



EMEA-EFPIA INFO DAY

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Analysis of Performance Indicators for Initial Applications/Full Applications **The 2007 trends: EMEA analysis**

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Analysis InfoDay 2005

Conclusions

- **Good compliance** with Qs – validation ongoing
- Average scores are **stable over time** – **Majority satisfaction**
- Lowest satisfaction with **Overview**
- **Learning curve** with experience (layout, analysis, reports) – feedback
- **Low scores** for long **Clockstop**, **list A** products (Q), **small company**, **orphan products** (C)



(Co) Rapporteurs' Questionnaires at Day 70-80

- Measure satisfaction with dossier
(0 dissatisfied to 10 satisfied)

	Quality	Non-clinical	Clinical
Layout	Global Score		
Analysis			
Overviews			
Summaries			
Study reports			

Bo Aronsson, EFPIA InfoDay 2005

Selection Criteria

- Study periods
 - ◆ 2006: 01-06-2005 to 31-09-2006
 - ◆ 2004: 25-02-2003 to 31-05-2005
 - ◆ 2003: 01-08-2002 to 24-02-2003
- Include
 - ◆ All centralised procedures with outcome in study period
- Exclude
 - ◆ Double-applications, WHO opinion
- Use average scores if 2 rapporteurs completed questionnaires
- Graph Kernel density estimates, non-parametric test (Kruskal-Wallis), logistic regression

Results

- Included products (2006)
 - ◆ 64 products (positive, negative or withdrawn)
- Excluded
 - ◆ 10 Double-applications, WHO opinion
- Outcome

	2003	2004	2006
Negative (%)	9 (26)	7 (23)	17 (27)
Positive (%)	26 (74)	24 (77)	47 (73)
All (%)	35 (100)	31 (100)	64 (100)

Compliance

No. applications	2003 (N=35)	2004 (N=31)	2006 (N=64)	Total (N=130)
≥ 1 form (%)	100	97	94	97
2 forms (%)	87	76	75	78



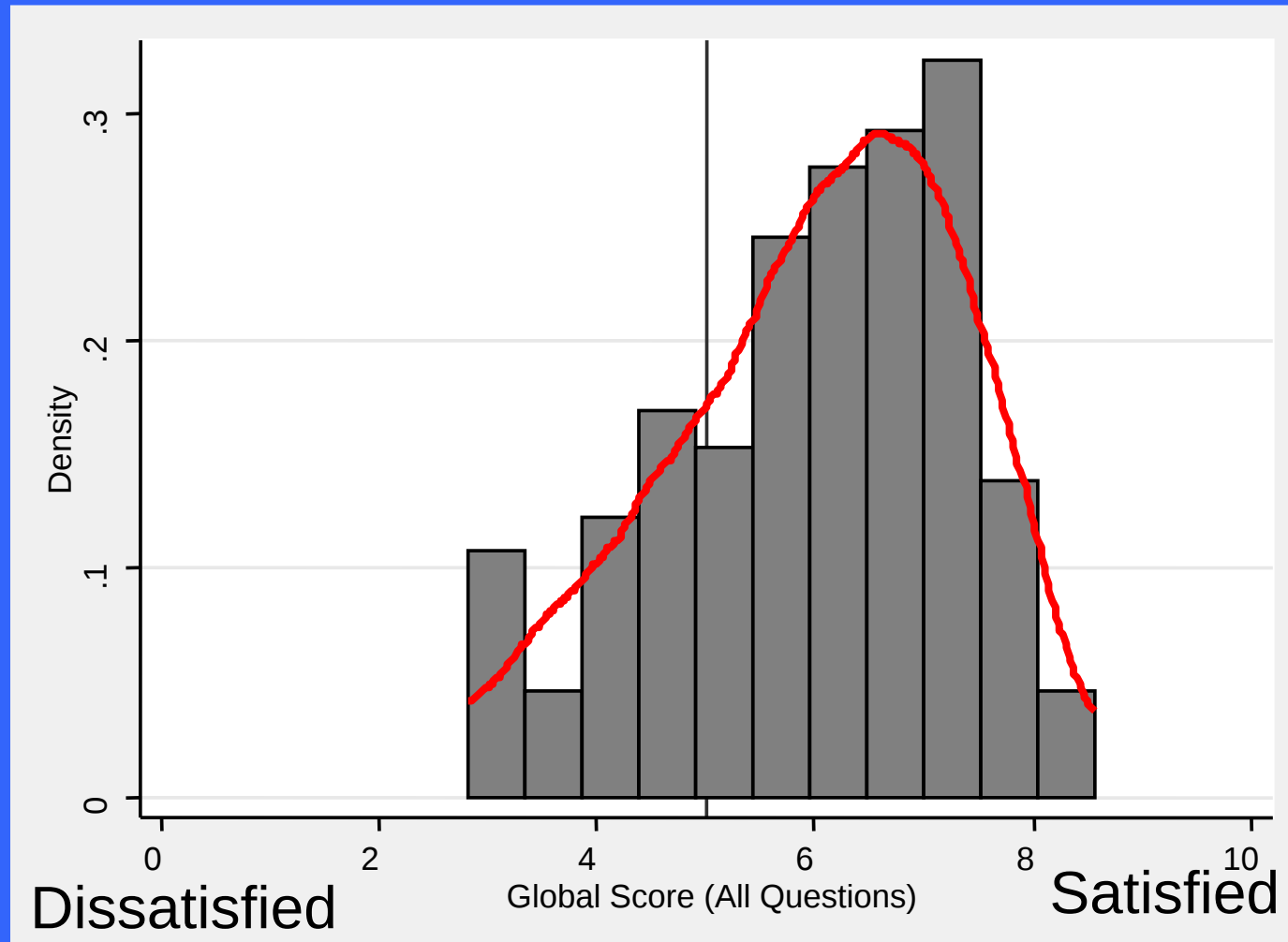
Product Characteristics

		2003 (N=35)	2004 (N=31)	2006 (N=64)	Total (N=130)
Part A/B	A	9(26)	6(19)	18(28)	33(25)
	B	26(74)	25(81)	46(72)	97(75)
ATC	L	14(40)	6(19)	11(17)	31(24)
	J	6(17)	7(23)	13(20)	26(20)
	A	5(14)	4(13)	8(13)	17(13)
	N	1(3)	7(23)	6(9)	14(11)
	Other	9(26)	7(23)	26(41)	42(32)

Product Characteristics

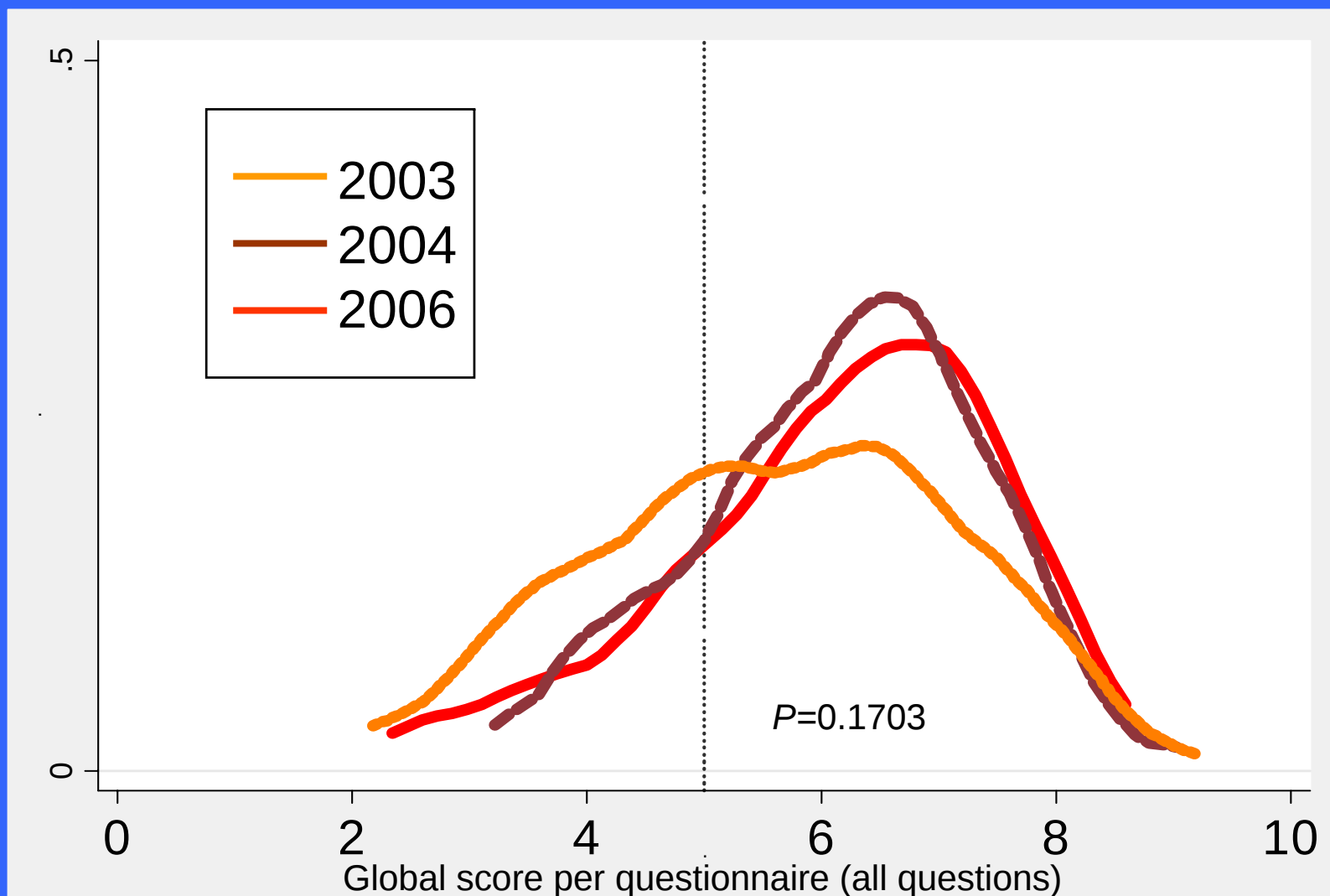
		2003 (N=35)	2004 (N=31)	2006 (N=64)	Total (N=130)
Orphan	Yes	10(29)	8(26)	15(23)	33(25)
	No	25(71)	23(74)	49(77)	97(75)
Scientific Advice	Yes	8(23)	11(35)	22(34)	41(32)
	No	27(77)	20(65)	42(66)	89(68)

Global Score (All Years, N=130)

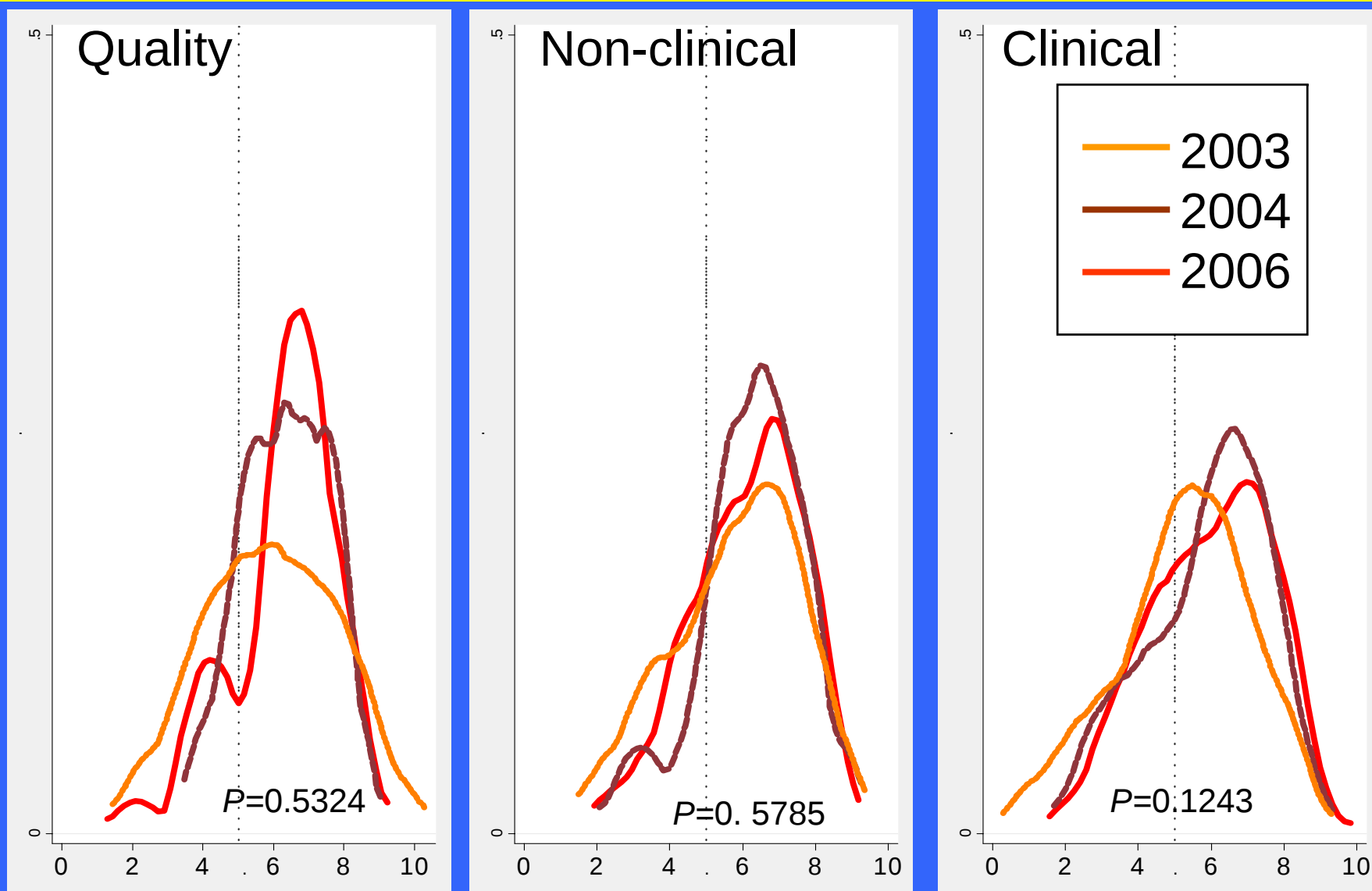


Average score per questionnaire (all questions)

Global Score by Period



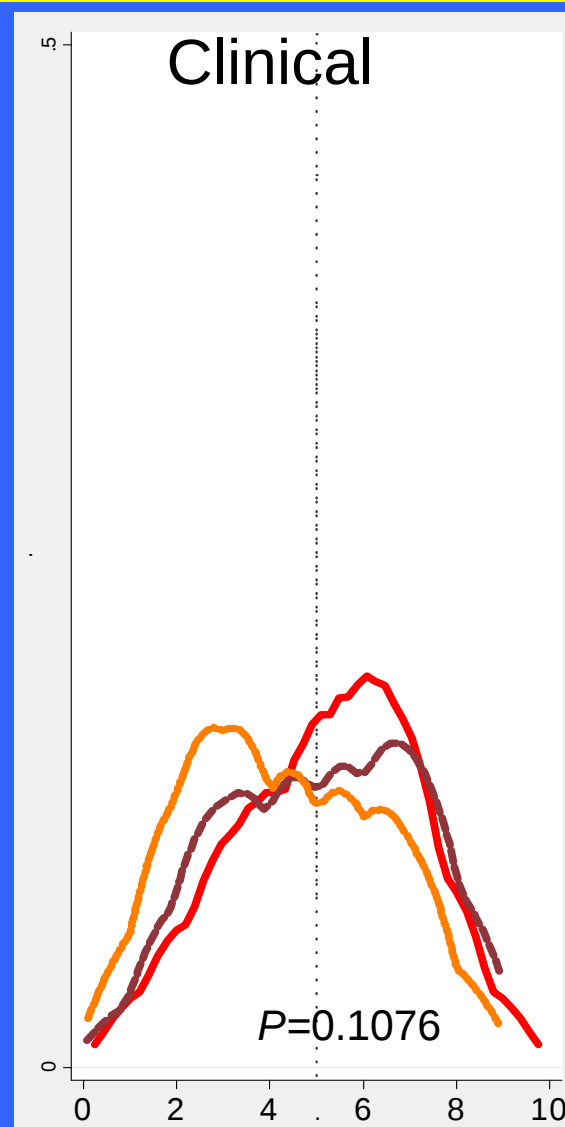
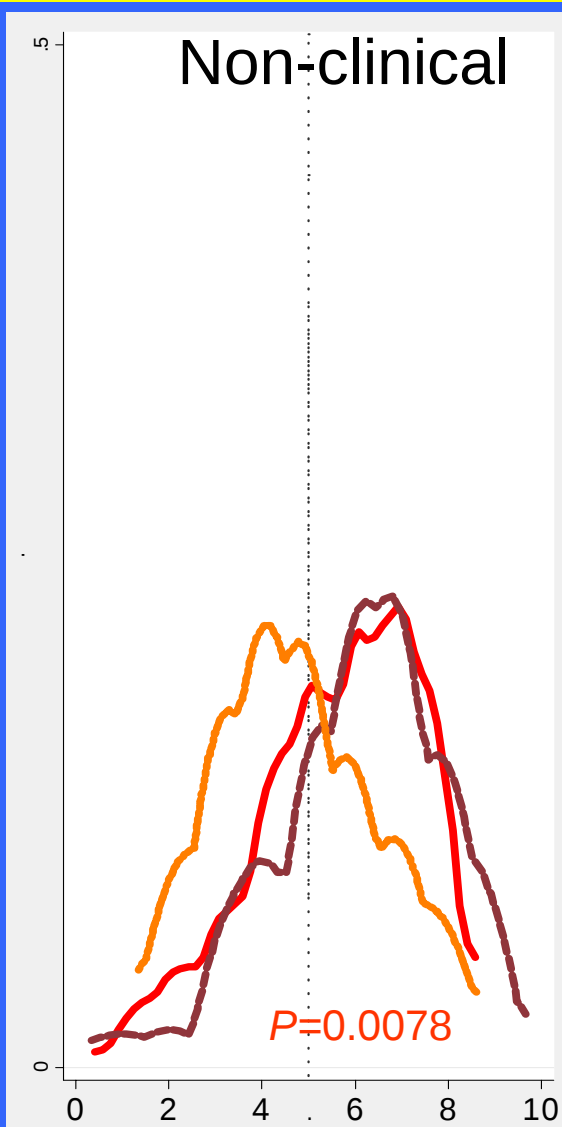
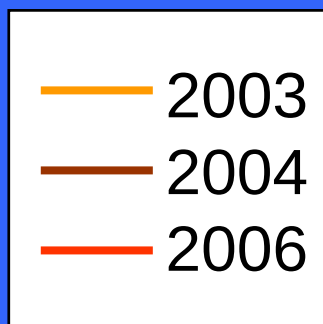
Score Part of Dossier by Period



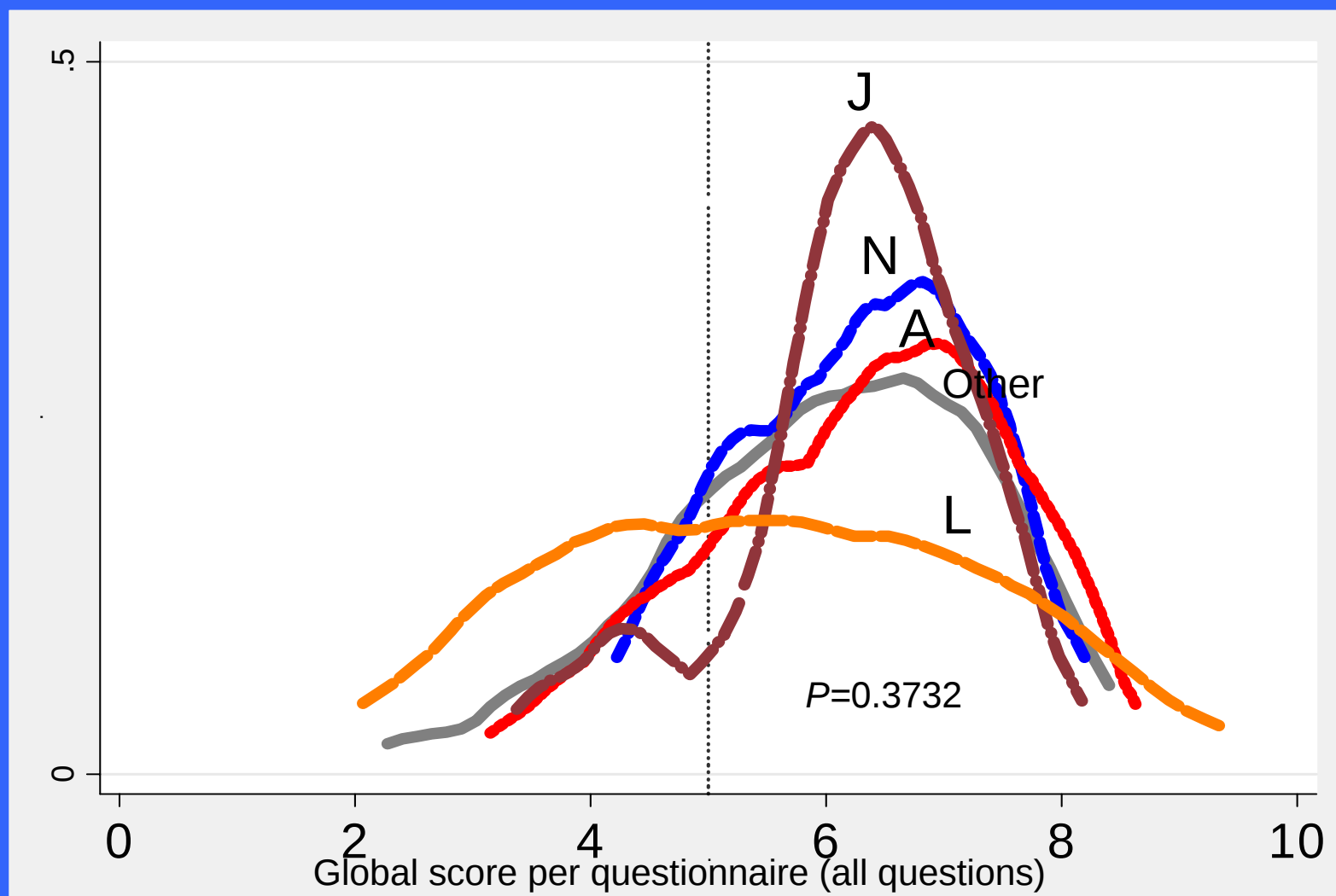
Overview by Period

The scientific overview was sufficiently critical

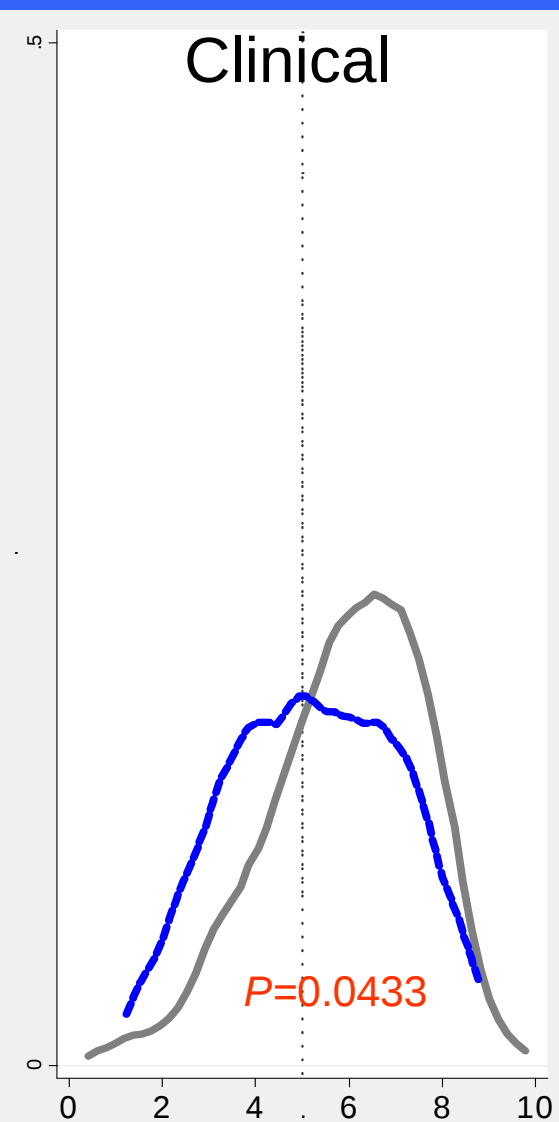
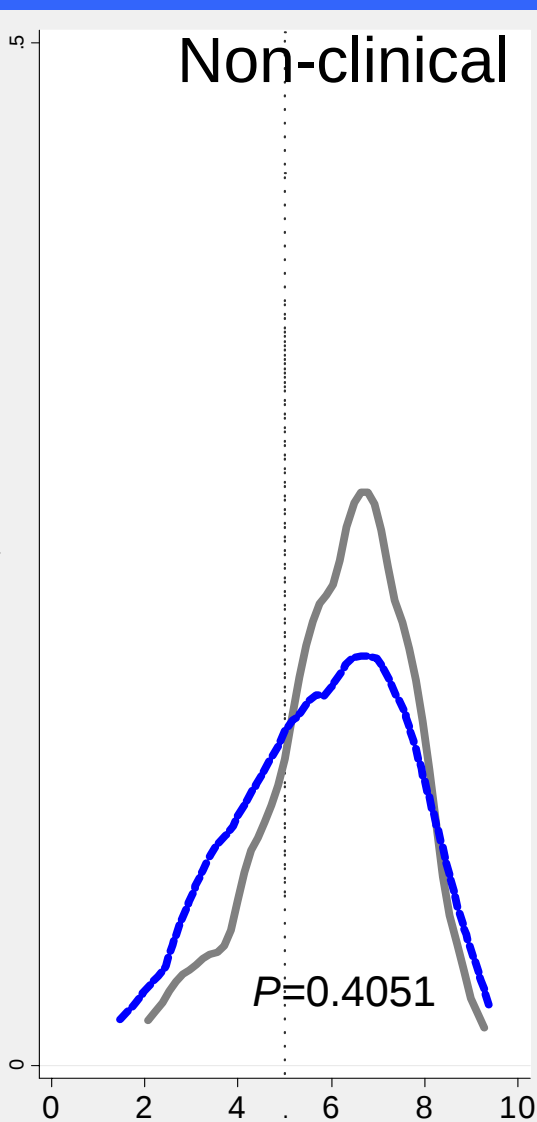
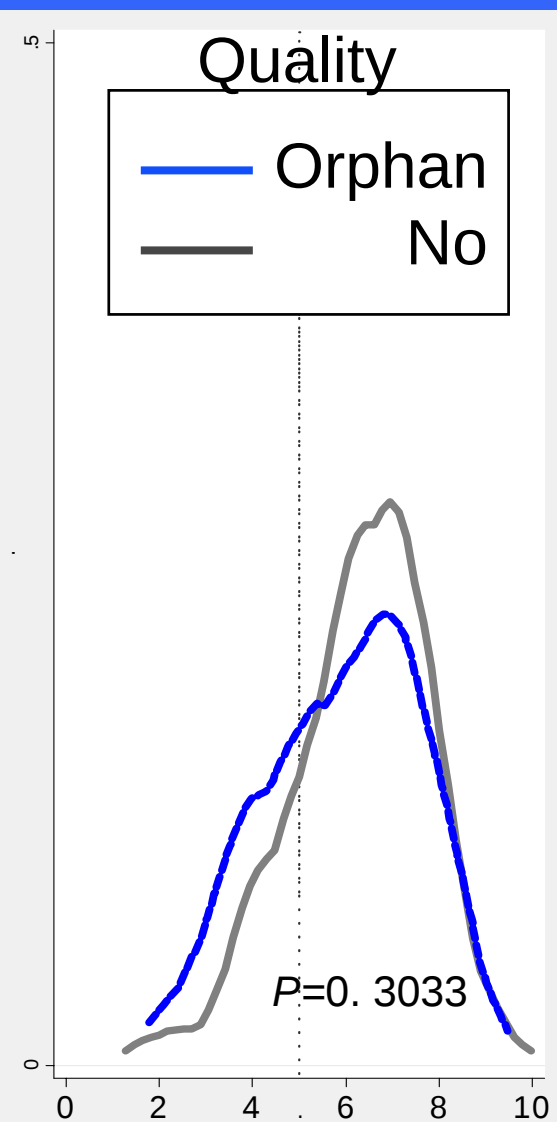
Quality



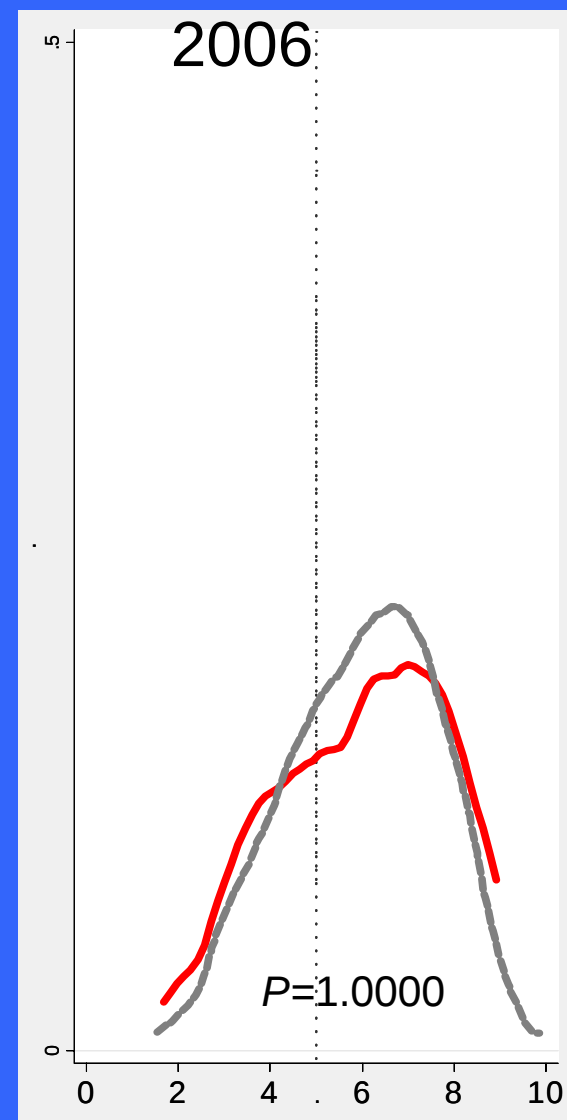
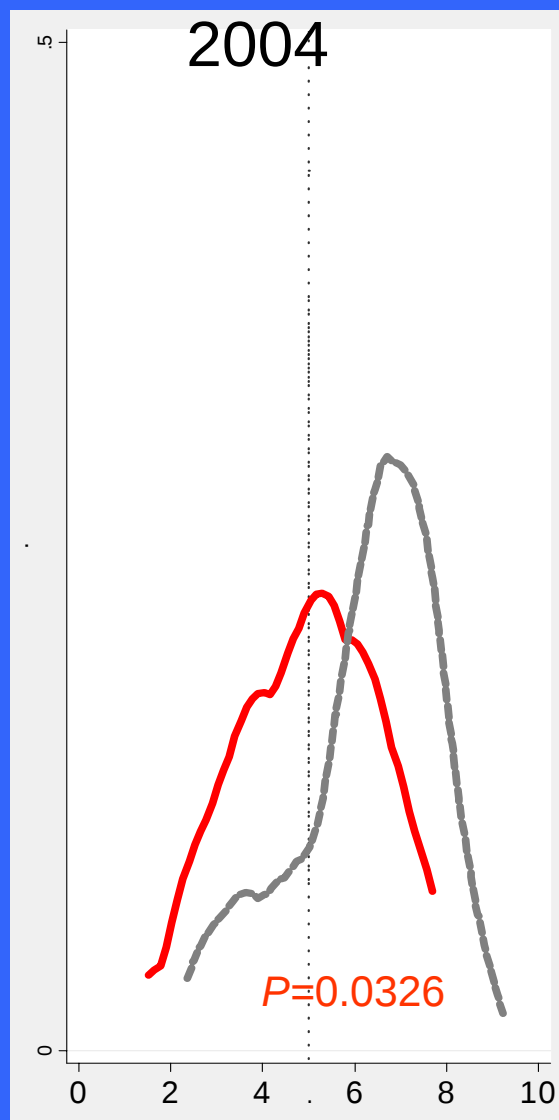
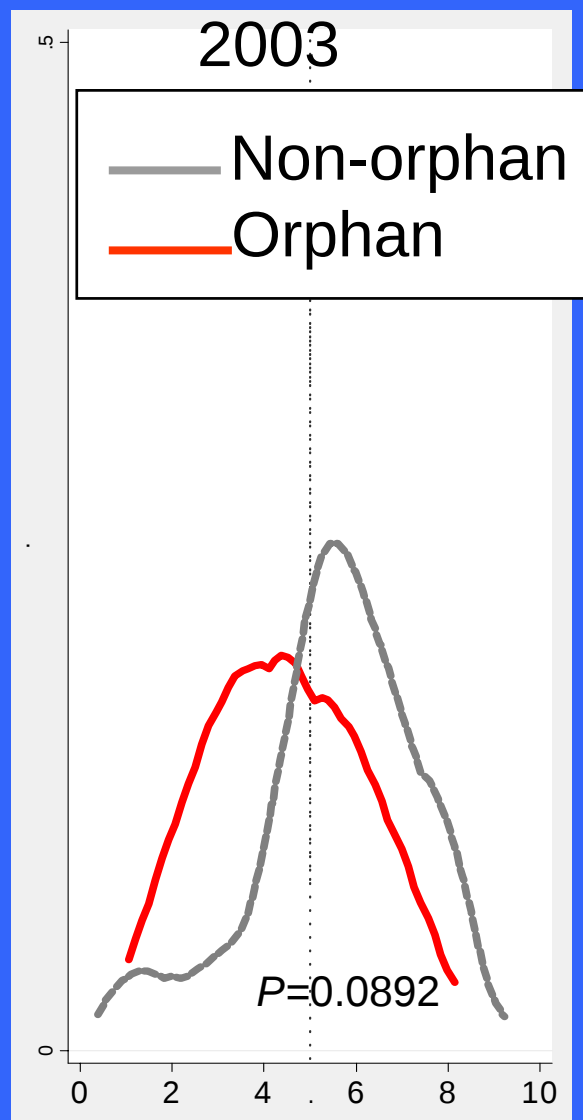
Global Score by ATC Code



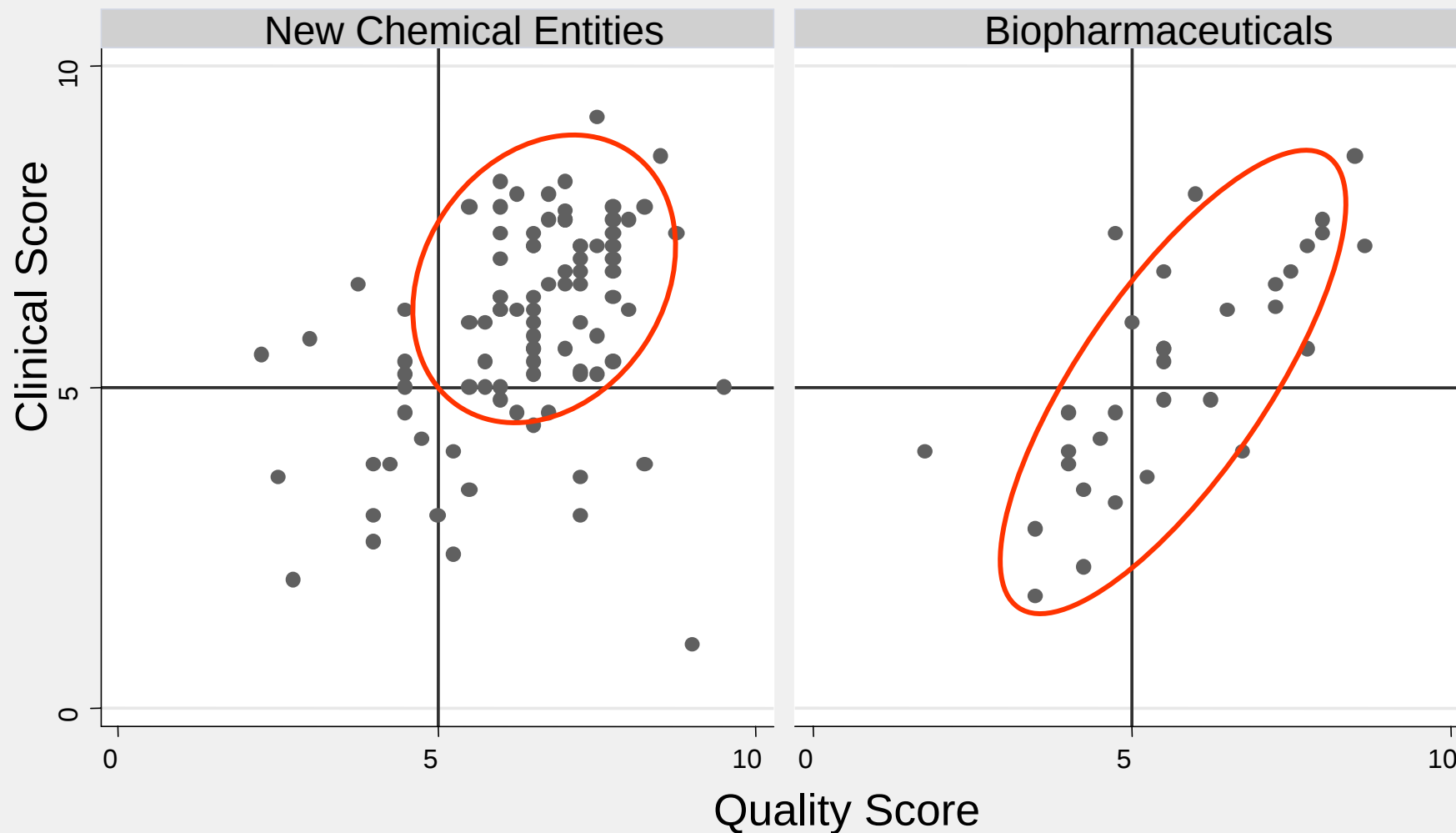
Score Part of Dossier by Orphan Design.



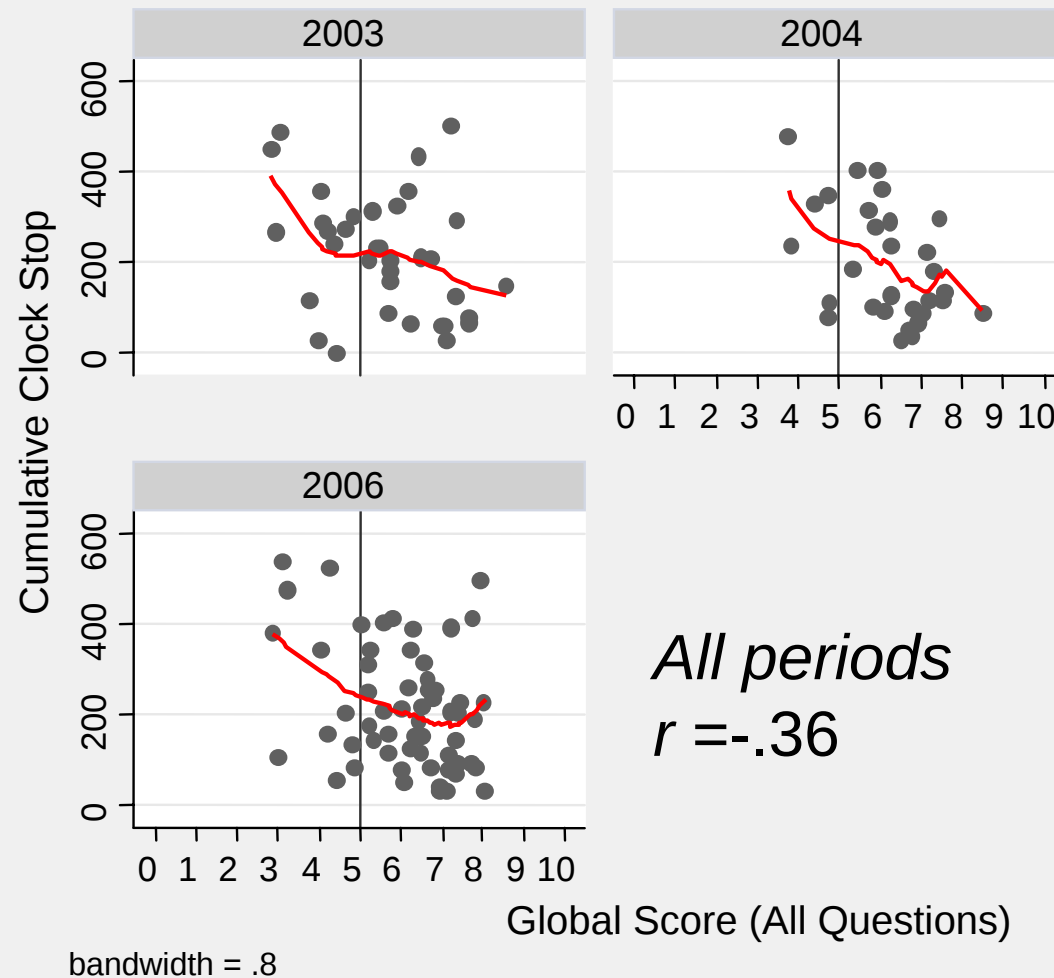
Trend in Clinical Score by Orphan



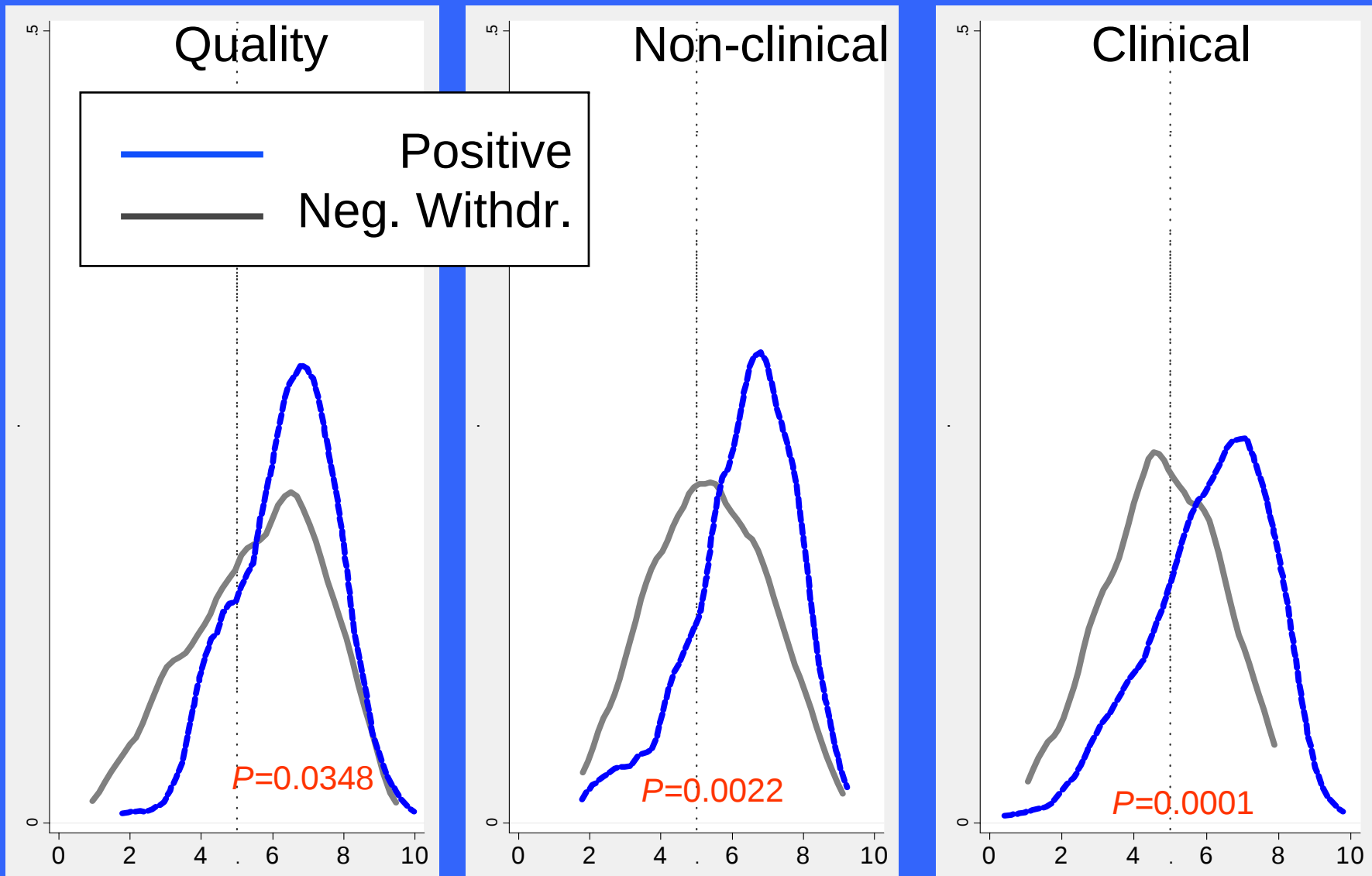
Part A (Biopharmaceuticals)



Global Score and Clock-stop



Score Part of Dossier by Outcome



Outcome

Multivariate logistic regression

		OR	95% C.I		P>z
2003	Clinical score	1.27	1.07	1.51	0.007
	Orphan	.52	.12	2.32	0.394
2004	Clinical score	1.56	1.17	2.08	0.002
	Orphan	.11	.01	.85	0.035
2006	Clinical score	1.27	1.12	1.43	0.000
	Orphan	.45	.12	1.68	0.235
All	Clinical score	1.31	1.20	1.44	0.000
	Orphan	.36	.15	.85	0.020

The 2007 trends

- Confirm 2005 analysis
- Good compliance
- Average scores are stable over time
 - ◆ Majority satisfaction
- Low scores associated with
 - ◆ Biopharmaceuticals (Q)
 - ◆ Orphan products (C), *trend reversing?*
 - ◆ Clockstop, Negative outcome
- High clinical score and non-orphan status are associated with positive outcome

Acknowledgments

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 - ◆ Bo Aronsson
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