

Appendix

Public availability of randomized clinical trial protocols: A repeated meta-research study

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S1) Information on participating ethic committees

Switzerland:

Basel: Ethikkommission Nordwest- und Zentralschweiz (EKNZ), Hebelstrasse 53, 4056 Basel

Bellinzona: Comitato etico cantonale, c/o Ufficio di sanità, Via Orico 5, 6501 Bellinzona

Bern: Kantonale Ethikkommission Bern, Murtenstrasse 31, 3010 Bern

Geneva: Ethics Committee Geneva, Rue Adrien-Lachenal 8, 1207 Genève

Lausanne: Ethics Committee Vaud, Avenue de Chailly 23, 1012 Lausanne

St. Gallen: Ethikkommission Ostschweiz, Oberer Graben 32, 9001 St.Gallen

Thurgau: Has joined the «Ethikkommission Ostschweiz» in 2016. See therefore details for “St. Gallen”

United Kingdom:

Bristol office of the UK National Research Ethics Service: Health Research Authority, Temple Quay House, 2 The Square, Temple Quay, Bristol BS1 6PN

Germany:

Freiburg: Ethik-Kommission der Albert-Ludwigs-Universität Freiburg, Engelberger Strasse 21, 79106 Freiburg

Canada:

Hamilton: Hamilton Integrated Research Ethics Board (HiREB), 293 Wellington Street North, Suite 102, Hamilton Ontario, L8L 8E7

S2) Model specification

Multivariable logistic regression model, 2016

$$\begin{aligned}\text{logit}(P(\text{protocol_identified} = 1)) = & \beta_0 + \beta_1(\text{target_ss_categorized} > 500) \\ & + \beta_2(\text{target_ss_categorized} \in [100, 500]) \\ & + \beta_3(\text{Protocol_Singlmult} = \text{Multi center}) \\ & + \beta_4(\text{Sponsor} = \text{Non-Industry}) \\ & + \beta_5(\text{Protocol_Intervention_cat} = \text{Drug})\end{aligned}$$

Where the predictors are binary for:

- Target sample size (categorized into >500, [100,500], and <100 [reference])
- RCT type (Multicenter vs. Single center [reference])
- Sponsorship (Non-Industry vs. Industry [reference])
- Type of intervention (Drug vs. No-drug [reference])

Multivariable logistic regression model

$$\begin{aligned}\text{logit}(P(\text{protocol_identified} = 1)) = & \beta_0 + \beta_1(\text{target_ss_categorized} > 500) \\ & + \beta_2(\text{target_ss_categorized} \in [100, 500]) \\ & + \beta_3(\text{Protocol_Singlmult} = \text{Multi center}) \\ & + \beta_4(\text{Sponsor} = \text{Non-Industry}) \\ & + \beta_5(\text{Protocol_Intervention_cat} = \text{Drug})\end{aligned}$$

Where the predictors are binary for:

- Target sample size (categorized into >500, [100,500], and <100 [reference])
- RCT type (Multicenter vs. Single center [reference])
- Sponsorship (Non-Industry vs. Industry [reference])
- Type of intervention (Drug vs. No-drug [reference])

Multivariable logistic regression model, combined data sets (2016 and 2012), with interaction term

$$\begin{aligned} \text{logit}(P(\text{protocol_identified} = 1)) = & \beta_0 + \beta_1(\text{target_ss_categorized} > 500) \\ & + \beta_2(\text{target_ss_categorized} \in [100, 500]) \\ & + \beta_3(\text{Protocol_Singlmult} = \text{Multi center}) \\ & + \beta_4(\text{Sponsor} = \text{Non-Industry}) \\ & + \beta_5(\text{Protocol_Intervention_cat} = \text{Drug}) \\ & + \beta_6(\text{year} = 2016) \\ & + \beta_7(\text{Sponsor} = \text{Non-Industry} \cap \text{year} = 2016) \end{aligned}$$

Where the predictors are binary for:

- Target sample size (categorized into >500, [100,500], and <100 [reference])
- RCT type (Multicenter vs. Single center [reference])
- Sponsorship (Non-Industry vs. Industry [reference])
- Type of intervention (Drug vs. No-drug [reference])
- Year (2016 vs. 2012 [reference])

Multivariable logistic regression model, combined data sets (2016 and 2012), without interaction term

$$\begin{aligned} \text{logit}(P(\text{protocol_identified} = 1)) = & \beta_0 + \beta_1(\text{target_ss_categorized} > 500) \\ & + \beta_2(\text{target_ss_categorized} \in [100, 500]) \\ & + \beta_3(\text{Protocol_Singlmult} = \text{Multi center}) \\ & + \beta_4(\text{Sponsor} = \text{Non-Industry}) \\ & + \beta_5(\text{Protocol_Intervention_cat} = \text{Drug}) \\ & + \beta_6(\text{year} = 2016) \end{aligned}$$

Where the predictors are binary for:

- Target sample size (categorized into >500, [100,500], and <100 [reference])
- RCT type (Multicenter vs. Single center [reference])
- Sponsorship (Non-Industry vs. Industry [reference])
- Type of intervention (Drug vs. No-drug [reference])
- Year (2016 vs. 2012 [reference])

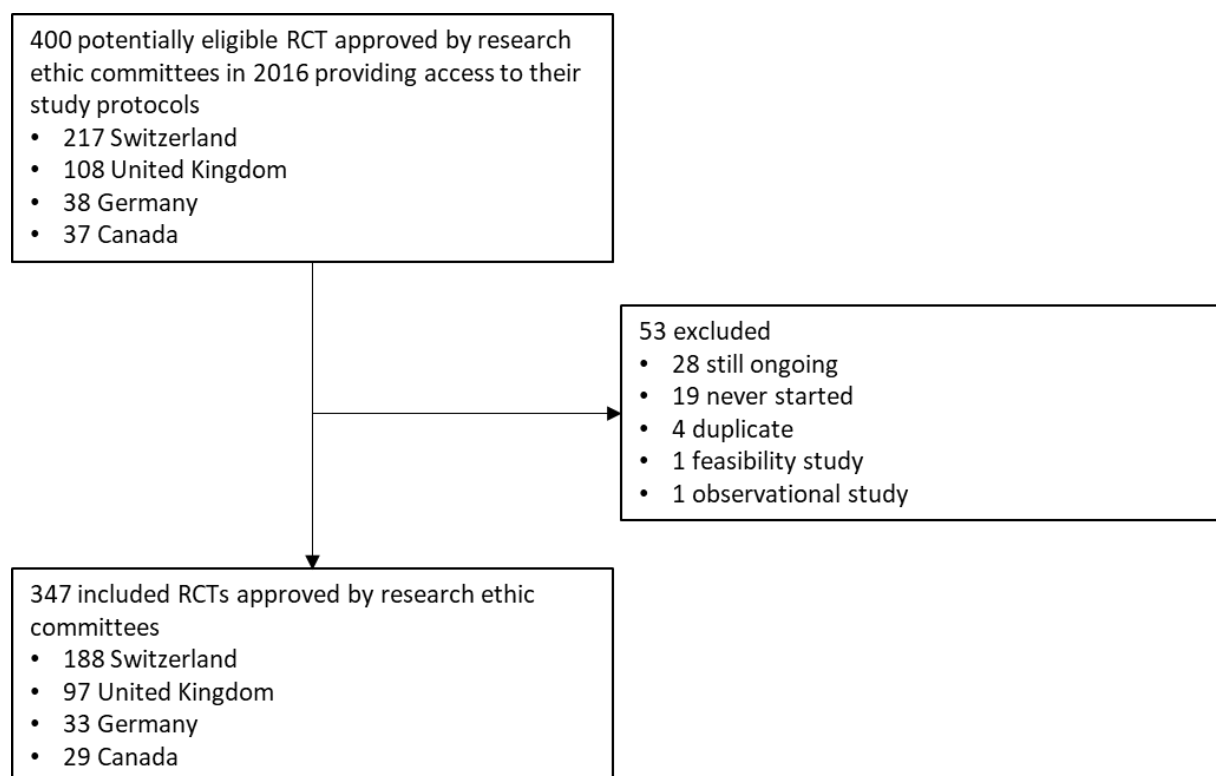
S3) R: Session info and used packages

R version 4.4.1 (2024-06-14)

Platform: x86_64-apple-darwin20
Running under: macOS 15.3.1

Tidyverse	Wickham H, Averick M, Bryan J, Chang W, McGowan LD, François R, Golemund G, Hayes A, Henry L, Hester J, Kuhn M, Pedersen TL, Miller E, Bache SM, Müller K, Ooms J, Robinson D, Seidel DP, Spinu V, Takahashi K, Vaughan D, Wilke C, Woo K, Yutani H (2019). "Welcome to the tidyverse." <i>Journal of Open Source Software</i> , *4*(43), 1686. doi: 10.21105/joss.01686 (URL: https://doi.org/10.21105/joss.01686).
knitr	Xie Y (2024). <i>_knitr: A General-Purpose Package for Dynamic Report Generation in R_</i> . R package version 1.48, https://yihui.org/knitr/
writexl	Ooms J (2024). <i>_writexl: Export Data Frames to Excel 'xlsx' Format_</i> . R package version 1.5.0, https://CRAN.R-project.org/package=writexl
margrittr	Stefan Milton Bache and Hadley Wickham (2022). <i>magrittr: A Forward-Pipe Operator for R</i> . R package version 2.0.3. https://CRAN.R-project.org/package=magrittr
readxl	Hadley Wickham and Jennifer Bryan (2023). <i>readxl: Read Excel Files</i> . R package version 1.4.3. https://CRAN.R-project.org/package=readxl
stringr	Wickham H (2023). <i>_stringr: Simple, Consistent Wrappers for Common String Operations_</i> . R package version 1.5.1, https://CRAN.R-project.org/package=stringr
kableExtra	Zhu H (2024). <i>_kableExtra: Construct Complex Table with 'kable' and Pipe Syntax_</i> . R package version 1.4.0, https://CRAN.R-project.org/package=kableExtra
tableone	Kazuki Yoshida and Alexander Bartel (2022). <i>tableone: Create 'Table 1' to Describe Baseline Characteristics with or without Propensity Score Weights</i> . R package version 0.13.2. https://CRAN.R-project.org/package=tableone
lubridate	Garrett Golemund, Hadley Wickham (2011). <i>Dates and Times Made Easy with lubridate</i> . <i>Journal of Statistical Software</i> , 40(3), 1-25. URL https://www.jstatsoft.org/v40/i03/ .
skimr	Elin Waring, Michael Quinn, Amelia McNamara, Eduardo Arino de la Rubia, Hao Zhu and Shannon Ellis (2022). <i>skimr: Compact and Flexible Summaries of Data</i> . R package version 2.1.5. https://CRAN.R-project.org/package=skimr
officer	Gohel D, Moog S (2024). <i>_officer: Manipulation of Microsoft Word and PowerPoint Documents_</i> . R package version 0.6.6, https://CRAN.R-project.org/package=officer
ggplot2	H. Wickham. <i>ggplot2: Elegant Graphics for Data Analysis</i> . Springer-Verlag New York, 2016.
broom	Robinson D, Hayes A, Couch S (2024). <i>_broom: Convert Statistical Objects into Tidy Tibbles_</i> . R package version 1.0.6, https://CRAN.R-project.org/package=broom
pscl	Simon Jackman (2024). <i>pscl: Classes and Methods for R Developed in the Political Science Computational Laboratory</i> . Sydney, Australia. R package version 1.5.9. URL https://github.com/atahk/pscl/
car	Fox J, Weisberg S (2019). <i>_An R Companion to Applied Regression_, Third edition</i> . Sage, Thousand Oaks CA. < https://www.john-fox.ca/Companion/ >.
lmtest	Achim Zeileis, Torsten Hothorn (2002). <i>Diagnostic Checking in Regression Relationships</i> . <i>R News</i> 2(3), 7-10. URL https://CRAN.R-project.org/doc/Rnews/
sandwich	Zeileis A (2004). "Econometric Computing with HC and HAC Covariance Matrix Estimators." <i>Journal of Statistical Software</i> , *11*(10), 1-17. doi:10.18637/jss.v011.i10 < https://doi.org/10.18637/jss.v011.i10 >.

S4) Flow chart of RCT selection



S5) Additional characteristics of included RCTs 2016

RCT characteristics	All included RCTs (n=347)	RCTs with publicly available protocol (n=228)	RCTs with <u>no</u> publicly available protocol (n=119)
Trial design			
Parallel	322 (92.8%)	217/322 (67.4%)	105/322 (32.6%)
Crossover	13 (3.7%)	3/13 (23.1%)	10/13 (76.9%)

Factorial	5 (1.4%)	4/5 (80.0%)	1/5 (20.0%)
Cluster	4 (1.2%)	3/4 (75.0%)	1/4 (25.0%)
Split Body	3 (0.9%)	1/3 (33.3%)	2/3 (66.7%)
Single center vs. multicenter			
Single center	82 (23.6%)	22/82 (26.8%)	60/82 (73.2%)
Multicenter	265 (76.4%)	206/265 (77.7%)	59/265 (22.3%)
International	207 (59.7%)	170/207 (82.1%)	37/207 (17.9%)
National	58 (16.7%)	36/58 (62.1%)	22/58 (37.9%)
Trial registration			
Yes	346 (99.7%)	228/346 (65.9%)	118/346 (34.1%)
No	1 (0.3%)	0/1 (0%)	1/1 (100%)
Status			
Completed	226 (65.1%)	174/226 (77.0%)	52/226 (24.8%)
Discontinued	108 (31.1%)	52/108 (48.1%)	56/108 (51.9%)
Unclear	13 (3.7%)	2/13 (15.4%)	11/13 (84.6%)

S6) Baseline characteristics of included RCTs 2016 vs 2012

	2016		2012	
Trial characteristics	All included RCTs (n=347)	RCTs with publicly available protocol (n=228)	All included RCTs (n=326)	RCTs with publicly available protocol (n=118)
Sponsorship (%)				
Industry	181 (52.2)	151/181 (83.4)	179 (54.9)	62/179 (34.6)
Non-Industry	166 (47.8)	77/166 (46.4)	147 (45.1)	56/147 (38.1)

Trial design (%)				
Cluster	4 (1.2)	3/4 (75.0)	4 (1.2)	3/4 (75.0)
Crossover	13 (3.7)	3/13 (23.1)	0/0 (0)	0/0 (0)
Factorial	5 (1.4)	4/5 (80.0)	10 (3.1)	6/10 (60.0)
Parallel	322 (92.8)	217/322 (67.4)	296 (90.8)	109/296 (36.8)
Split Body	3 (0.9)	1/3 (33.4)	0/0 (0)	0/0 (0)
Drug vs. non-drug intervention				
Drug	212 (61.1)	163/212 (76.8)	207 (63.5)	77/207 (37.2)
Non-Drug	135 (38.9)	65/135 (48.1)	119 (36.5)	41/119 (34.5)
Single center vs. multicenter				
Single center	82 (23.6)	22/82 (26.8)	60 (18.4)	12/60 (20.0)
Multicenter	265 (76.4)	206/265 (77.7)	266 (81.6)	106/266 (39.8)
RCT result publication available (%)				
Yes	248 (71.5)	189/248 (76.2)	256 (78.5)	110/256 (43.0)
Number of participants				
<100	79 (22.8)	29/79 (36.7)	73 (22.4)	14/73 (19.2)
100-500	191 (55.0)	131/191 (68.6)	151 (46.3)	45/151 (29.8)
>500	77 (22.2)	68/77 (88.3)	102 (31.3)	59/102 (57.8)
Country of ethical approval (%)				
Canada	29 (8.4)	22/29 (75.9)	35 (10.7)	20/35 (57.1)
Germany	33 (9.5)	24/33 (72.7)	37 (11.3)	9/37 (24.3)
Switzerland	188 (54.2)	109/188 (58.0)	165 (50.6)	54/165 (32.7)
UK	97 (28.0)	73/97 (75.3)	89 (27.3)	35/89 (39.3)

S7) Protocol availability and sources of available protocols; 2016 compared to 2012 stratified by sponsor

Protocol availability	2016			2012		
Sponsorship	Industry (n=181)	Non-Industry (n=166)	Overall (n=347)	Industry (n=179)	Non-Industry (n=147)	Overall (n=326)
No protocol Identified (%)	30/181 (16.6%)	89/166 (53.6%)	119/347 (34.3)	117/179 (65.4%)	91/147 (61.9%)	208/326 (63.8)
Protocol identified (%)	151/181 (83.4%)	77/166 (46.4%)	228/347 (65.7)	62/179 (36.8%)	56/147 (38.1%)	118/326 (36.2)

As a file on a clinical trial registry	135/181 (74.6%)	15/166 (9.0%)	150/347 ¹ (43.2%)	11/179 (6.1%)	2/147 (1.4%)	13/326 (4.0%) ²
As a supplementary file to the result publication	61/181 (33.7%)	30/166 (18.1%)	91/347 (26.2%)	37/179 (20.7%)	11/147 (7.5%)	48/326 (14.7%)
Peer-reviewed publication	31/181 (17.1%)	50/166 (30.1%)	81/347 (23.3%)	13/179 (7.3%)	43/147 (29.3%)	56/326 (17.2%)
As a file on the trial website	5/181 (2.8%)	4/166 (2.4%)	9/347 (2.6%)	2/179 (1.1%)	0/147	2/326 (0.6%)
As a PDF file on google scholar	0/181	2/166 (1.2%)	2/347 (0.6%)	0/179	0/147	1/326 (0.3%)
Other	0/181	4/166 (1.2%)	4/347 ³ (1.2%)	0/179	0/147	0/326 ⁴

¹ clinicaltrials.gov (n=146), ISRCTN registry (n=2), DRKS registry (n=1), ANZCTR registry (n=1)

² clinicaltrials.gov (n=12), DRKS registry (n=1)

³Other 2016: PDF on Google (n=1), Study protocol for the pilot RCT (n=1), pre-print (n=1)

⁴Other 2012: DRKS registry (n=1)

S8) Linkage of available trial protocols to registries and result publications

Trial characteristics	RCTs with publicly available protocol 2016 (n=228)	RCT with publicly available protocol 2012 (n=118)
Protocol linked to trial registry		
No	32/228 (14.0%)	52/118 (44.1%)
Yes	196/228 (86.0%)	66/118 (55.9%)
Protocol linked to RCT result publication		
No	43/228 (18.9%)	10/118 (8.5%)
Not applicable since no result publication available	45/228 (19.7%)	8/118 (6.8%)
Yes	140/228 (61.4%)	100/118 (84.7%)

S9) Characteristics associated with protocol availability (logistic regression); 2016 compared to 2012

2016								
Characteristics		Protocol not	OR	95% CI	P value	OR	95% CI	P value

	Protocol available (n=228)	available (n=119)	Univariable			Multivariable		
Sample size <100	29 (12.7%)	50 (42.0%)	Reference					
Sample size 100-500	131 (57.5%)	60 (50.4%)	3.76	2.17-6.53	<0.001	2.36	1.25-4.43	0.008
Sample size >500	68 (29.8%)	9 (7.6%)	13.03	5.67-29.94	<0.001	6.00	2.39-15.06	<0.001
Multicenter (vs. single center)	206 (90.4%)	59 (49.6%)	9.52	5.40-16.80	<0.001	3.17	1.61-6.24	0.001
Non-industry (vs. industry)	77 (33.8%)	89 (74.8%)	0.17	0.11-0.28	<0.001	0.37	0.20-0.68	0.002
Drug (vs. non-drug)	163 (71.5)	49 (41.2)	3.58	2.251-5.702	<0.001	1.447	0.81-2.60	0.216
2012								
Characteristics	Protocol available (n=118)	Protocol not available (n=208)	OR	95% CI	P value	OR	95% CI	P value
			Univariable			Multivariable		
Sample size <100	14 (11.9%)	59 (28.4%)	Reference					
Sample size 100-500	45 (38.1%)	106 (51.0%)	1.79	0.93-3.63	0.093	1.83	0.91-3.83	0.09
Sample size >500	59 (50%)	43 (20.7%)	5.78	2.93-12.02	<0.001	5.90	2.75-13.31	<0.001
Multicenter (vs. single center)	106 (89.8%)	160 (76.9%)	2.65	1.38-5.44	0.005	2.01	0.92-4.62	0.087
Non-industry (vs. industry)	56 (47.5%)	91 (43.8%)	1.16	0.74-1.83	0.518	1.99	1.11-3.59	0.021
Drug (vs. non-drug)	77 (65.3%)	130 (62.5%)	1.13	0.71-1.81	0.619	0.92	0.51-1.68	0.788

S10) Characteristics associated with protocol availability (logistic regression); 2012 and 2016 combined (pooled data sets) without interaction term

Characteristics	Protocol available (n=346)	Protocol not available (n=327)	OR	95% CI	P value
Univariable					
Sample size <100	14 (4.0%)	29 (8.9%)	Reference		
Sample size 100-500	176 (50.9%)	166 (50.8%)	2.69	1.78-4.06	<0.001
Sample size >500	127 (36.7%)	52 (15.9%)	6.19	3.84-9.99	<0.001

Characteristics	Protocol available (n=346)	Protocol not available (n=327)	OR	95% CI	P value
Multicenter (vs. single center)	312 (90.2)	219 (67.0%)	4.53	2.97-6.90	<0.001
Non-industry (vs. industry)	133 (38.4%)	180 (55.0%)	0.51	0.38-0.69	<0.001
Drug (vs. non-drug)	240 (69.4%)	179 (54.7%)	1.87	1.37-2.57	<0.001
2016 (vs. 2012)	228 (65.9%)	119 (36.4%)	3.38	2.46-4.64	<0.001
Multivariable					
Sample size <100	14 (4.01%)	29 (8.9%)	Reference		
Sample size 100-500 (multi)	176 (50.9%)	166 (50.8%)	1.97	1.23-3.13	0.005
Sample size >500 (multi)	127 (36.7%)	52 (15.9%)	5.08	2.90-8.90	<0.001
Multicenter (vs. single center) (multi)	312 (90.2%)	219 (67.0%)	3.41	1.99-5.84	<0.001
Non-industry (vs. industry)	133 (38.4)	180 (55.0%)	0.92	0.61-1.40	0.696
Drug (vs. non-drug) (multi)	240 (69.4)	179 (54.7%)	1.14	0.75-1.72	0.543
2016 (vs. 2012) (multi)	228 (65.9)	119 (36.4%)	5.03	3.49-7.27	<0.001

S11) Characteristics associated with protocol availability (logistic regression); 2012 and 2016 combined (pooled data sets) with interaction term

The significant interaction term indicates dependence of sponsorship and year. If the year is fixed to 2012, non-industry sponsored trials have higher odds for protocol availability (OR: 2.38; 95% CI 1.39-4.11; p=0.001) similar to trials approved in 2016 when sponsorship is fixed to industry (OR: 13.47; 95% CI 7.96-23.50; p<0.001).

Characteristics	Protocol available (n=346)	Protocol not available (n=327)	OR	95% CI	P value
Sample size <100	14 (4.01%)	29 (8.9%)	Reference		
Sample size 100-500 (multi)	176 (50.9%)	166 (50.8%)	2.12	1.32-3.43	0.001

Characteristics	Protocol available (n=346)	Protocol not available (n=327)	OR	95% CI	P value
Sample size >500 (multi)	127 (36.7%)	52 (15.9%)	6.12	3.45-11.07	<0.001
Multicenter (vs. single center) (multi)	312 (90.2%)	219 (67.0%)	2.66	1.59-4.52	<0.001
Drug (vs. non-drug) (multi)	240 (69.4)	179 (54.7%)	1.15	0.75-1.74	0.520
Non-industry (vs. industry) ¹	133 (38.4)	180 (55.0%)	2.38	1.39-4.11	0.001
2016 (vs. 2012) (multi) ²	228 (65.9)	119 (36.4%)	13.47	7.96-23.50	<0.001
Non-Industry*2016 ³			0.13	0.06-0.27	<0.001

¹ Fixed on year=2012

² Fixed on sponsorship=industry

³ Interaction term to account for interaction of year of RCT approval and sponsorship.

S12) Characteristics associated with protocol availability (logistic regression); 2012 and 2016 combined (pooled data sets) with interaction term and robust standard errors

Sensitivity analysis to assess factors associated with making trial RCT protocols available using conservative cluster-robust standard errors with covariance matrix estimation HC3 bias adjustment to account for potential country-level correlation in the data.¹

Characteristics	Protocol available (n=346)	Protocol not available (n=327)	OR	95% CI	P value
Sample size <100	14 (4.01%)	29 (8.9%)	Reference		
Sample size 100-500 (multi)	176 (50.9%)	166 (50.8%)	2.12	1.56- 2.88	<0.001
Sample size >500 (multi)	127 (36.7%)	52 (15.9%)	6.12	3.37- 11.13	<0.001

Characteristics	Protocol available (n=346)	Protocol not available (n=327)	OR	95% CI	P value
Multicenter (vs. single center) (multi)	312 (90.2%)	219 (67.0%)	2.66	1.22-5.79	0.014
Drug (vs. non-drug) (multi)	240 (69.4)	179 (54.7%)	1.15	0.75-1.75	0.523
Non-industry (vs. industry) ¹	133 (38.4)	180 (55.0%)	2.38	0.62-9.05	0.204
2016 (vs. 2012) (multi) ²	228 (65.9)	119 (36.4%)	13.47	8.28-21.93	<0.001
Non-Industry*2016 ³			0.13	0.06-0.30	<0.001

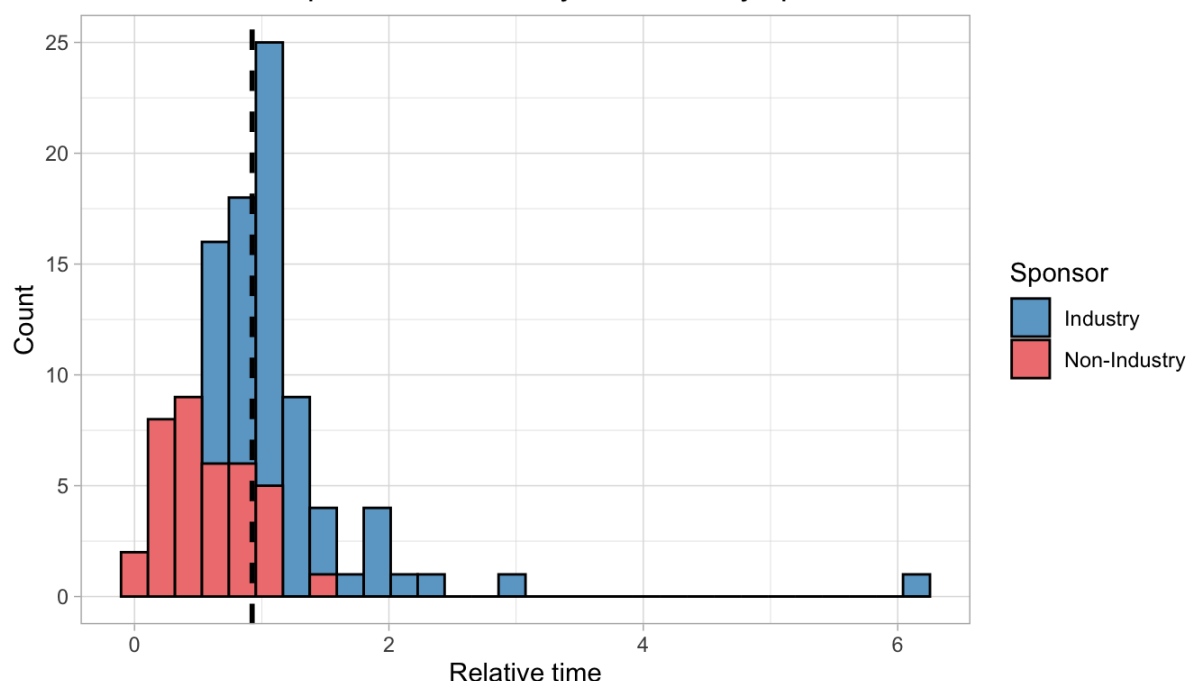
¹ Fixed on year=2012

² Fixed on sponsorship=industry

³ Interaction term to account for interaction of year of RCT approval and sponsorship.

S13) Relative Time Ration (RTR) excluding protocols only available as supplementary material to trial result publication; stratified by sponsor

Relative time of protocol availability, stratified by sponsor



Note:

*relative time = days to protocol availability from start of trial/ days to publication from start of trial

0 = start of trial

1 = publication of trial results

--- median relative time

References

1. Zeileis A. Econometric Computing with HC and HAC Covariance Matrix Estimators. *Journal of Statistical Software* 2004;11(10):1 - 17. DOI: 10.18637/jss.v011.i10.