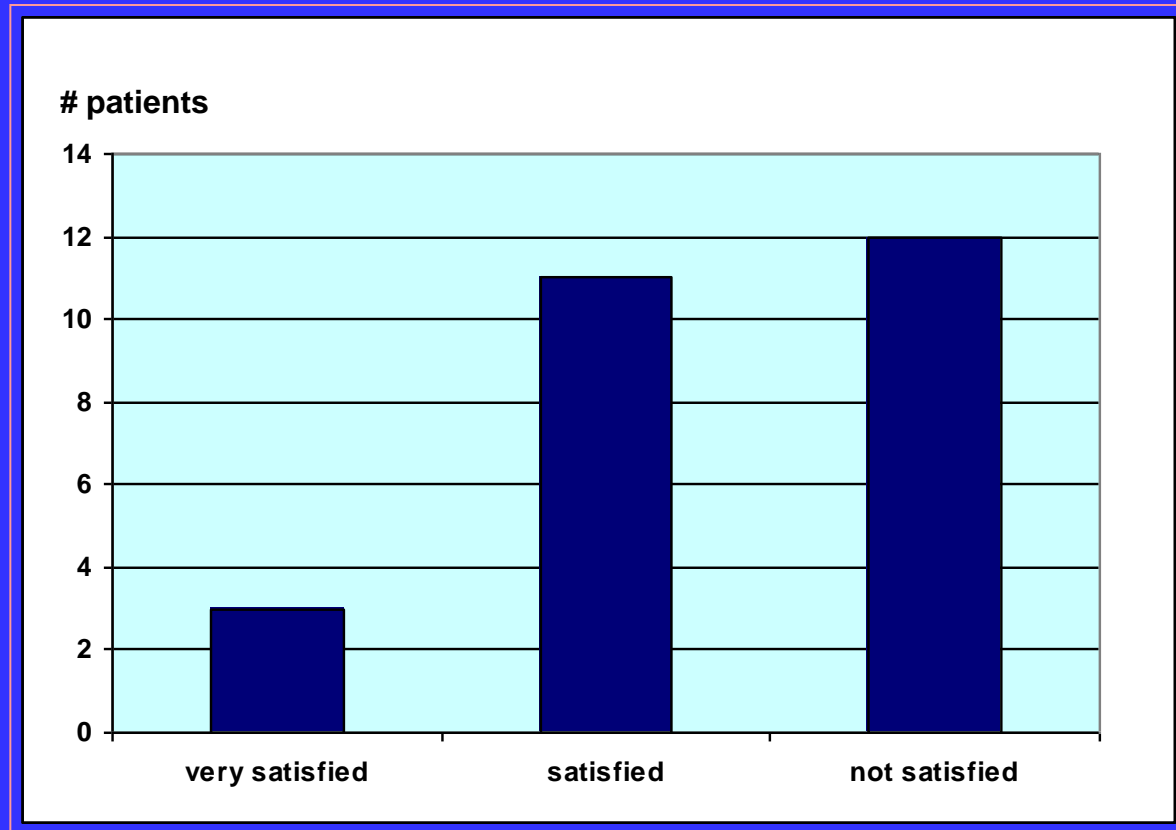
Reason for trial participation



Effect of study drug



Satisfaction with drug administration



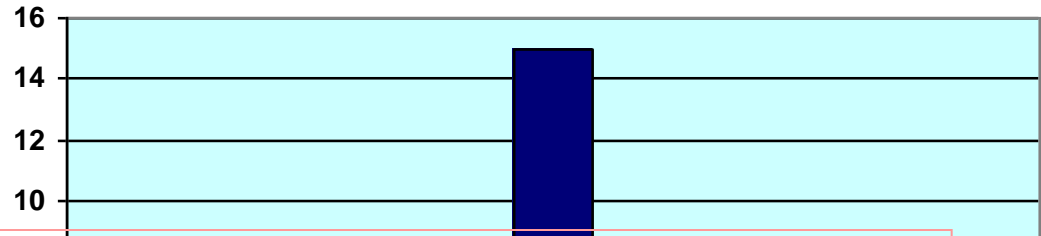
Positive Influence on Adherence

patients

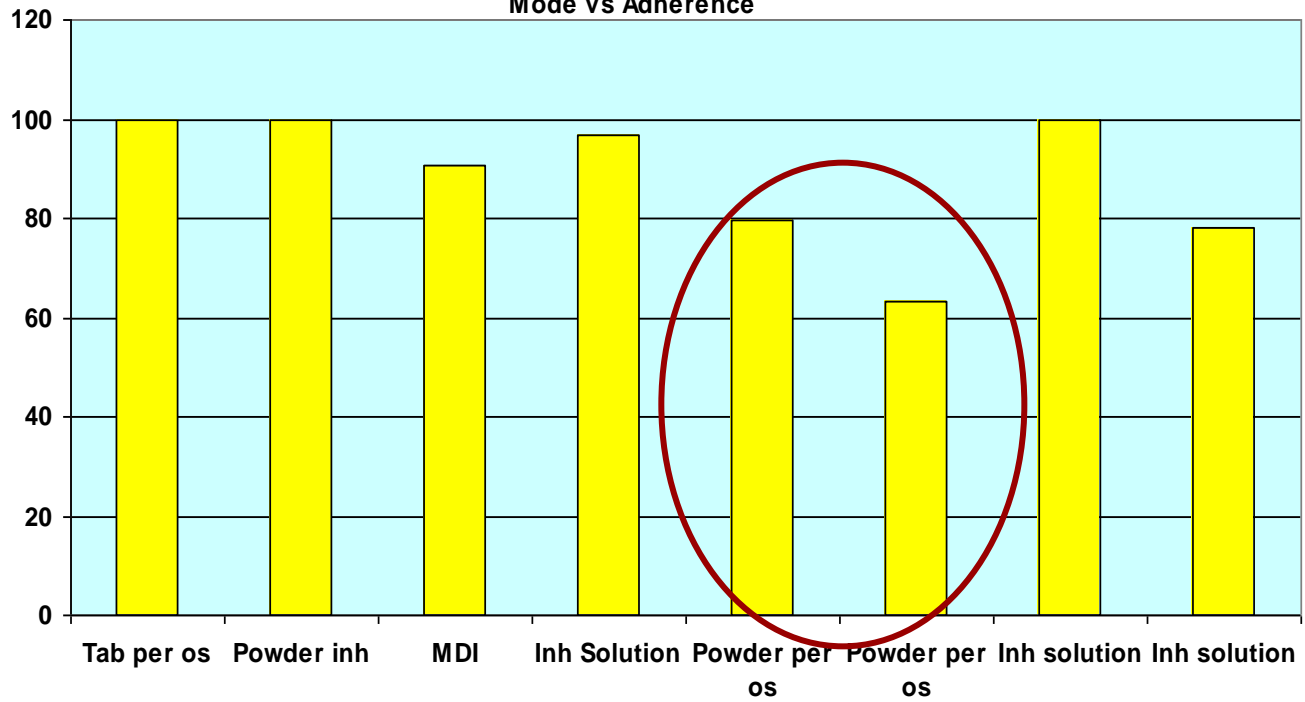


Negative Influence on Adherence

patients



Mode vs Adherence

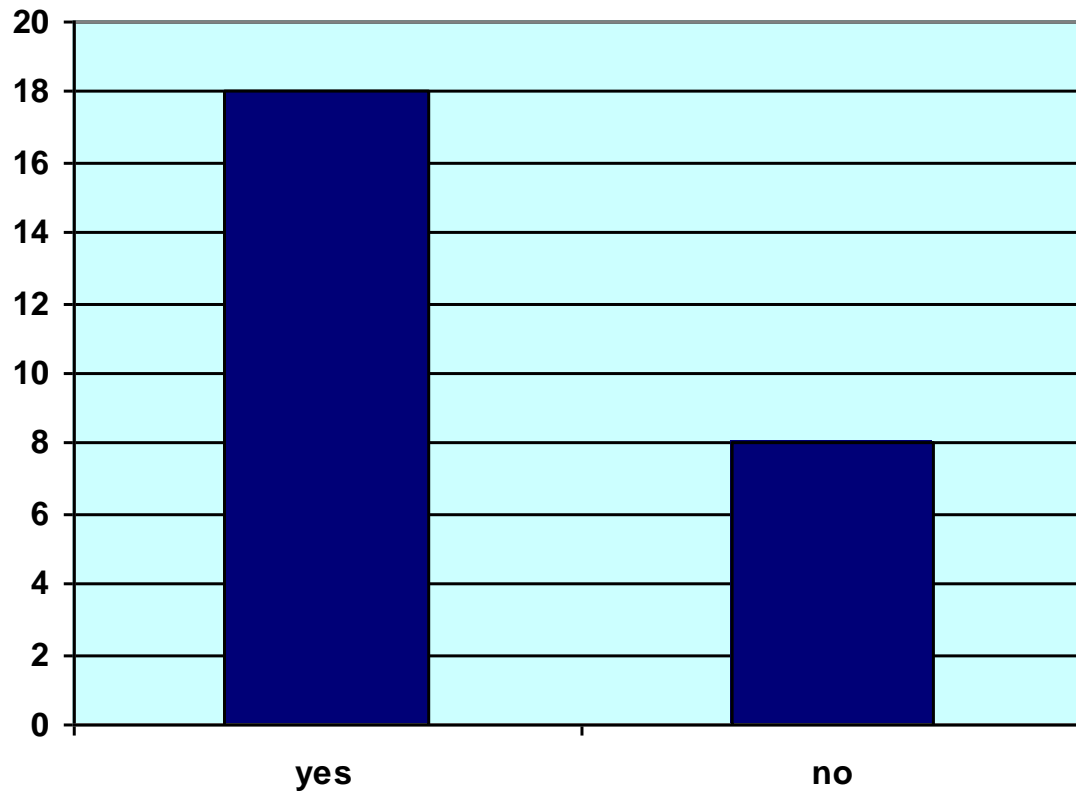


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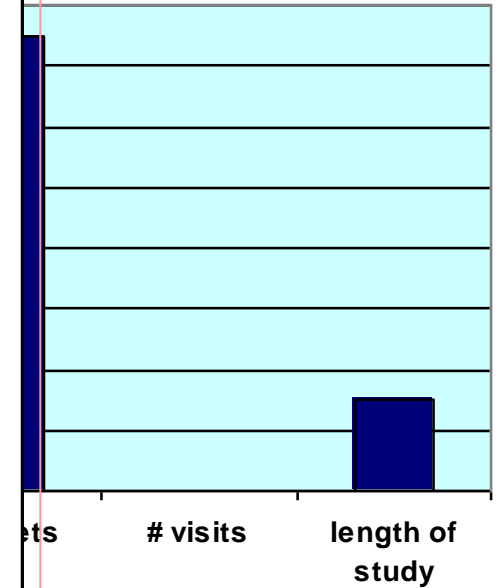
Surprise, surprise!

Adherence

patients Do you want to receive study drug again?

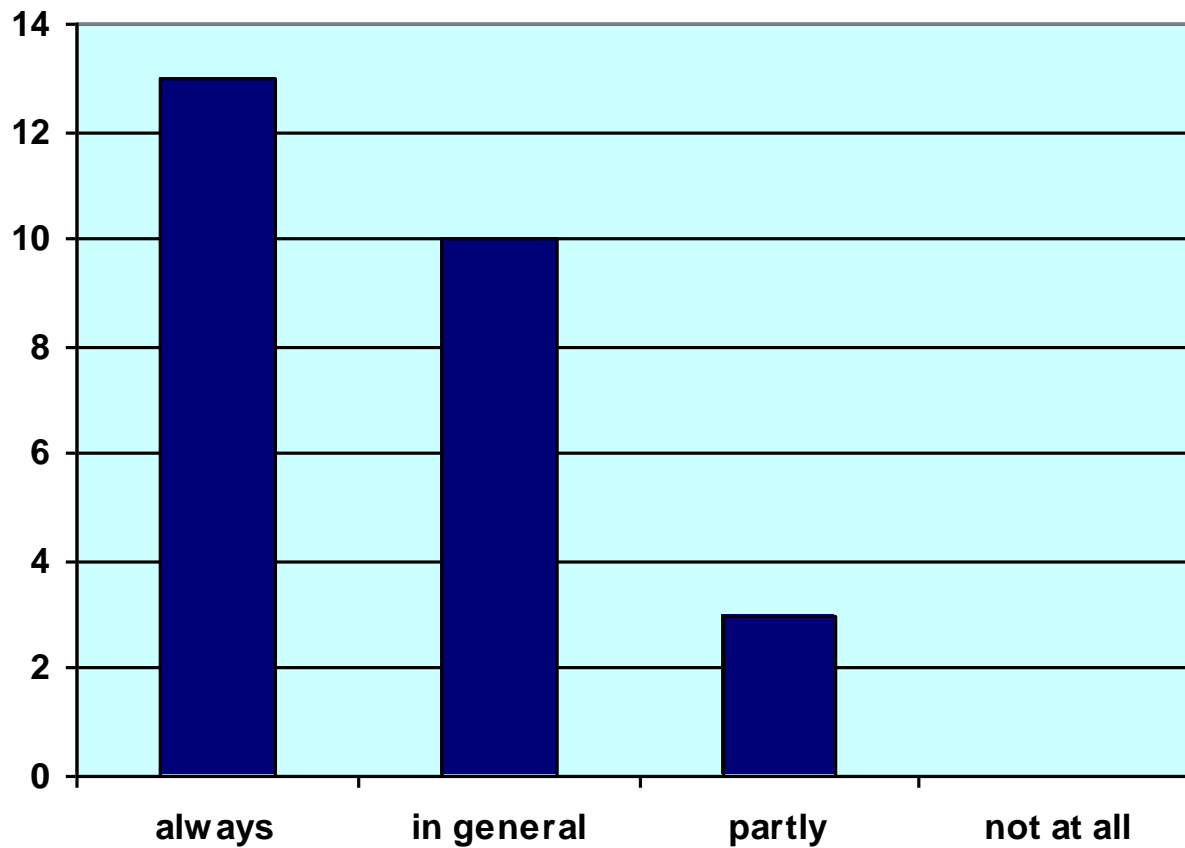


Compliance

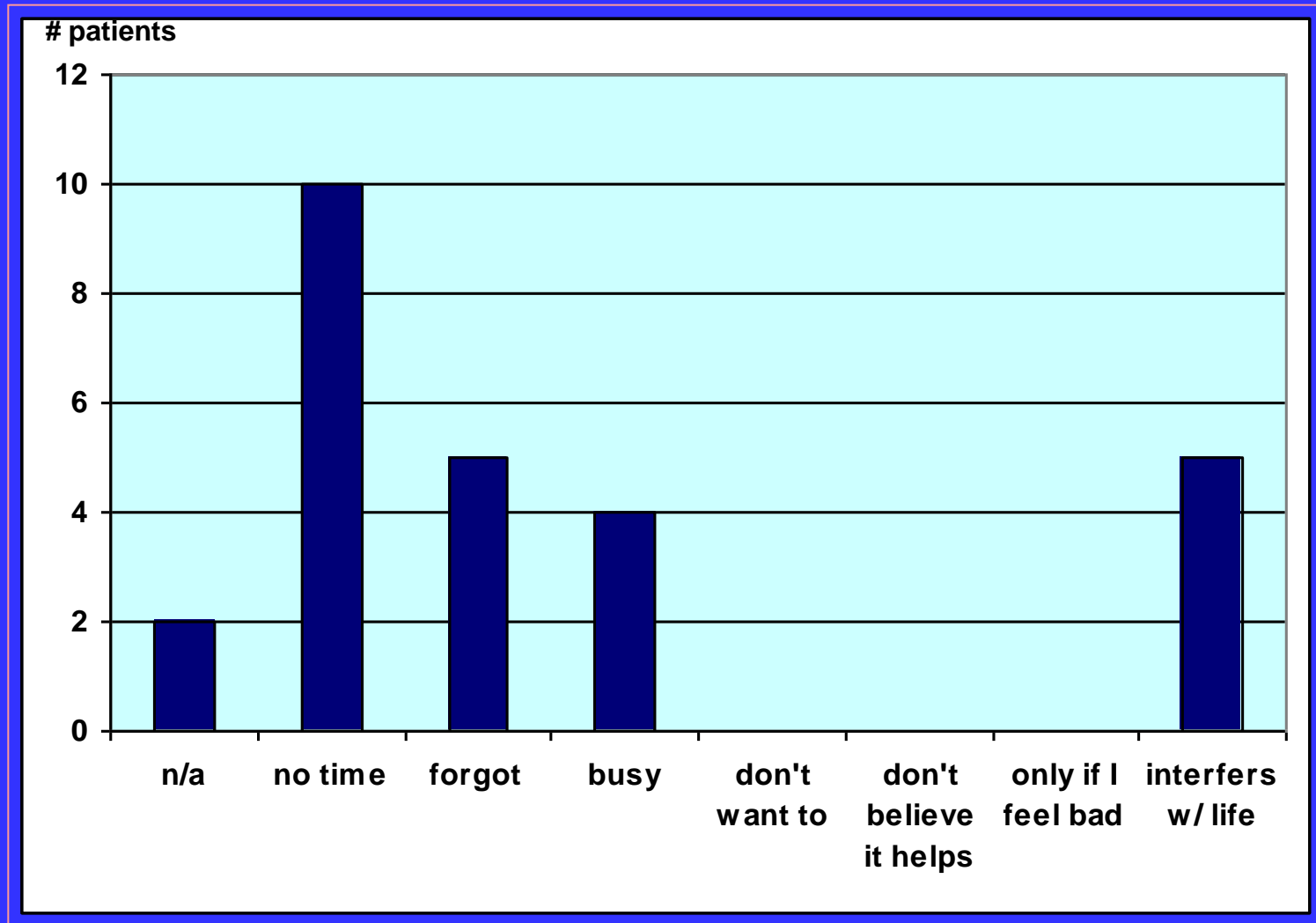


General compliance

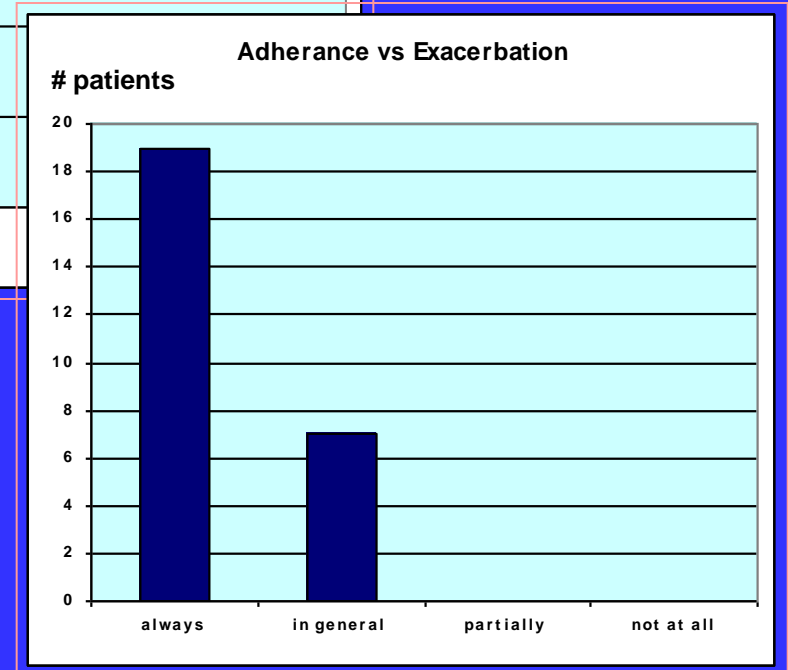
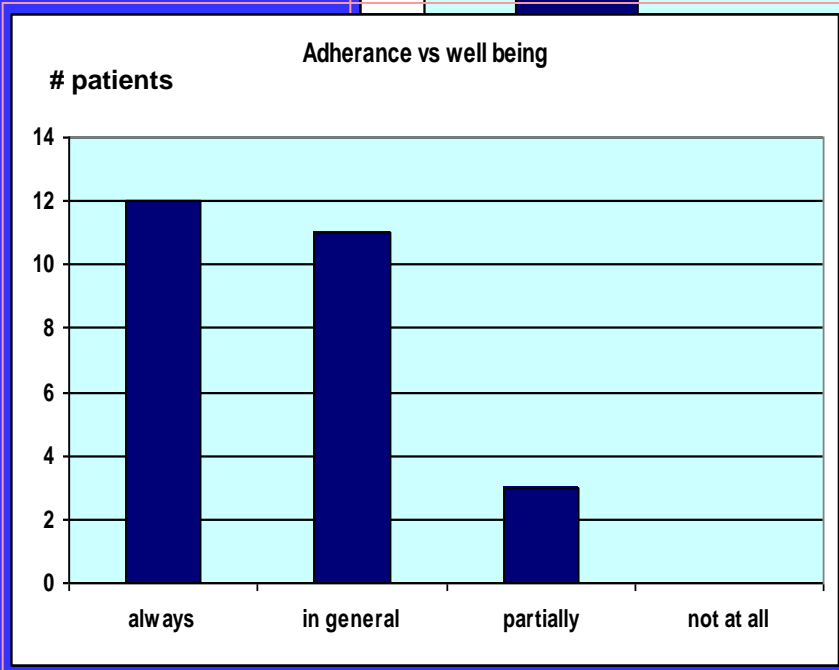
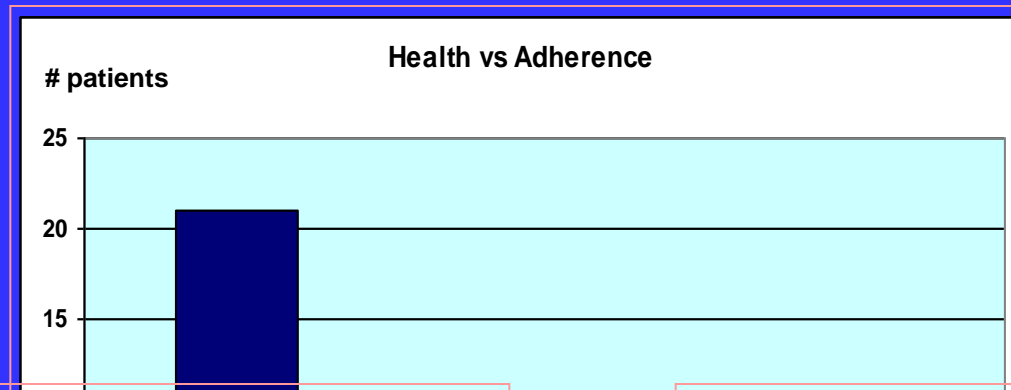
patients



Reasons for non-compliance



The patient and his/her health



Conclusion 1

**Patients participate in clinical trials
mostly based on recommendation of
the treating physician**

**Patients hope that the study drug will
increase their health and maybe cure**

**Timing is crucial, summer months or
holidays decrease adherence**

**Drug mode and Study length influence
adherence**

Conclusion 2

Recommendations

- ✚ Clinical studies should be as simple as possible
- ✚ Clinical studies should be patient friendly
- ✚ Clinical studies should avoid summer months and religious holidays

Good luck with the next trial