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Centralised Procedure
Analysis of Performance Indicators

Extensions of Indications 2006 EMEA analysis

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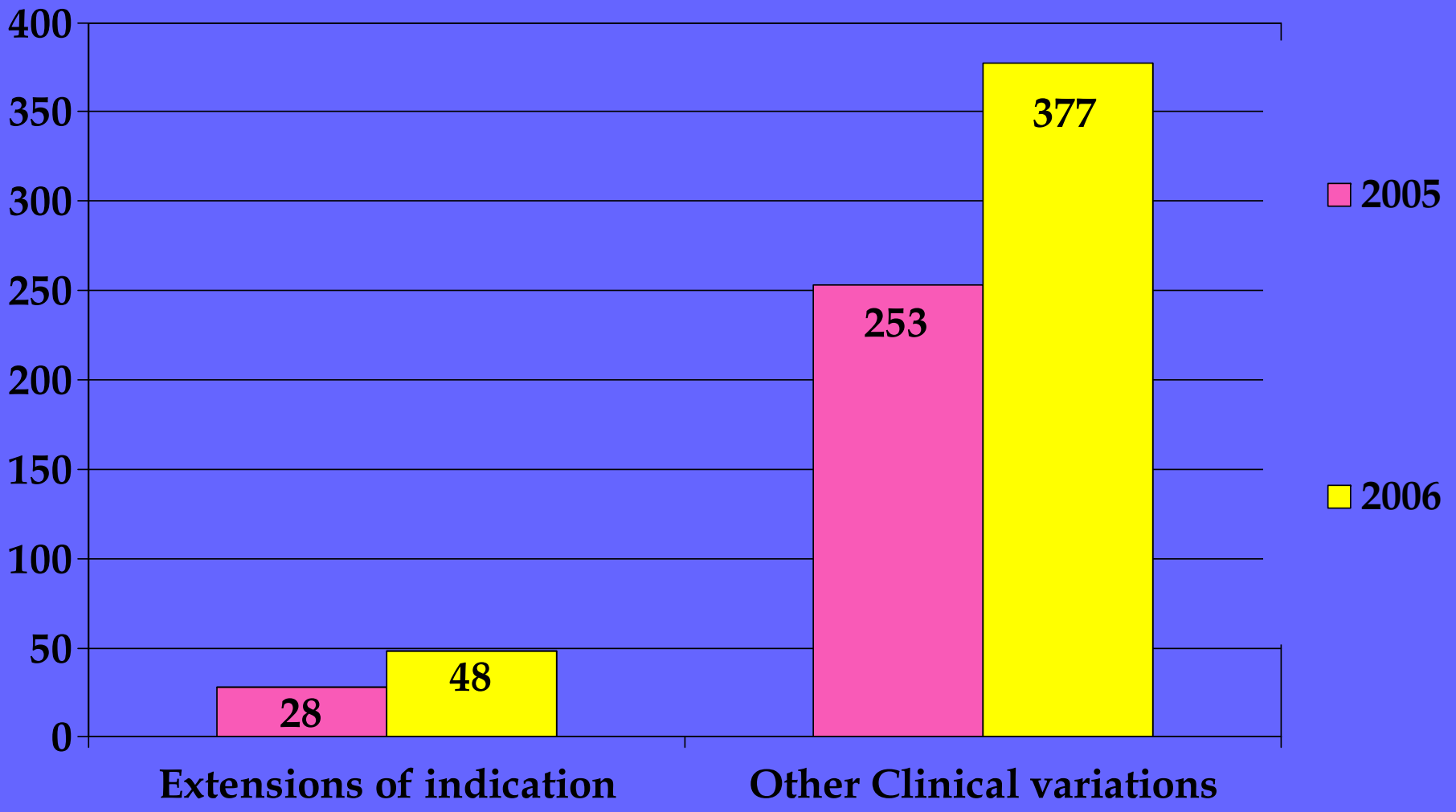
Number of Extensions of Indications vs other clinical Type II variations



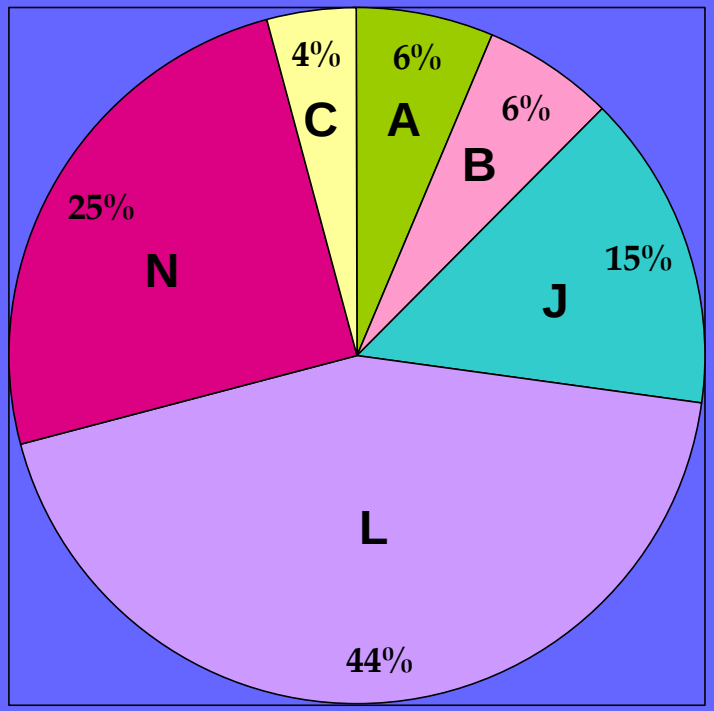
Extensions of Indications

Procedures finalised between June 2005 and Sept 2006

N= 48 opinions (39 excluding duplicates)

Duplicates are not counted in the statistics

Extensions of Indications
ATC code distribution



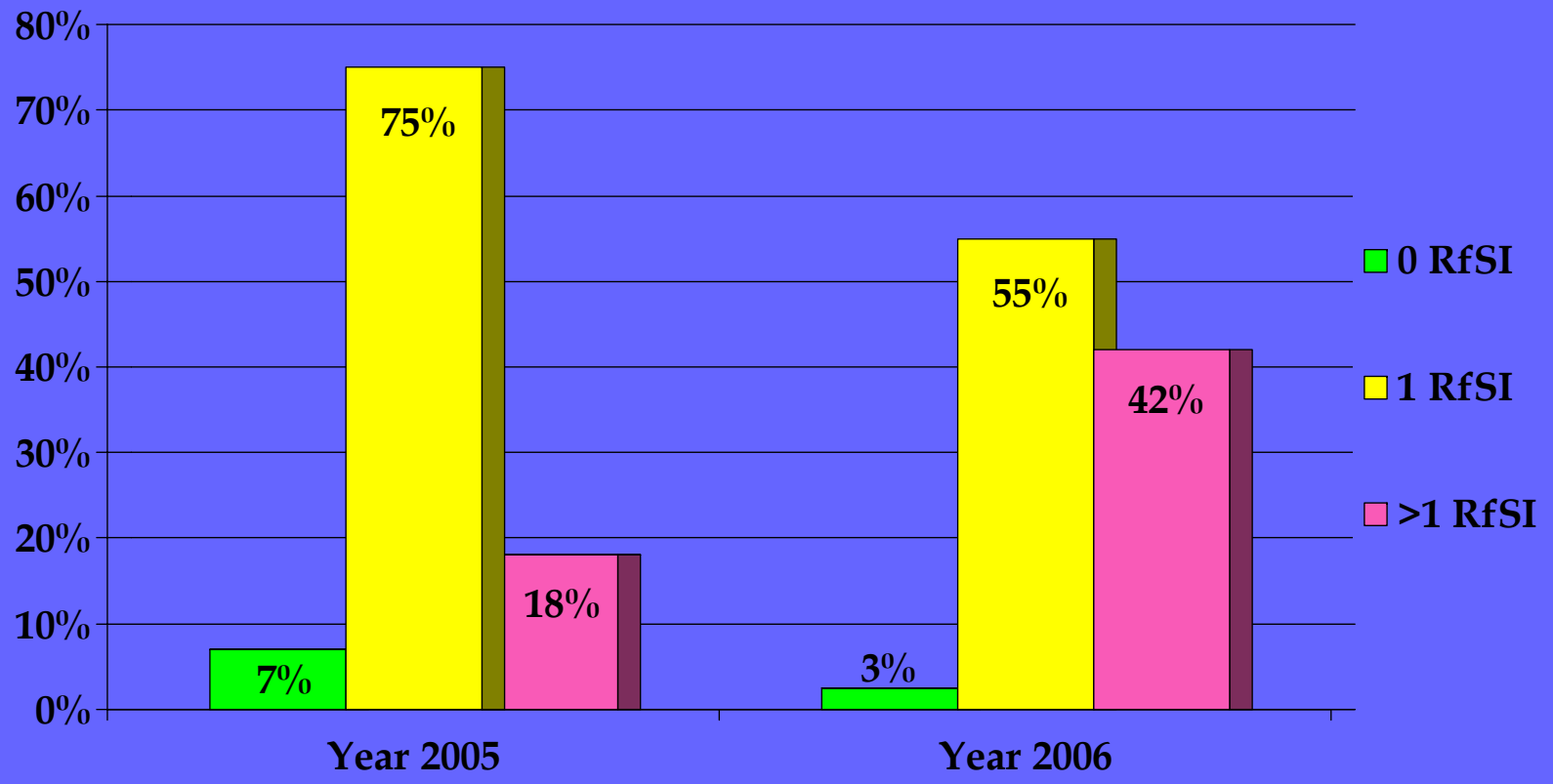
- A (alimentary tract & metabolism)
- B (Blood and blood forming organs)
- J (anti-infective for systemic use)
- L (antineoplastic & immunomodulating agents)
- N (nervous system)
- Other

Extensions of Indications

	2006	2005
• Scientific Advice:	20.5% (9/39)	11% (3/28)
• Pre Submission meeting:	26% (10/39)	32% (9/28)
• Involvement of Co-Rapporteur:	95% (37/39)	79% (22/28)
• Oral Explanations:	7.7% (3/39)	10.7% (3/28)
• SAG / Expert Group:	2.5% (1/39)	-
• RMPs:	33% (13/39)	-

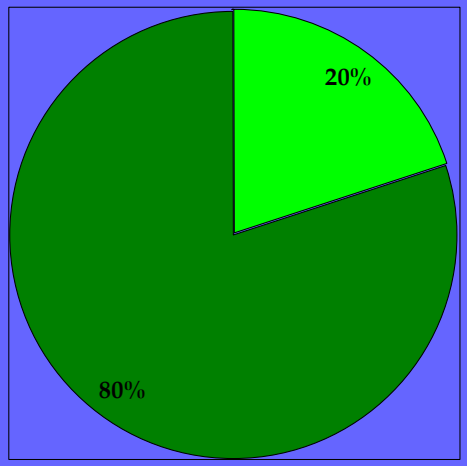
Requests for Supplementary Information (RfSI)

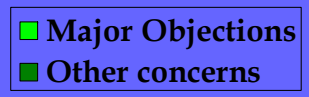
Percentage of Procedures with RfSI

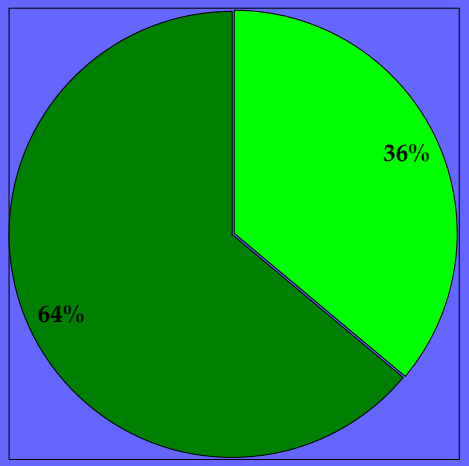


Requests for Supplementary Information (RfSI)

Major Objections vs Other Concerns





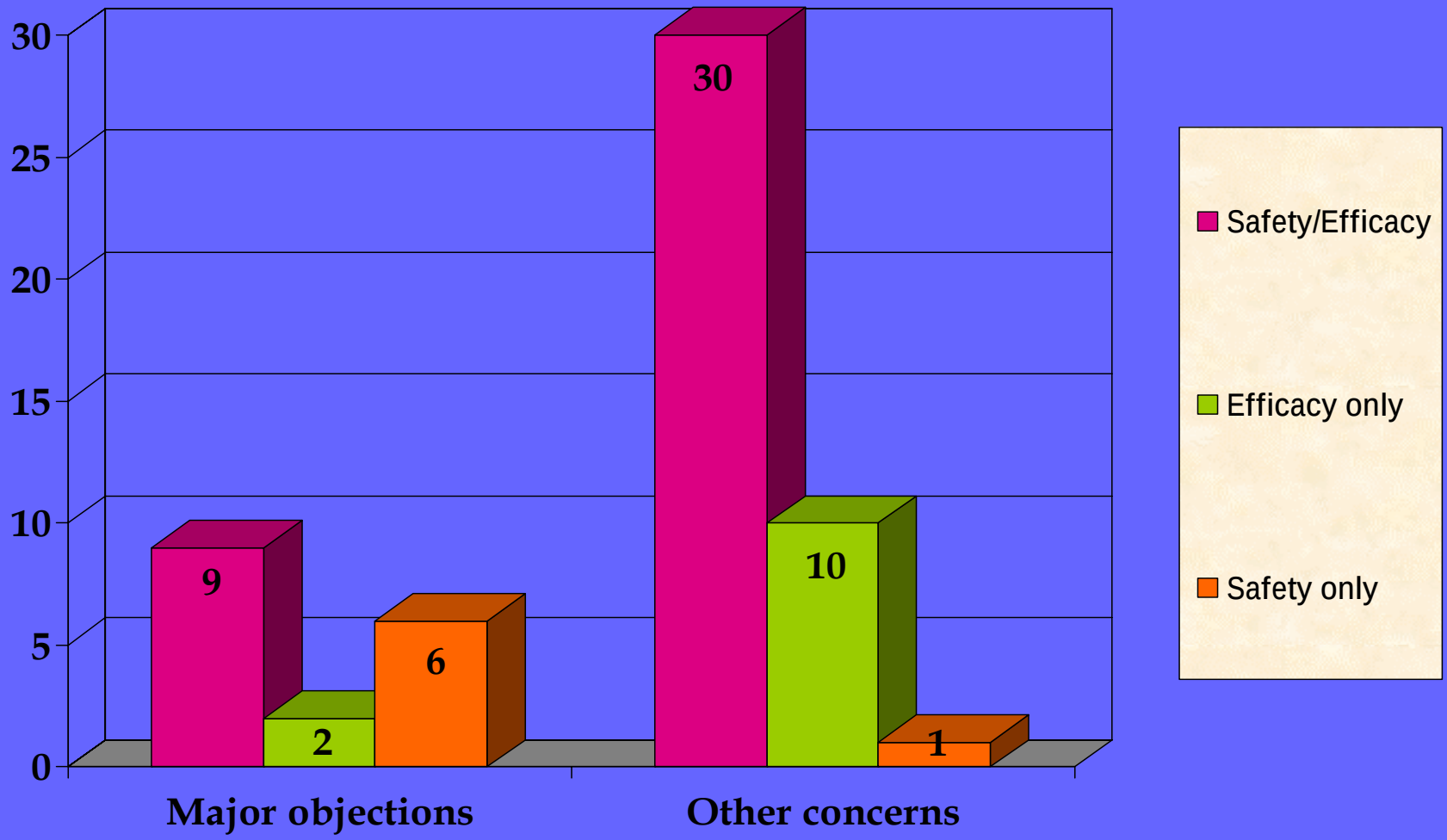


2005

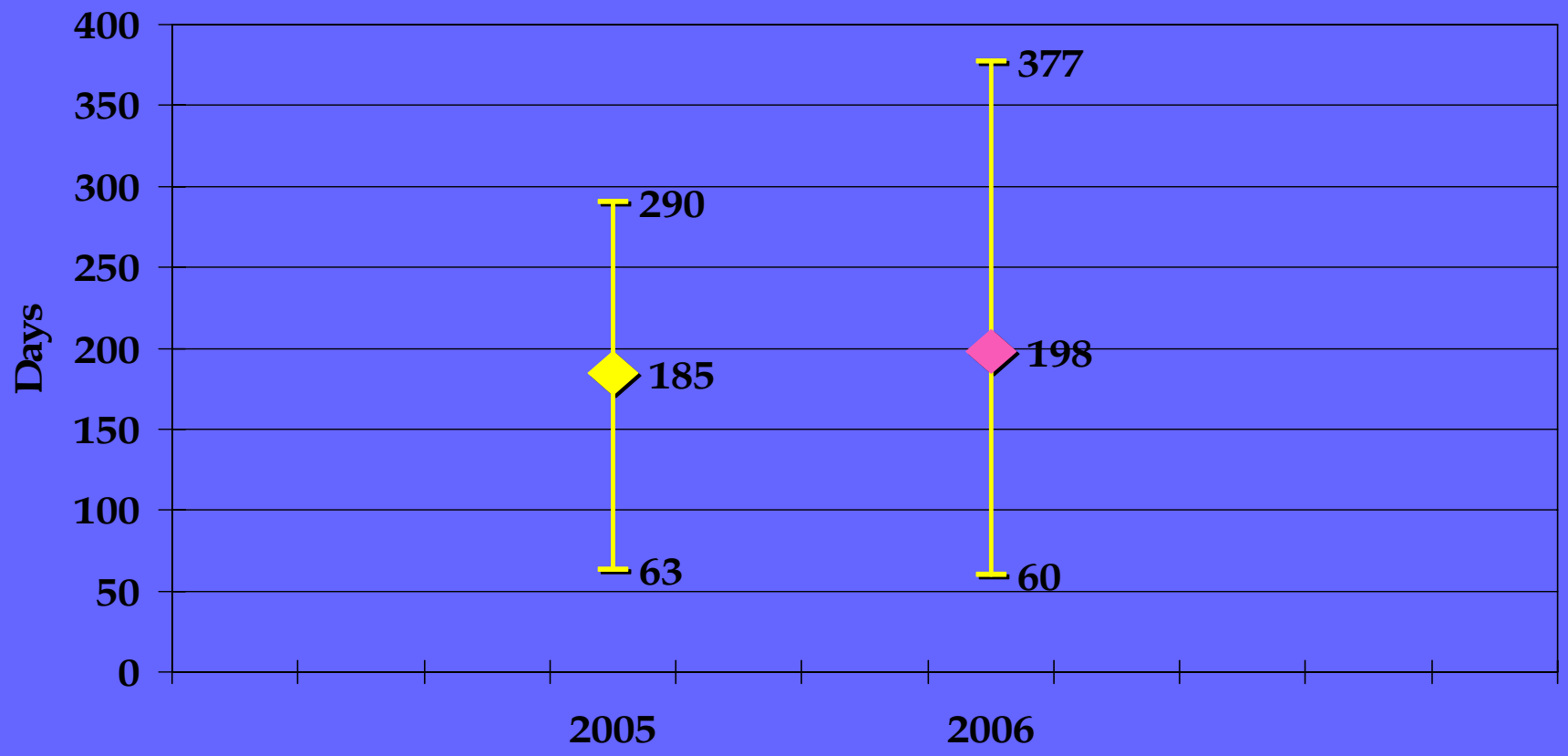
2006

Requests for Supplementary Information (RfSI)

Type of questions 2006

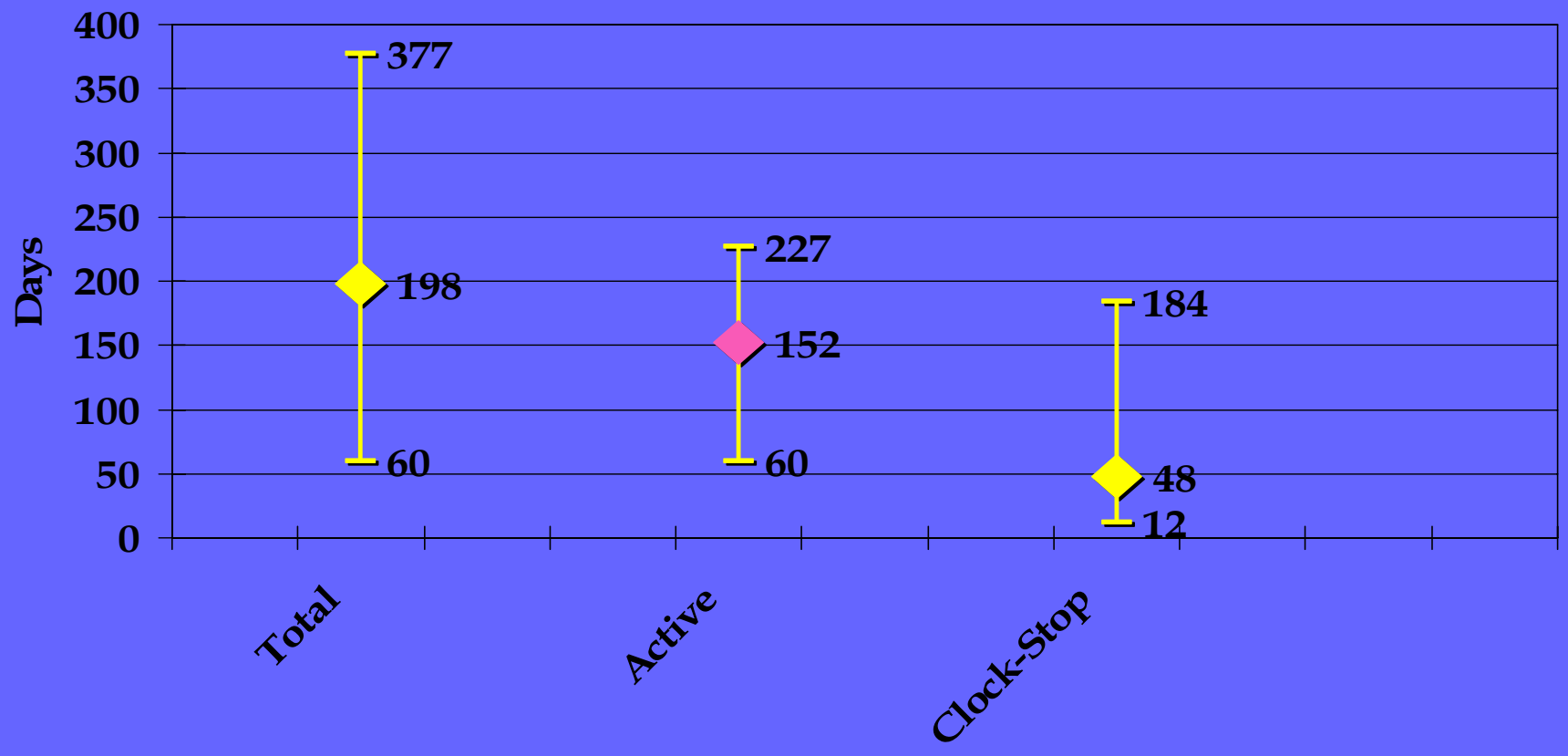


Average overall processing times 2005 vs 2006



The time for re-examination has not been included

Active time vs clock-stop time 2006



The time for re-examination has not been included

Extension of Indications
OUTCOMES 2006

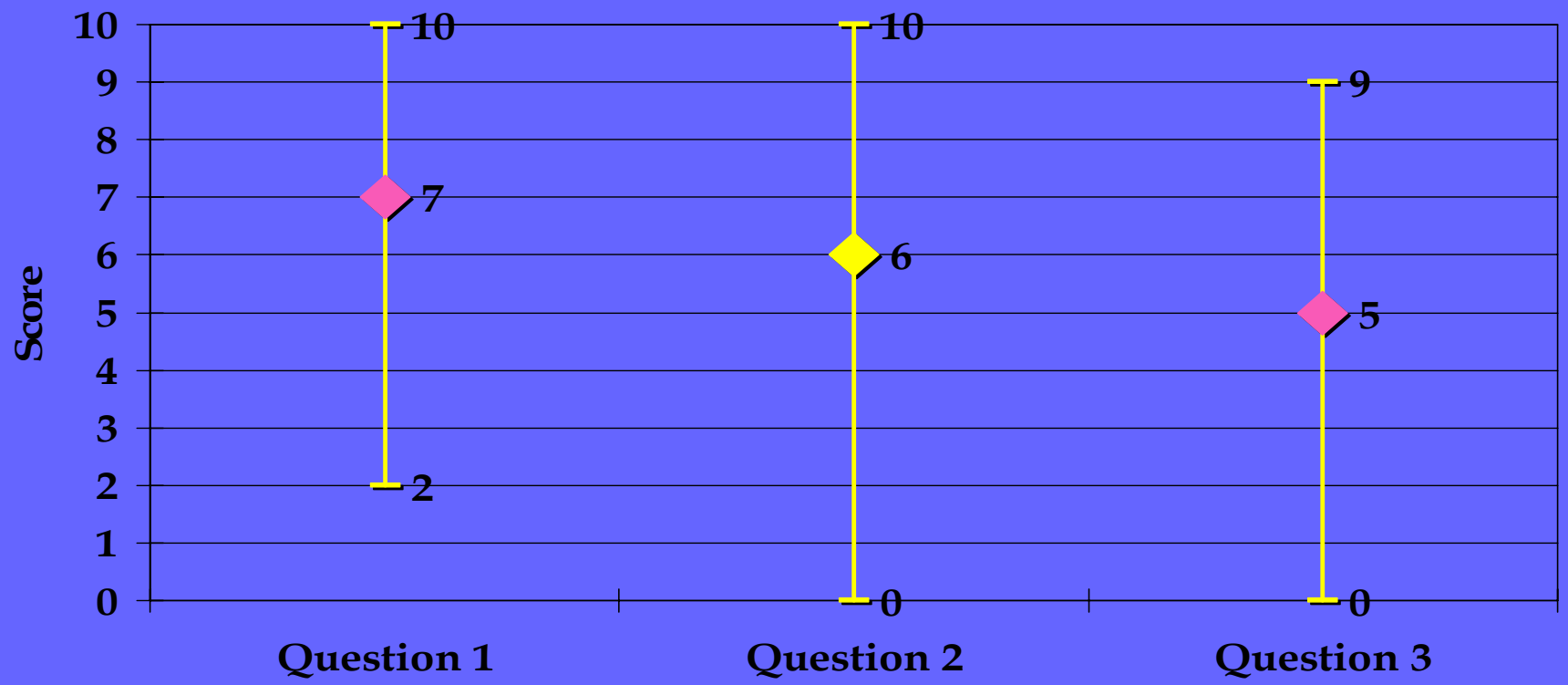
- **CHMP positive Opinion in all finalised procedures**
- **1 re-examination procedure**
- **4 withdrawals**
- **3 oral explanations**
- **Clinical commitments: 74% (29/39)**
  - Efficacy and Safety (14)
  - Efficacy only (6)
  - Safety only (8)
  - Non-clinical (1)

Questionnaire to the (Co-)Rapporteurs

- ***Question 1**: The dossier was presented in a satisfactory way (layout, organisation of data, etc)?*
- ***Question 2**: All important data/analysis were included in the dossier thereby making benefit risk assessment easy?*
- ***Question 3**: The "scientific overview" (expert report) was sufficiently critical?*

Percentage of procedures with (Co)Rapporteurs' response: 72%

Results of (Co-)Rapporteur's Questionnaires



0 “strongly disagree” – 10 “strongly agree”

Results of (Co-)Rapporteur's Questionnaires Additional Comments

- <u>Format</u>: Comments received from (Co-)Rapporteurs re format of the applications included:

- Product information submitted in pdf format only.
- Too vague ToC making search for specific data/tables difficult.
- Pagination not allowing easy review of study report.

- <u>Content</u>: Comments received re content tend to be too product specific to be cited.

- Lack of critical clinical assessment / adequate discussion on CHMP issues raised was occasionally reported.

Results of (Co-)Rapporteur's Questionnaires Conclusions and Comparison with 2005

- Responses from (Co-) Rapp:

Slight decrease in 2006 (72% vs 80%)

- Questions 1 and 2 (format and completeness of the dossier):

Similar scores in 2005 and 2006

- Question 3 (critical scientific overview):

Slight improvement in 2006, although it remains the lowest score.

Extension of Indications Overall Conclusions (1)

- **As in previous years, high success rates for the type II variation "extension of indication", with positive opinion for <u>all</u> finalised procedures.**
- **BUT 1 re-examination and 4 withdrawals.**
- **However, increase in the number of RfSI, processing time and number of clinical commitments.**
- **Higher Co-Rapporteur involvement.**

Extension of Indications
Overall Conclusions (2)

- **Dossier presentation remains good.**
- **Quality of clinical overview provided by the MAHs is better than last year, although there is still considerable room for improvement.**