Publication of summary results for clinical trials without therapeutic or prophylactic intent

Date of survey launch: Wednesday 27 May 2015

94

Responders

88

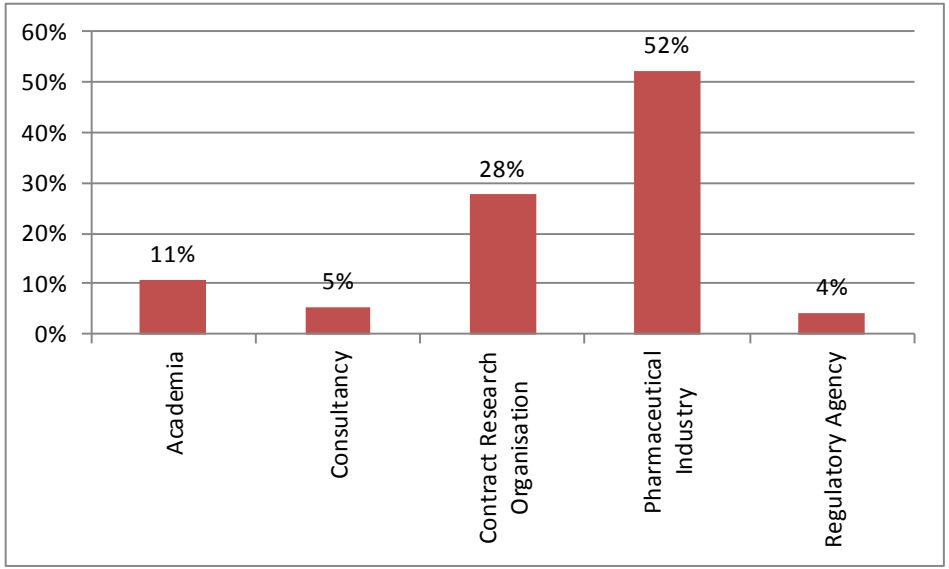
Full Responders

Survey Report; 10 June 2015

© EUFEMED

Q1: This questionnaire is anonymous. Please could you indicate your current professional background (more than one choice is possible):

Answered: 94 Skipped: 0



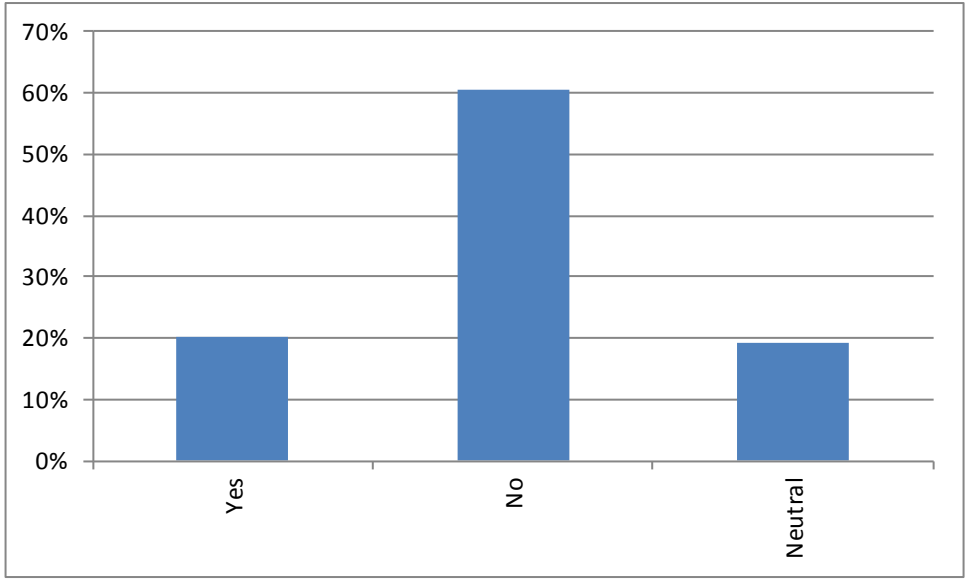
Answer Choices	Responses	Percentage
Academia	10	11%
Consultancy	5	5%
Contract Research Organisation	26	28%
Pharmaceutical Industry	49	52%
Regulatory Agency	4	4%
Grand Total	94	

© EUFEMED

Q2: With regards to academic and commercial clinical trials without therapeutic (or prophylactic) intent (Phase 0, Phase 1, BE and BA trials) and the requirement to publish their (lay) summary results 12 months after the end of the trial;

1. "The information/data provided are relevant to patients, healthcare professionals and the general public; therefore their publication at that time is beneficial to these stakeholders"

Answered: 94 Skipped: 0



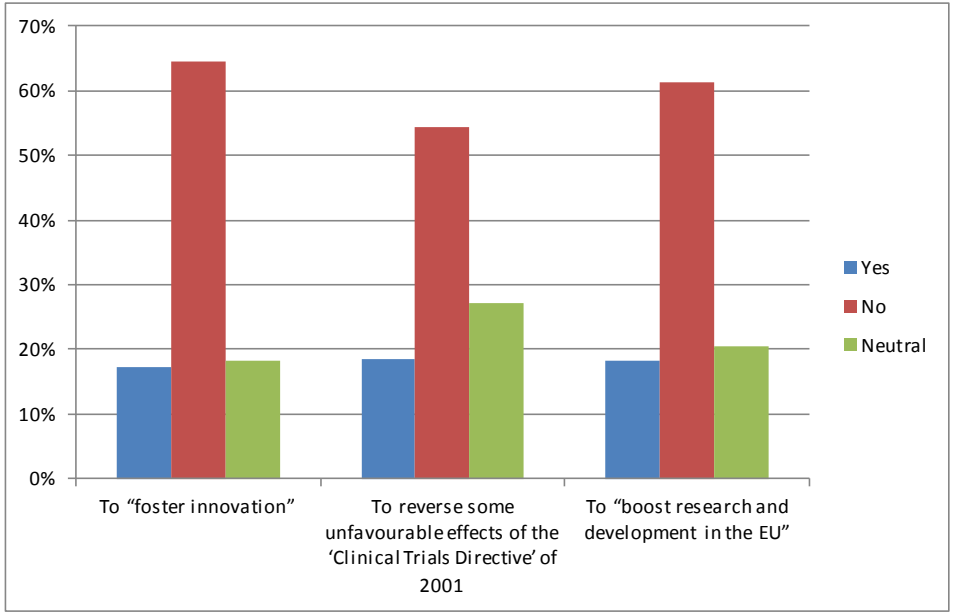
Answer Choices	Responses	Percentage
Yes	19	20%
No	57	61%
Neutral	18	19%
Grand Total	94	

© EUFEMED

Q2: With regards to academic and commercial clinical trials without therapeutic (or prophylactic) intent (Phase 0, Phase 1, BE and BA trials) and the requirement to publish their (lay) summary results 12 months after the end of the trial;

2. "The public availability of these summary results at that time meets the objectives of the new EU CTR"

Answered: 93 Skipped: 1



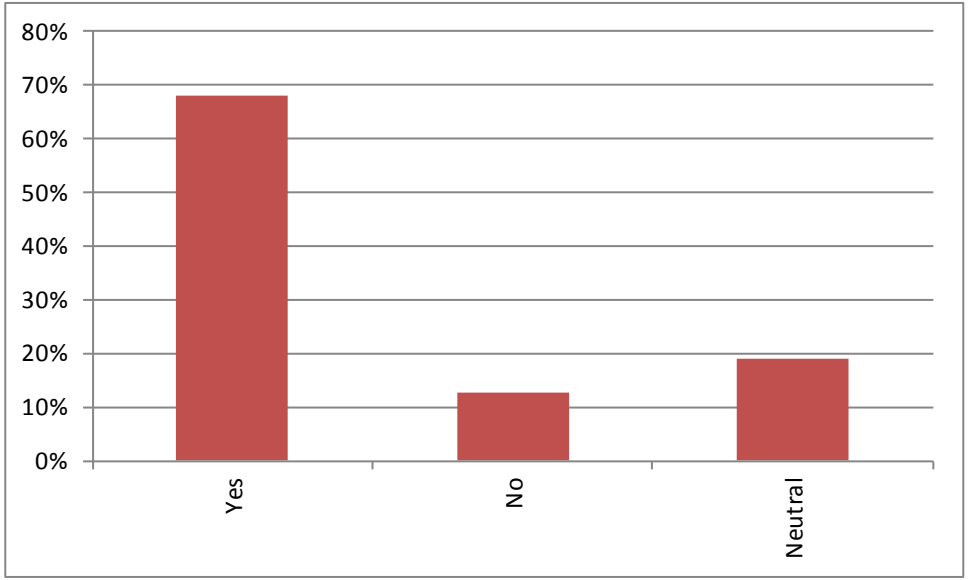
	Yes	No	Neutral	Total
To "foster innovation"	16	60	17	93
	17%	65%	18%	
To reverse some unfavourable effects of the 'Clinical Trials Directive' of 2001 which have contributed to a "decrease of 25% of clinical trials conducted in the period between 2007 and 2011"	17	50	25	92
	18%	54%	27%	
To "boost research and development in the EU"	17	57	19	93
	18%	61%	20%	

© EUFEMED

Q2: With regards to academic and commercial clinical trials without therapeutic (or prophylactic) intent (Phase 0, Phase 1, BE and BA trials) and the requirement to publish their (lay) summary results 12 months after the end of the trial;

3. "The information/data contained are commercially confidential and the requirement to publish at that time will have a significant negative impact on academic and commercial innovation and early phase drug development in Europe"

Answered: 94 Skipped: 0



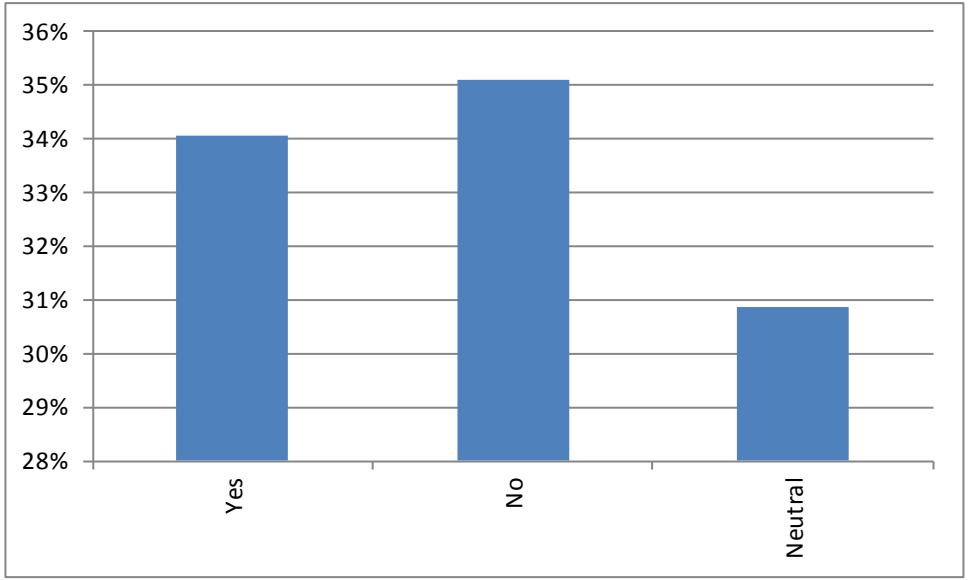
Answer Choices	Responses	Percentage
Yes	64	68%
No	12	13%
Neutral	18	19%
Grand Total	94	

© EUFEMED

Q2: With regards to academic and commercial clinical trials without therapeutic (or prophylactic) intent (Phase 0, Phase 1, BE and BA trials) and the requirement to publish their (lay) summary results 12 months after the end of the trial;

4. "The public availability of summary results at that time will reduce the interest of authors and medical journals to publish these clinical trial results in peer-reviewed journals"

Answered: 94 Skipped: 0

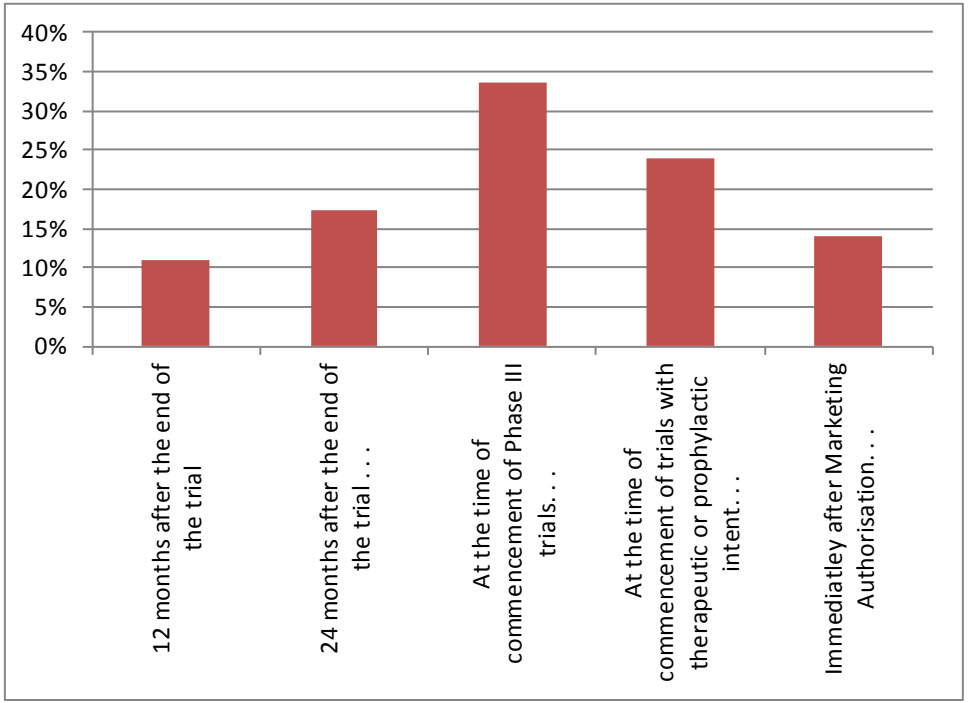


Answer Choices	Responses	Percentage
Yes	32	34%
No	33	35%
Neutral	29	31%
Grand Total	94	

© EUFEMED

Q3: The objectives of the new EU CTR would therefore be best met by publishing (lay) summary results at the following time-point after the end of a trial or in the drug development process (please select one option):

Answered: 92 Skipped: 2



Answer Choices	Responses	Percentage
12 months after the end of the trial	10	11%
24 months after the end of the trial (to allow sufficient time for patent filing)	16	17%
At the time of commencement of Phase III trials of the active substance and indication and formulation and route of administration under study	31	34%
At the time of commencement of trials with therapeutic or prophylactic intent of the active substance and indication and formulation and route of administration under study	22	24%
Immediatley after Marketing Authorisation of the active substance and indication and formulation and route of administration under study, or 10 years after the end of the trial, whichever is earlier	13	14%
Grand Total	92	

© EUFEMED