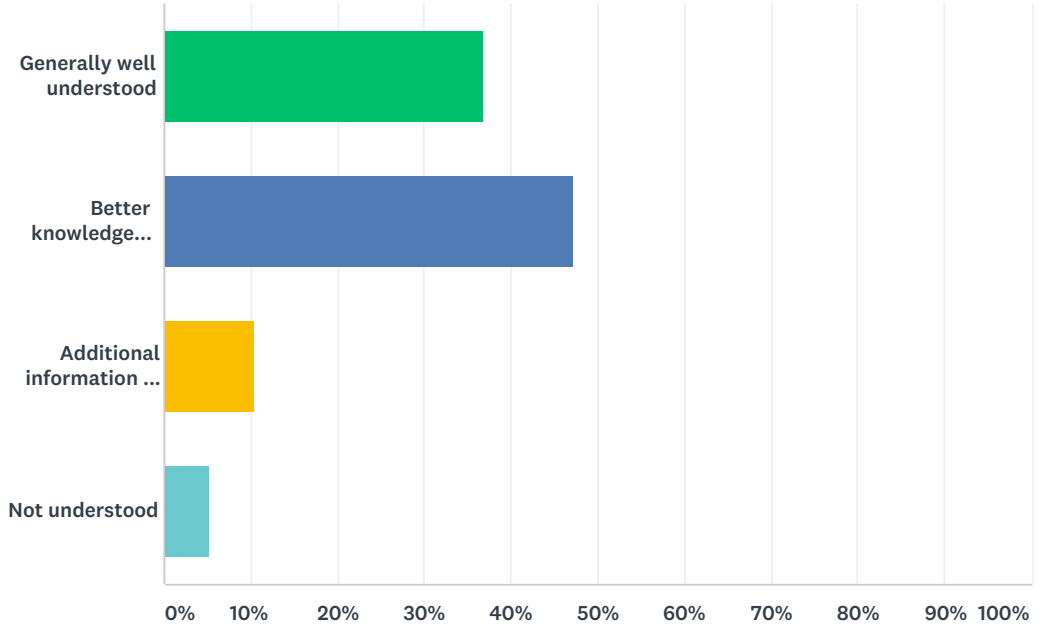
Q1 Please insert the survey code you were given by Covington & Burling (Jenny Green) This code will be used only to assure that each company submits only one response, and to remind companies about submitting the survey. The code key will be maintained only by Covington and Burling (Legal Monitor) and will not be shared with members of the I-PWG.

Answered: 25 Skipped: 0

Q2 Is the VXDS concept well understood in your company?

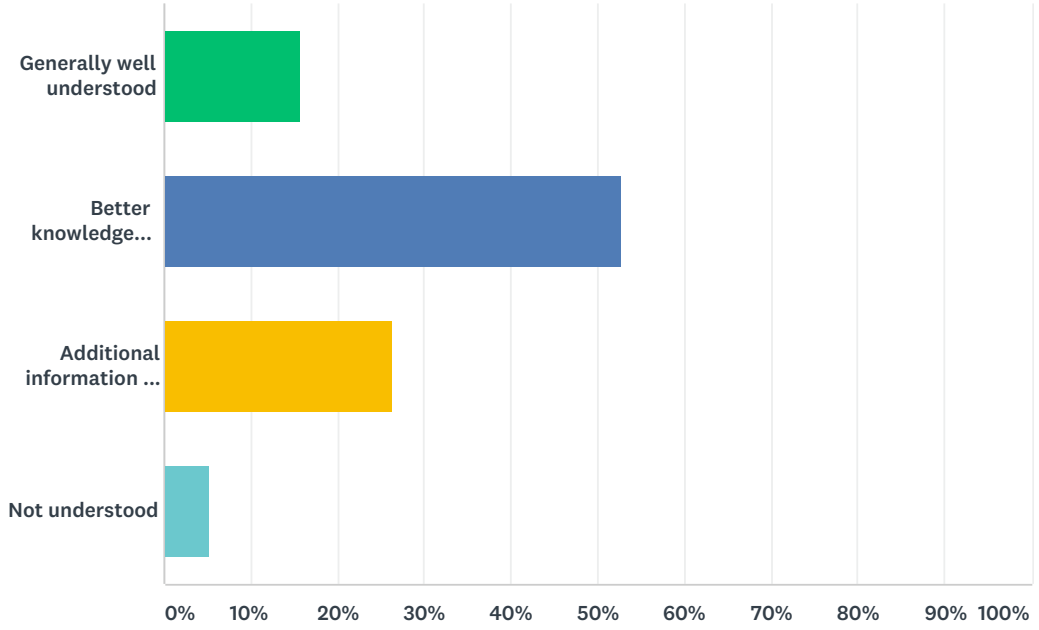
Answered: 19 Skipped: 6



ANSWER CHOICES	RESPONSES	
Generally well understood	36.84%	7
Better knowledge sharing and communication within the company needed	47.37%	9
Additional information and knowledge sharing from FDA recommended	10.53%	2
Not understood	5.26%	1
TOTAL		19

Q3 Is the VXDS process well understood in your company?

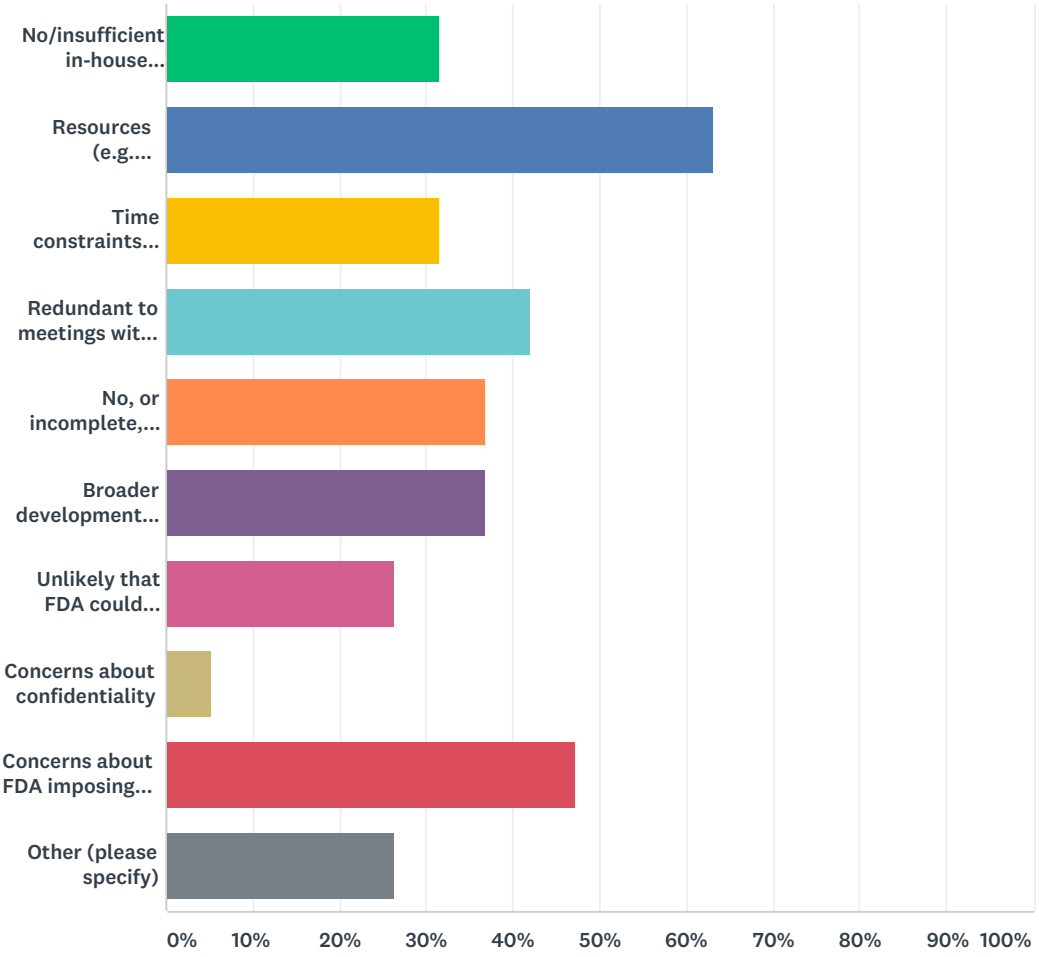
Answered: 19 Skipped: 6



ANSWER CHOICES	RESPONSES	
Generally well understood	15.79%	3
Better knowledge sharing and communication within the company needed	52.63%	10
Additional information and knowledge sharing from FDA recommended	26.32%	5
Not understood	5.26%	1
TOTAL		19

Q4 What are key obstacles for engaging in VXDS meetings? (Select all that apply)

Answered: 19 Skipped: 6

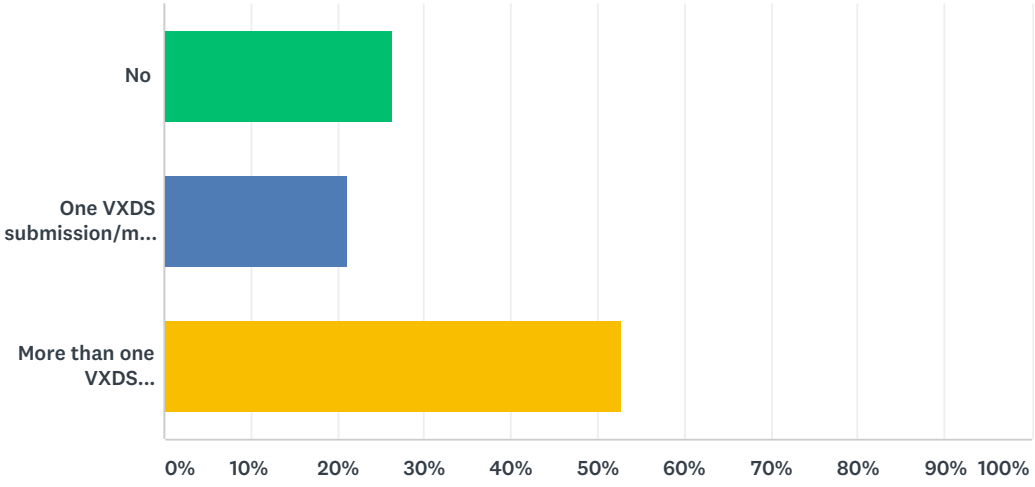


ANSWER CHOICES	RESPONSES	
No/insufficient in-house experience	31.58%	6
Resources (e.g. insufficient resource/manpower allocations, conflicting priorities)	63.16%	12
Time constraints (e.g. avoid delaying next step in development plan)	31.58%	6
Redundant to meetings with reviewing Division (e.g. EOP2 Meeting)	42.11%	8
No, or incomplete, data available for submission	36.84%	7
Broader development and/or regulatory issues not enough discussed at VXDS meetings	36.84%	7
Unlikely that FDA could provide answers to scientific questions related to in-house research projects	26.32%	5
Concerns about confidentiality	5.26%	1
Concerns about FDA imposing more work/studies	47.37%	9
Other (please specify)	26.32%	5

Total Respondents: 19	

Q5 Did your company participate in FDA's VXDS program?

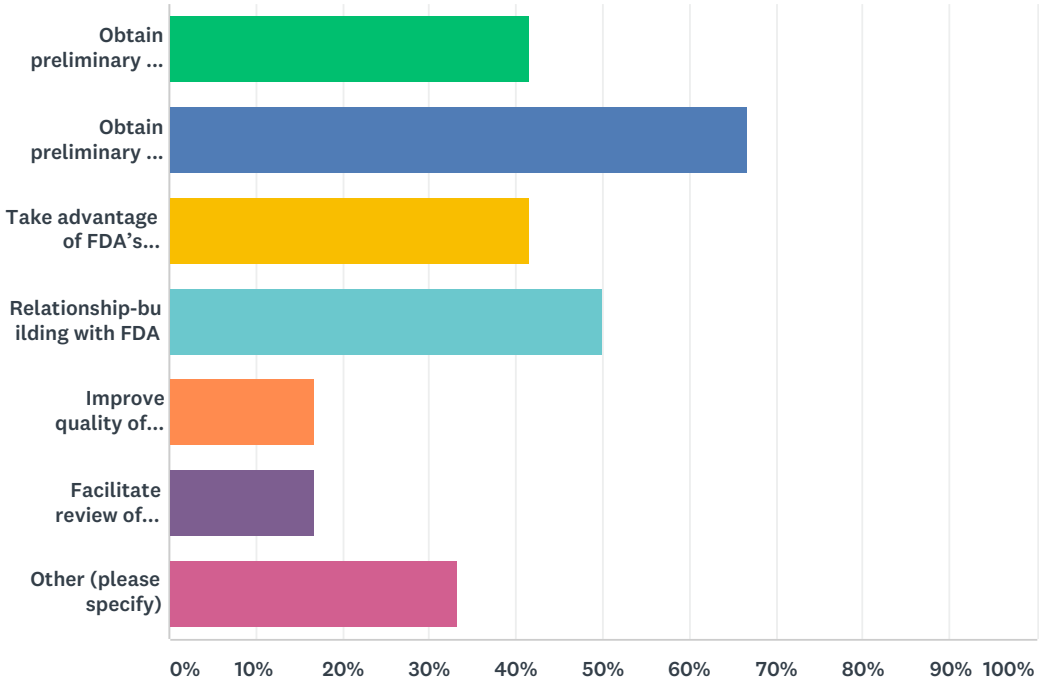
Answered: 19 Skipped: 6



ANSWER CHOICES	RESPONSES	
No	26.32%	5
One VXDS submission/meeting	21.05%	4
More than one VXDS submission/meeting	52.63%	10
TOTAL		19

Q6 What are key incentives in your company for engaging in VXDS meeting? (Select 2)

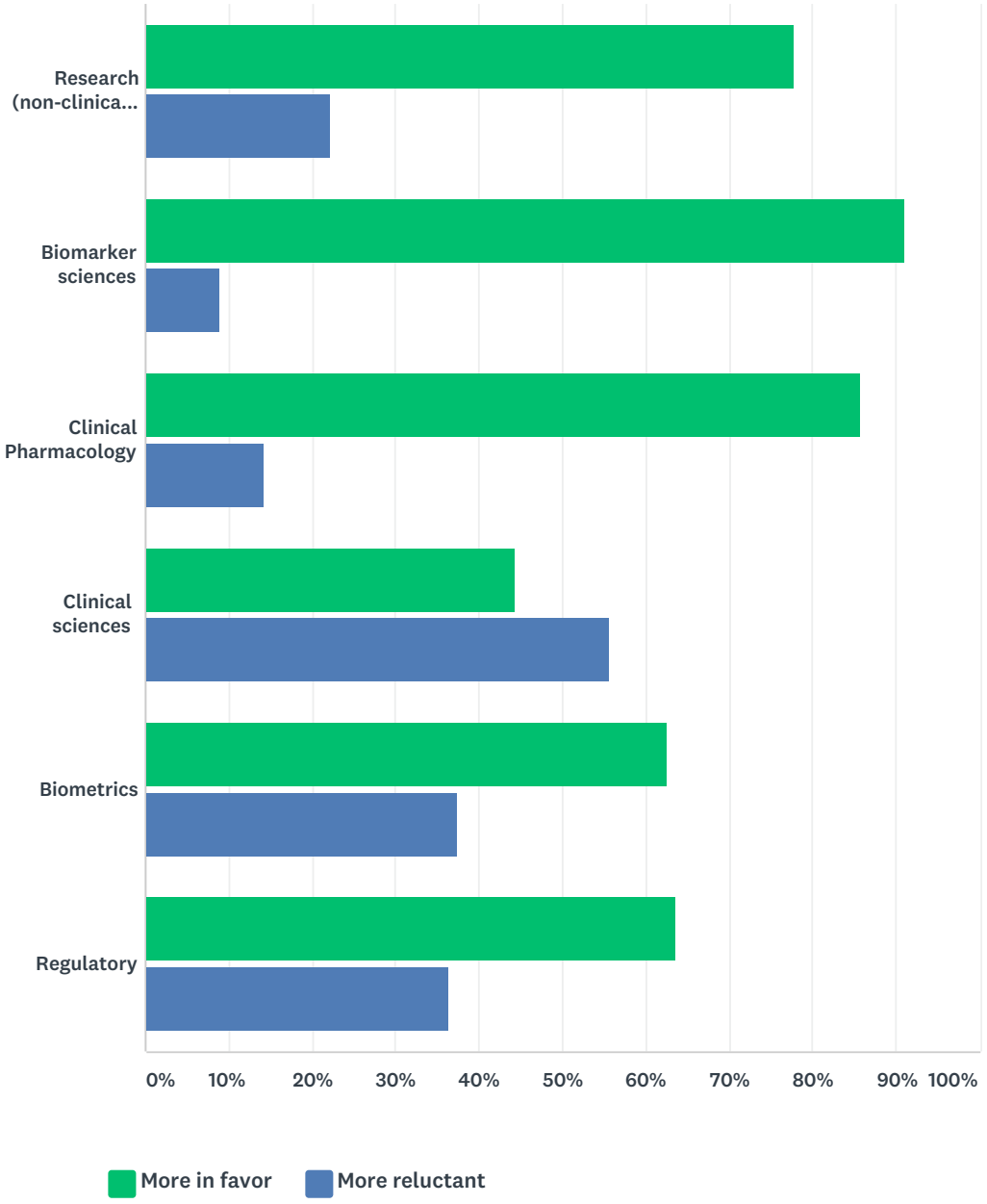
Answered: 12 Skipped: 13



ANSWER CHOICES	RESPONSES	
Obtain preliminary FDA feedback on scientific issues	41.67%	5
Obtain preliminary FDA feedback on broad development issues	66.67%	8
Take advantage of FDA's knowledge across projects	41.67%	5
Relationship-building with FDA	50.00%	6
Improve quality of future IND/NDA submissions	16.67%	2
Facilitate review of future IND/NDA submissions	16.67%	2
Other (please specify)	33.33%	4
Total Respondents: 12		

Q7 What company functions are especially in favor of - or reluctant to - VXDS meetings?

Answered: 11 Skipped: 14

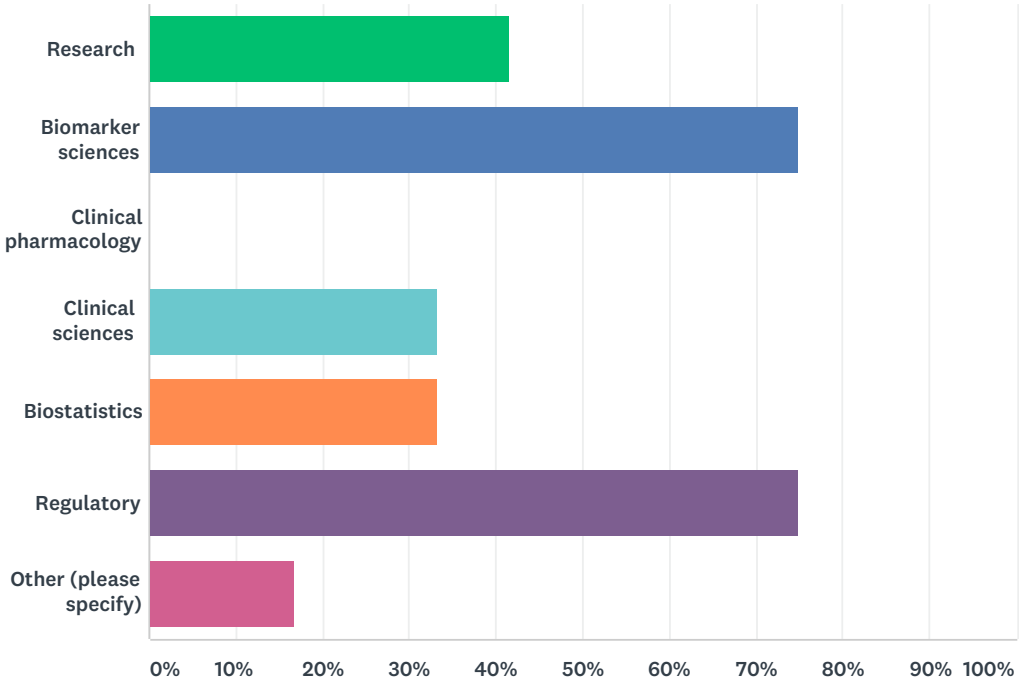


	MORE IN FAVOR	MORE RELUCTANT	TOTAL
Research (non-clinical pharmacology/ toxicology)	77.78% 7	22.22% 2	9
Biomarker sciences	90.91% 10	9.09% 1	11
Clinical Pharmacology	85.71% 6	14.29% 1	7
Clinical sciences	44.44% 4	55.56% 5	9

Biometrics	62.50% 5	37.50% 3	8
Regulatory	63.64% 7	36.36% 4	11

Q8 What functions are contributing the most to VXDS meetings? (Select up to 3 functions)

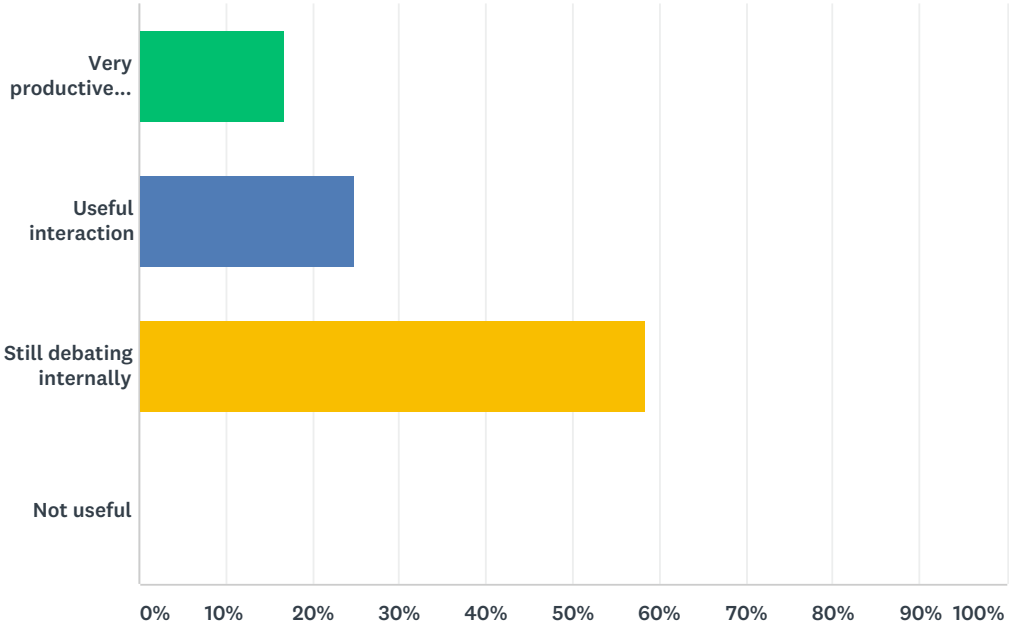
Answered: 12 Skipped: 13



ANSWER CHOICES	RESPONSES	
Research	41.67%	5
Biomarker sciences	75.00%	9
Clinical pharmacology	0.00%	0
Clinical sciences	33.33%	4
Biostatistics	33.33%	4
Regulatory	75.00%	9
Other (please specify)	16.67%	2
Total Respondents: 12		

Q9 How are VXDS meetings viewed by your company?

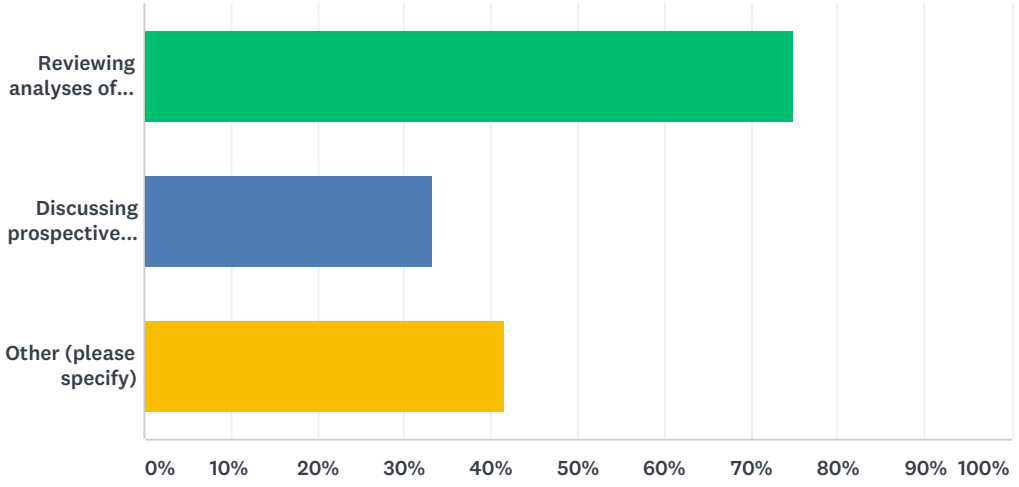
Answered: 12 Skipped: 13



ANSWER CHOICES	RESPONSES	
Very productive interaction	16.67%	2
Useful interaction	25.00%	3
Still debating internally	58.33%	7
Not useful	0.00%	0
TOTAL		12

Q10 Have your VXDS focused on (select up to two 2 focus areas)

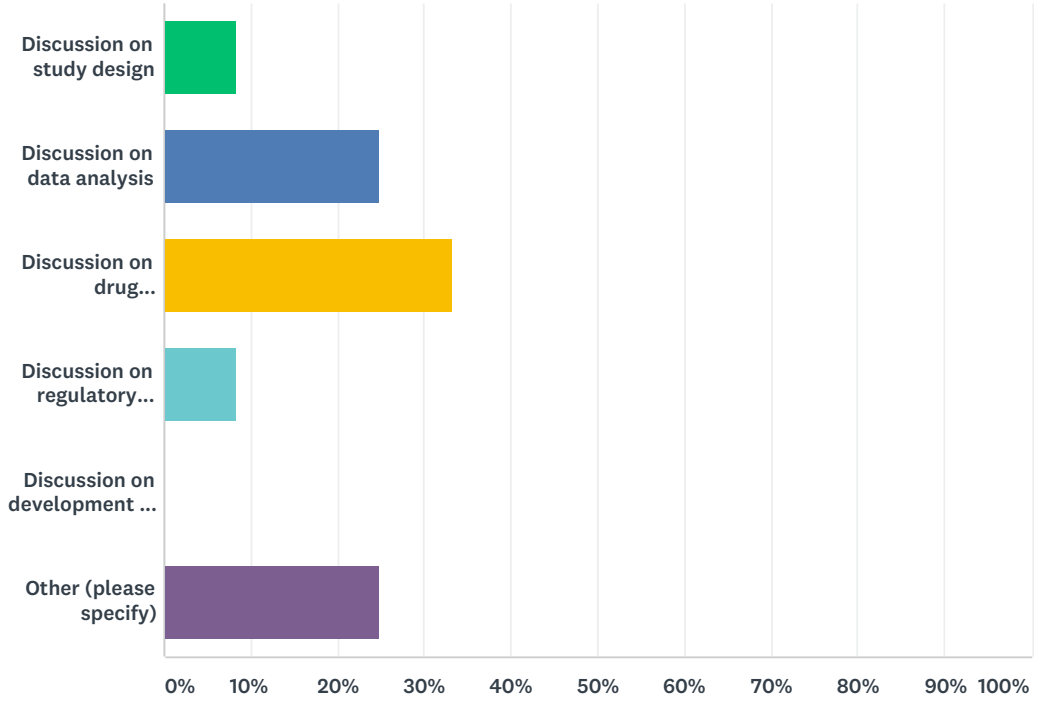
Answered: 12 Skipped: 13



ANSWER CHOICES	RESPONSES	
Reviewing analyses of previous studies	75.00%	9
Discussing prospective biomarker study designs	33.33%	4
Other (please specify)	41.67%	5
Total Respondents: 12		

Q11 What has been the main value of VXDS to your company to date?

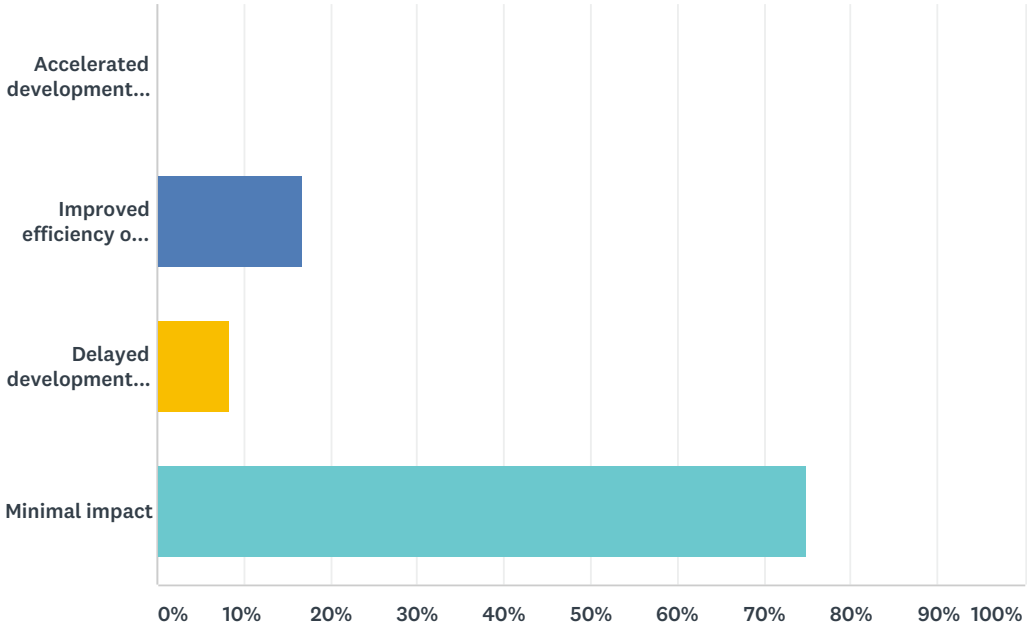
Answered: 12 Skipped: 13



ANSWER CHOICES	RESPONSES	
Discussion on study design	8.33%	1
Discussion on data analysis	25.00%	3
Discussion on drug development program	33.33%	4
Discussion on regulatory submission path	8.33%	1
Discussion on development of diagnostic test	0.00%	0
Other (please specify)	25.00%	3
TOTAL		12

Q12 How did the VXDS process influence the development program of your product?

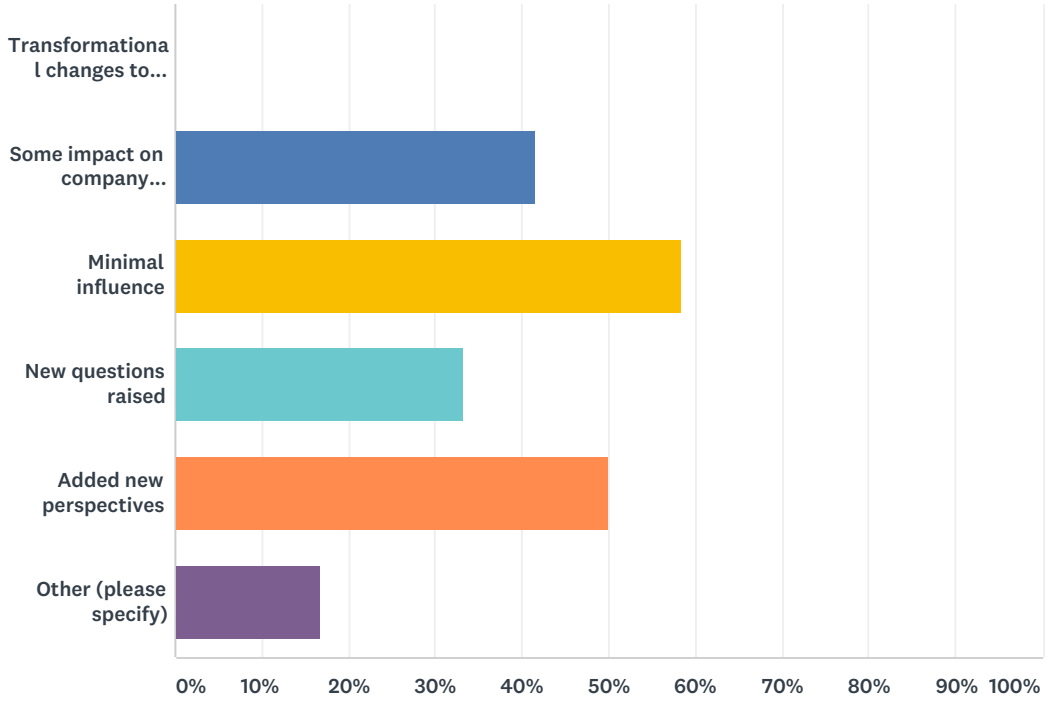
Answered: 12 Skipped: 13



ANSWER CHOICES	RESPONSES	
Accelerated development program	0.00%	0
Improved efficiency of development program	16.67%	2
Delayed development program	8.33%	1
Minimal impact	75.00%	9
TOTAL		12

Q13 How did the VXDS process influence other projects or general company practices? (Select all that apply)

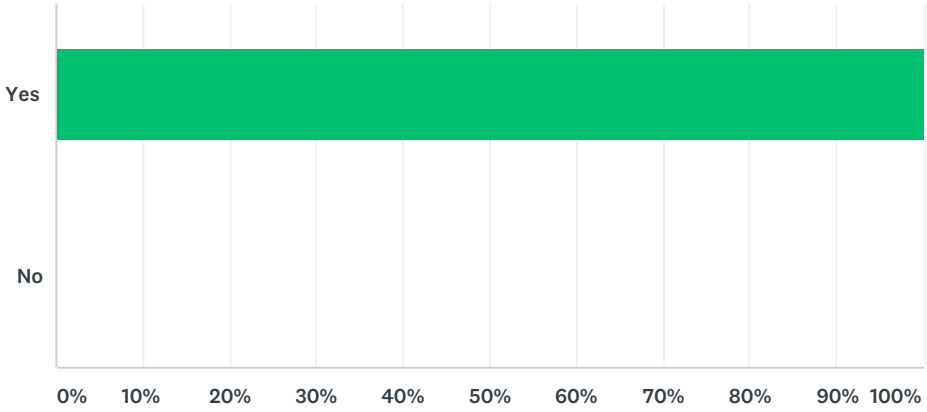
Answered: 12 Skipped: 13



ANSWER CHOICES	RESPONSES	
Transformational changes to company practice(s)	0.00%	0
Some impact on company practices	41.67%	5
Minimal influence	58.33%	7
New questions raised	33.33%	4
Added new perspectives	50.00%	6
Other (please specify)	16.67%	2
Total Respondents: 12		

Q14 Would your company consider submitting a VXDS request jointly with one or more technology and/or clinical partners or other Sponsors?

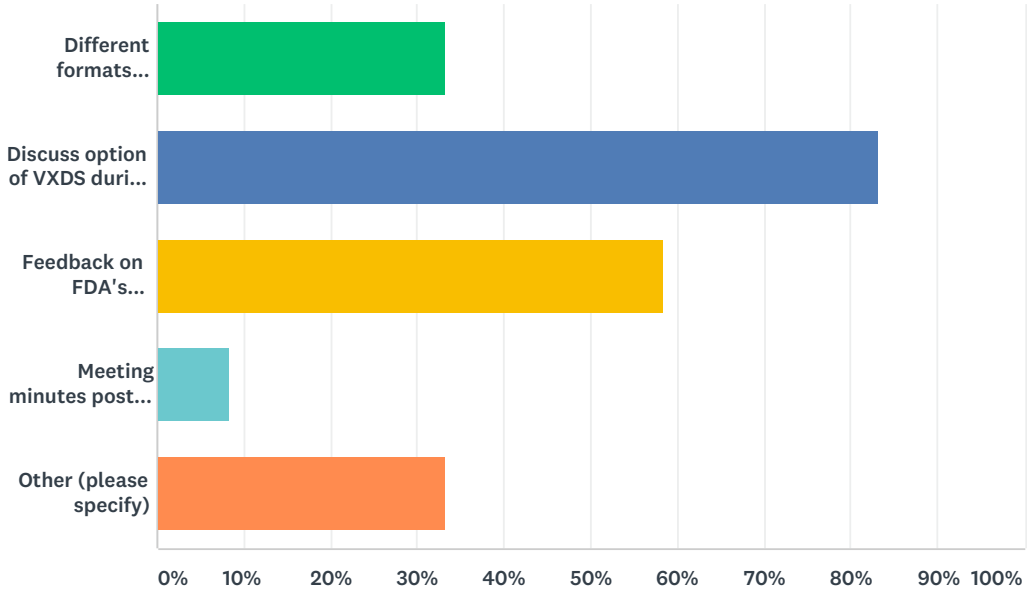
Answered: 10 Skipped: 15



ANSWER CHOICES	RESPONSES	
Yes	100.00%	10
No	0.00%	0
TOTAL		10

Q15 What could be done to enhance the interest in VXDS in your company (Select all that apply)

Answered: 12 Skipped: 13



ANSWER CHOICES	RESPONSES	
Different formats allowed: VC/net meeting, webinars instead of traditional face-to-face	33.33%	4
Discuss option of VXDS during routine Agency interactions with reviewing division	83.33%	10
Feedback on FDA's advice/experience more routinely/widely available	58.33%	7
Meeting minutes posted (redacted) on FDA website	8.33%	1
Other (please specify)	33.33%	4
Total Respondents: 12		

Q16 How can benefits of VXDS meetings be maximized?

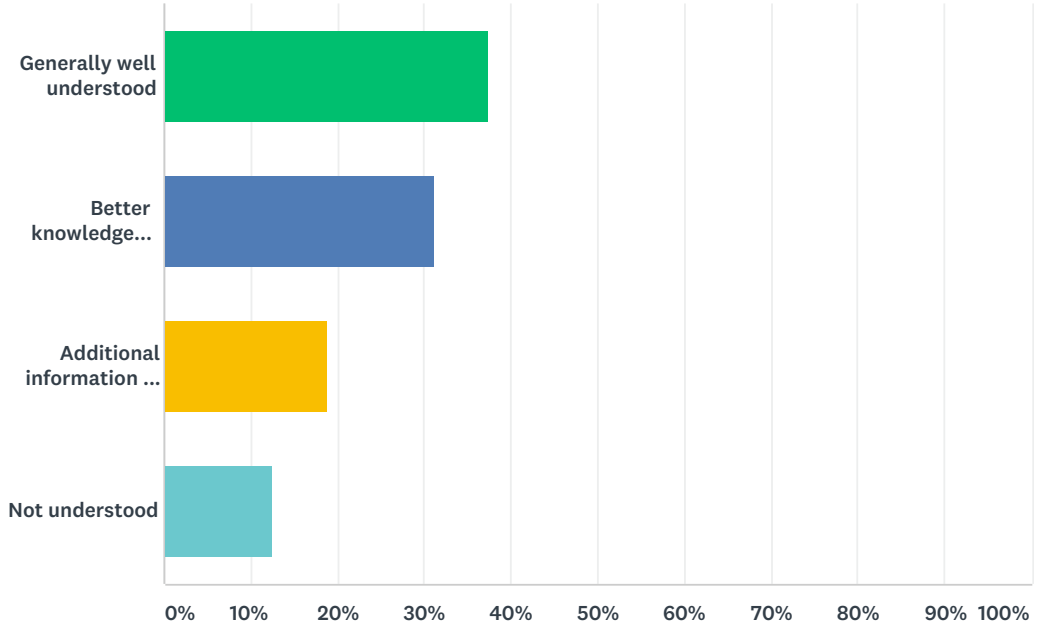
Answered: 9 Skipped: 16

Q17 What would be good additions/modifications to VXDS meetings in the future?

Answered: 6 Skipped: 19

Q18 Is the Briefing Meeting concept well understood in your company?

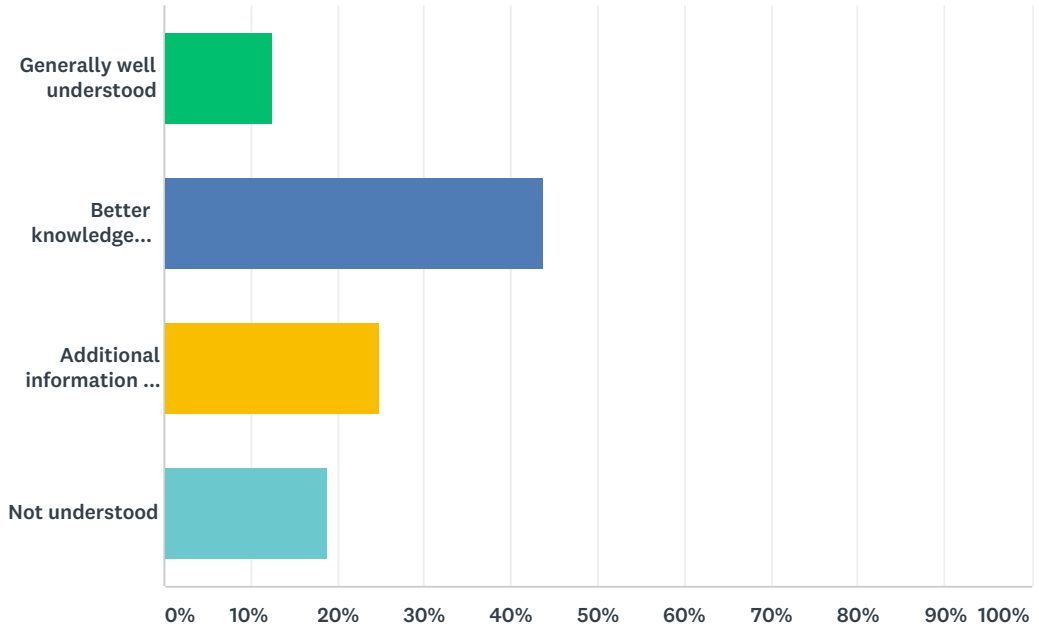
Answered: 16 Skipped: 9



ANSWER CHOICES	RESPONSES	
Generally well understood	37.50%	6
Better knowledge sharing and communication within the company needed	31.25%	5
Additional information and knowledge sharing from EMEA recommended	18.75%	3
Not understood	12.50%	2
TOTAL		16

Q19 Is the Briefing Meeting process well understood in your company?

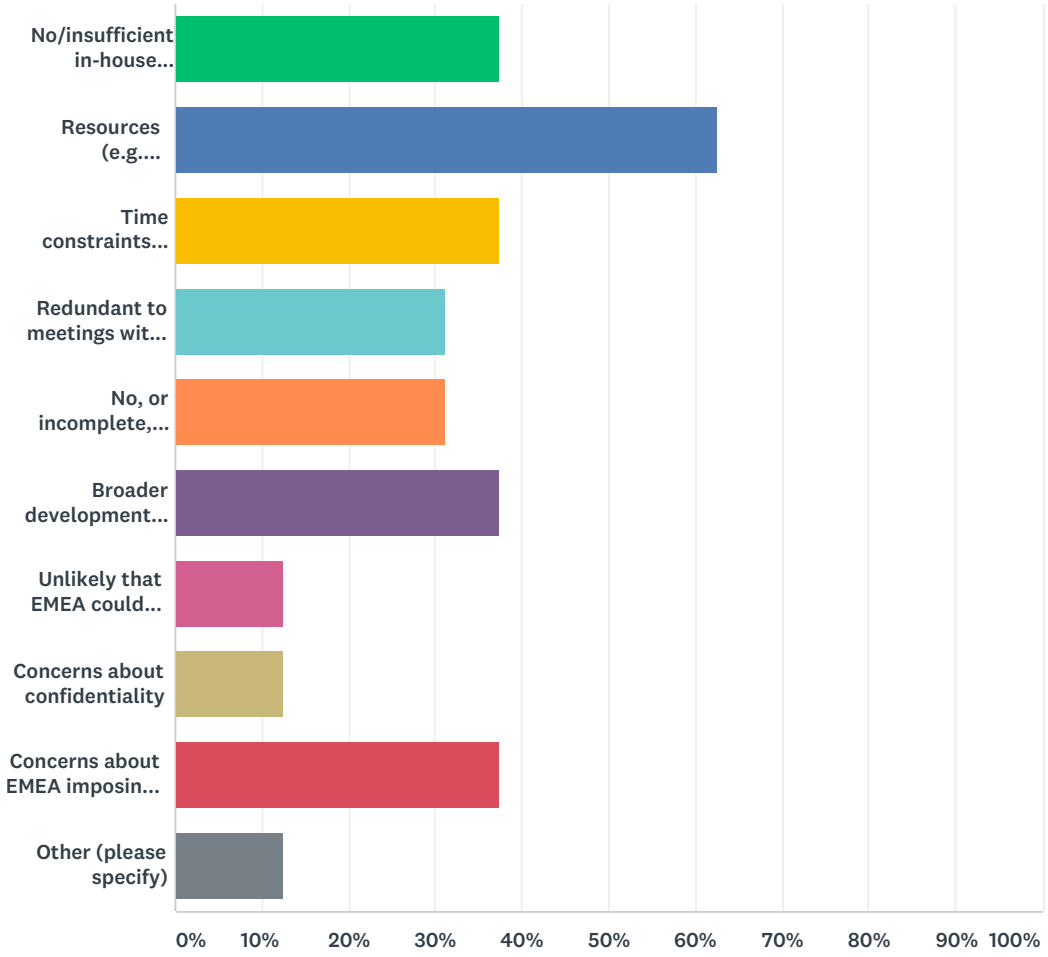
Answered: 16 Skipped: 9



ANSWER CHOICES	RESPONSES	
Generally well understood	12.50%	2
Better knowledge sharing and communication within the company needed	43.75%	7
Additional information and knowledge sharing from EMEA recommended	25.00%	4
Not understood	18.75%	3
TOTAL		16

Q20 What are key obstacles for engaging in Briefing meetings? (Select all that apply)

Answered: 16 Skipped: 9

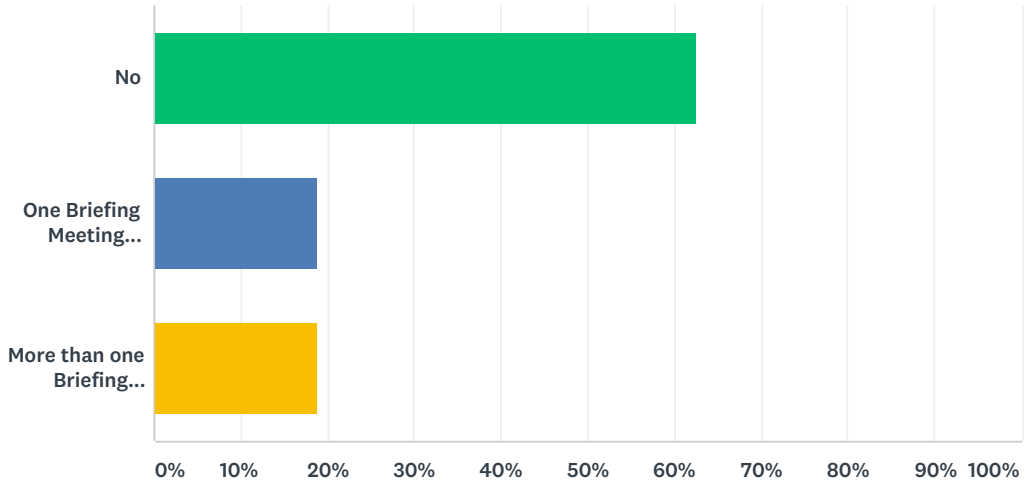


ANSWER CHOICES	RESPONSES	
No/insufficient in-house experience	37.50%	6
Resources (e.g. insufficient resource/manpower allocations, conflicting priorities)	62.50%	10
Time constraints (e.g. avoid delaying next step in development plan)	37.50%	6
Redundant to meetings within formal procedures (e.g. Scientific Advice)	31.25%	5
No, or incomplete, data available for submission	31.25%	5
Broader development and/or regulatory issues not enough discussed at Briefing meetings	37.50%	6
Unlikely that EMEA could provide answers to scientific questions related to in-house research projects	12.50%	2
Concerns about confidentiality	12.50%	2
Concerns about EMEA imposing more work/studies	37.50%	6
Other (please specify)	12.50%	2

Total Respondents: 16	

Q21 Did your company participate in EMEA's Briefing meetings?

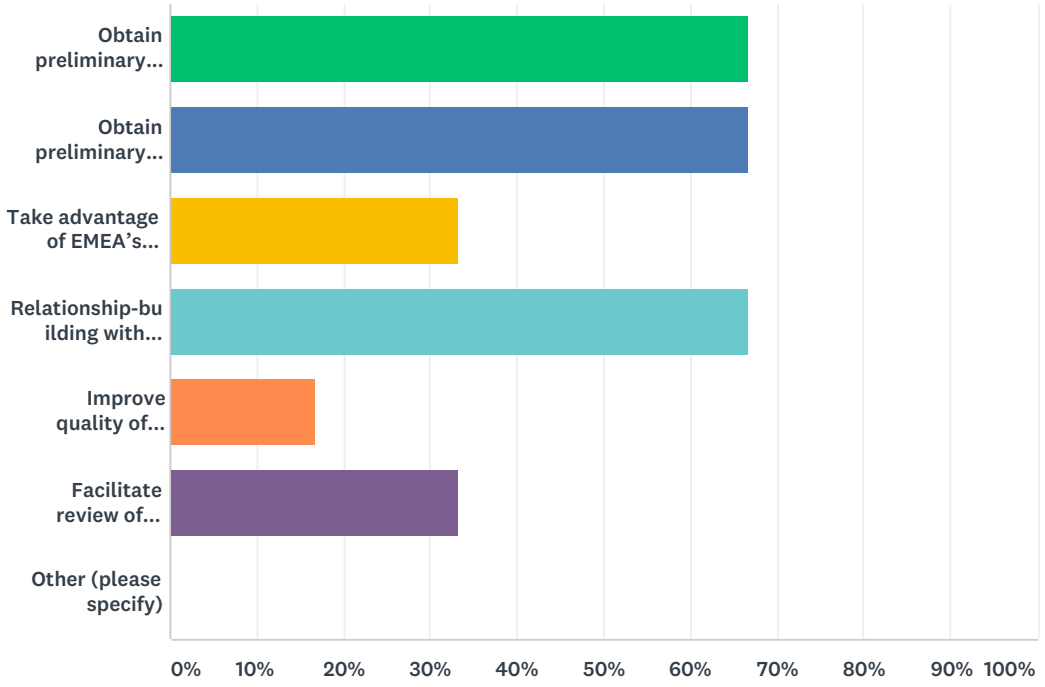
Answered: 16 Skipped: 9



ANSWER CHOICES	RESPONSES	
No	62.50%	10
One Briefing Meeting submission/meeting	18.75%	3
More than one Briefing Meeting submission/meeting	18.75%	3
TOTAL		16

Q22 What are key incentives in your company for engaging in Briefing Meetings? (Select 2)

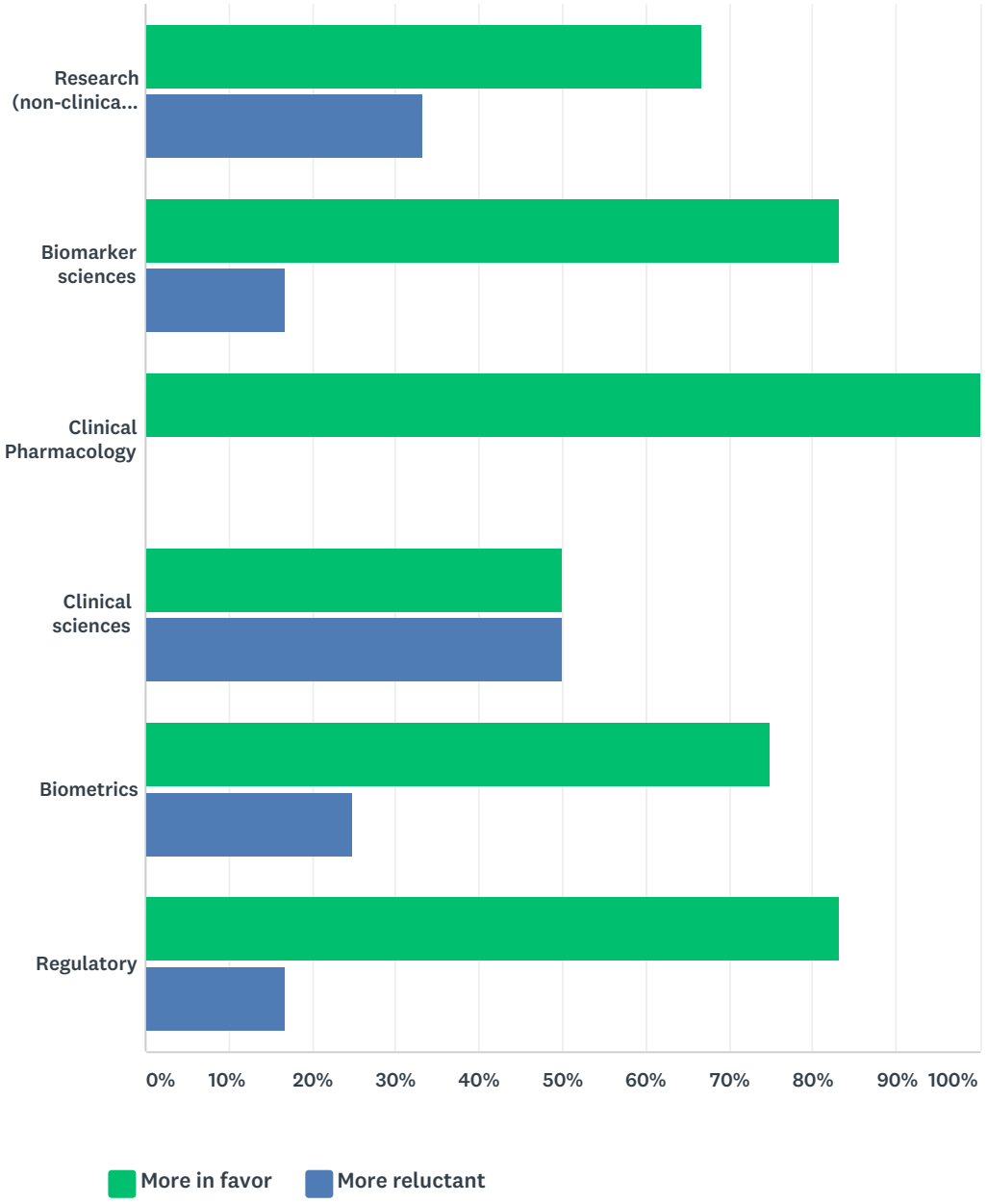
Answered: 6 Skipped: 19



ANSWER CHOICES	RESPONSES	
Obtain preliminary EMEA feedback on scientific issues	66.67%	4
Obtain preliminary EMEA feedback on broad development issues	66.67%	4
Take advantage of EMEA's knowledge across projects	33.33%	2
Relationship-building with EMEA	66.67%	4
Improve quality of future formal submissions	16.67%	1
Facilitate review of future formal submissions	33.33%	2
Other (please specify)	0.00%	0
Total Respondents: 6		

Q23 What company functions are especially in favor of - or reluctant to - Briefing Meetings?

Answered: 6 Skipped: 19

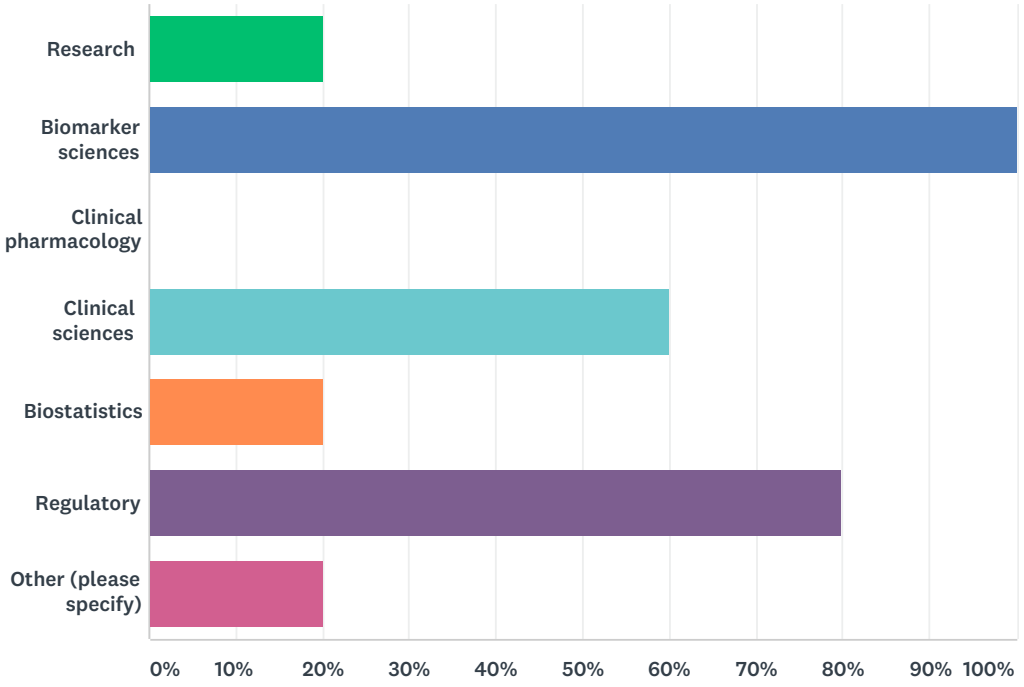


	MORE IN FAVOR	MORE RELUCTANT	TOTAL
Research (non-clinical pharmacology/ toxicology)	66.67% 2	33.33% 1	3
Biomarker sciences	83.33% 5	16.67% 1	6
Clinical Pharmacology	100.00% 2	0.00% 0	2
Clinical sciences	50.00% 2	50.00% 2	4

Biometrics	75.00% 3	25.00% 1	4
Regulatory	83.33% 5	16.67% 1	6

Q24 What functions are contributing the most to Briefing Meetings? (Select up to 3 functions)

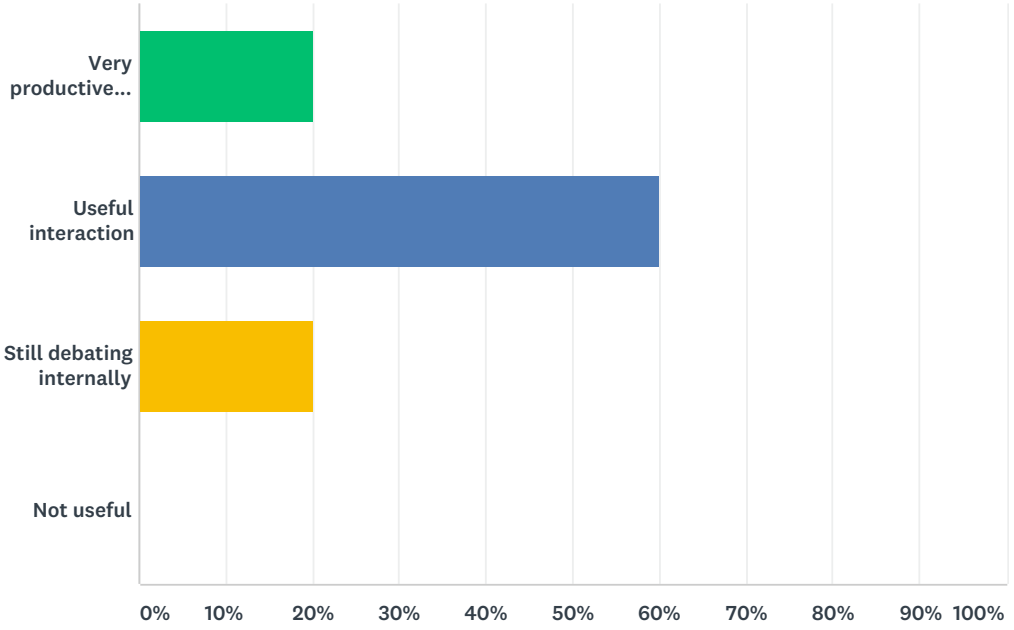
Answered: 5 Skipped: 20



ANSWER CHOICES	RESPONSES	
Research	20.00%	1
Biomarker sciences	100.00%	5
Clinical pharmacology	0.00%	0
Clinical sciences	60.00%	3
Biostatistics	20.00%	1
Regulatory	80.00%	4
Other (please specify)	20.00%	1
Total Respondents: 5		

Q25 How are Briefing Meetings viewed by your company?

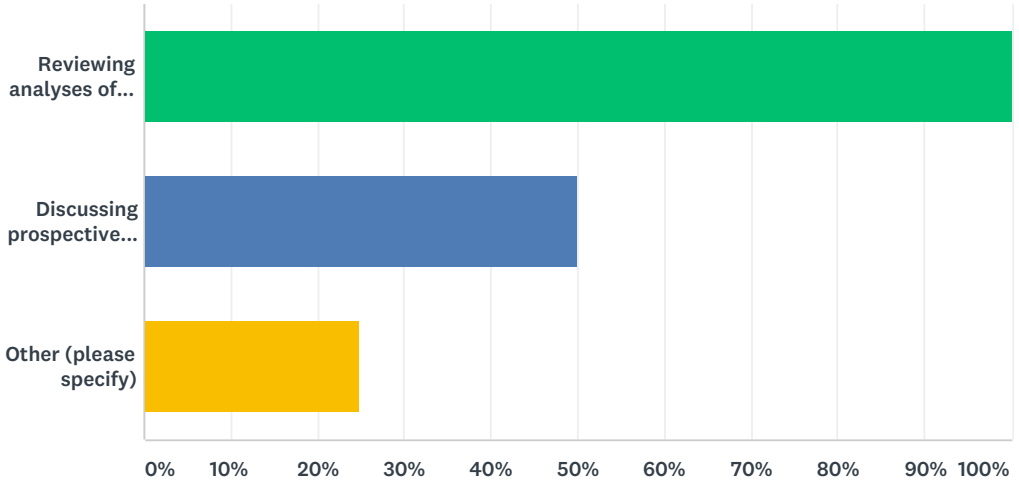
Answered: 5 Skipped: 20



ANSWER CHOICES	RESPONSES	
Very productive interaction	20.00%	1
Useful interaction	60.00%	3
Still debating internally	20.00%	1
Not useful	0.00%	0
TOTAL		5

Q26 Have your Briefing Meeting focused on (select up to two 2 focus areas)

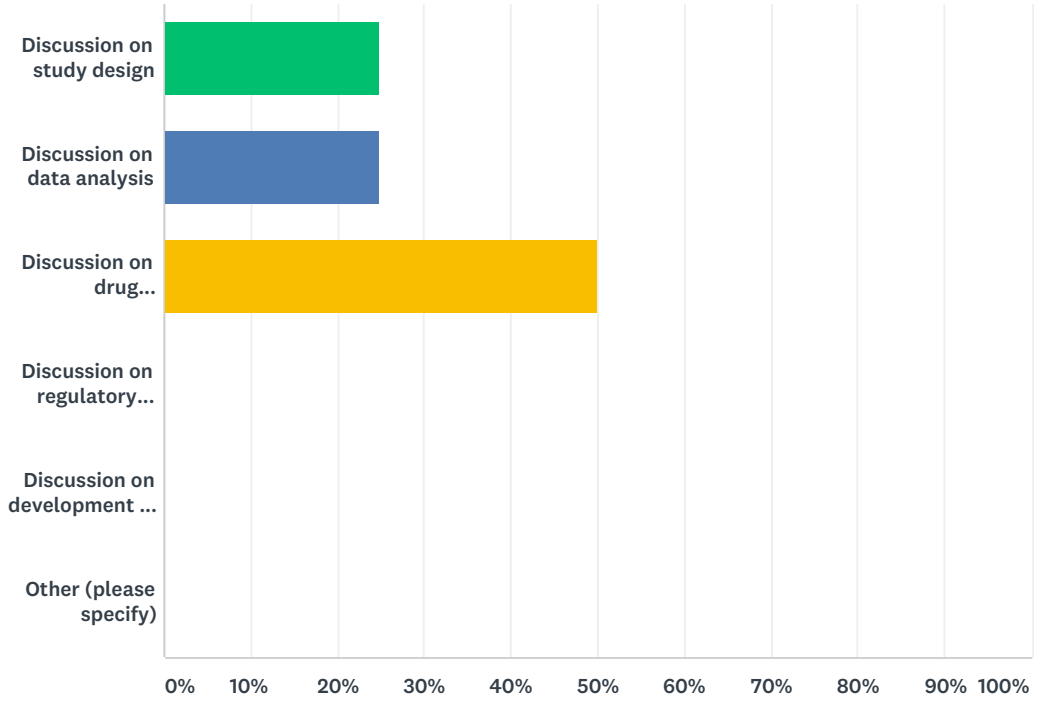
Answered: 4 Skipped: 21



ANSWER CHOICES	RESPONSES	
Reviewing analyses of previous studies	100.00%	4
Discussing prospective biomarker study designs	50.00%	2
Other (please specify)	25.00%	1
Total Respondents: 4		

Q27 What has been the main value of Briefing Meeting to your company to date?

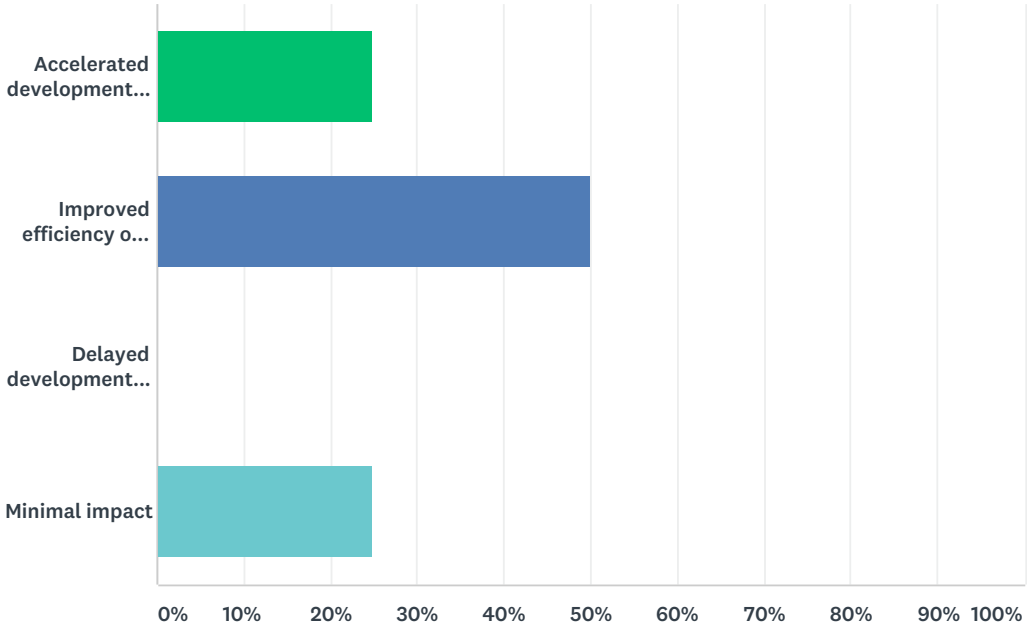
Answered: 4 Skipped: 21



ANSWER CHOICES	RESPONSES	
Discussion on study design	25.00%	1
Discussion on data analysis	25.00%	1
Discussion on drug development program	50.00%	2
Discussion on regulatory submission path	0.00%	0
Discussion on development of diagnostic test	0.00%	0
Other (please specify)	0.00%	0
TOTAL		4

Q28 How did the Briefing Meeting process influence the development program of your product?

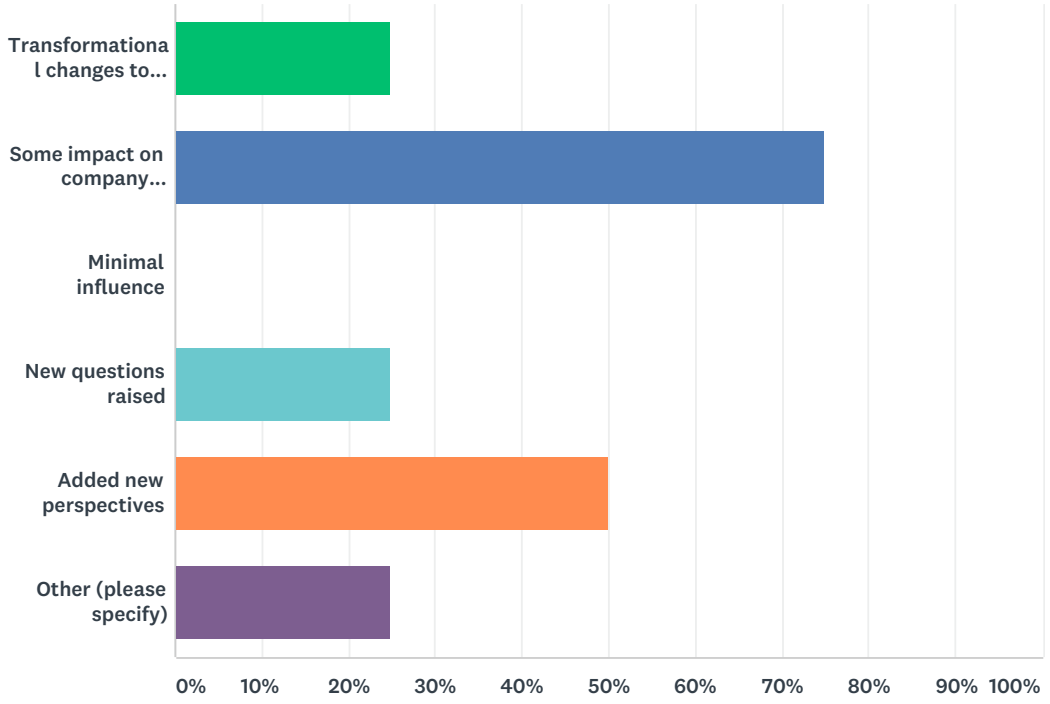
Answered: 4 Skipped: 21



ANSWER CHOICES	RESPONSES	
Accelerated development program	25.00%	1
Improved efficiency of development program	50.00%	2
Delayed development program	0.00%	0
Minimal impact	25.00%	1
TOTAL		4

Q29 How did the Briefing Meeting process influence other projects or general company practices? (Select all that apply)

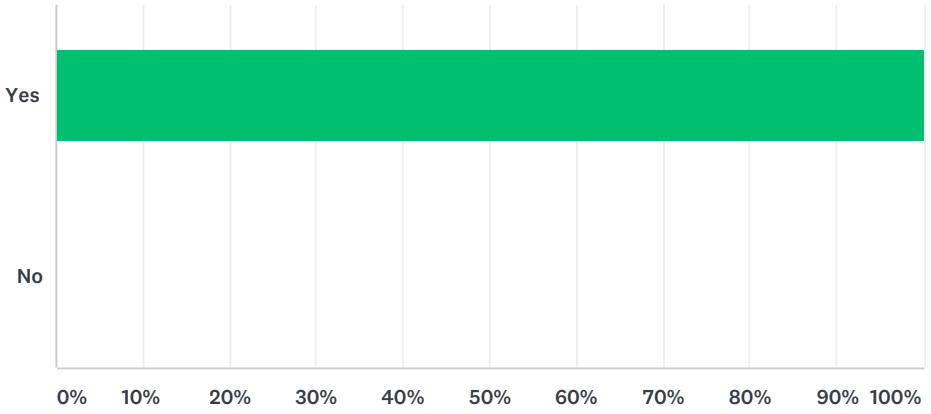
Answered: 4 Skipped: 21



ANSWER CHOICES	RESPONSES	
Transformational changes to company practice(s)	25.00%	1
Some impact on company practices	75.00%	3
Minimal influence	0.00%	0
New questions raised	25.00%	1
Added new perspectives	50.00%	2
Other (please specify)	25.00%	1
Total Respondents: 4		

Q30 Would your company consider submitting a Briefing Meeting request jointly with one or more technology and/or clinical partners or other Sponsors?

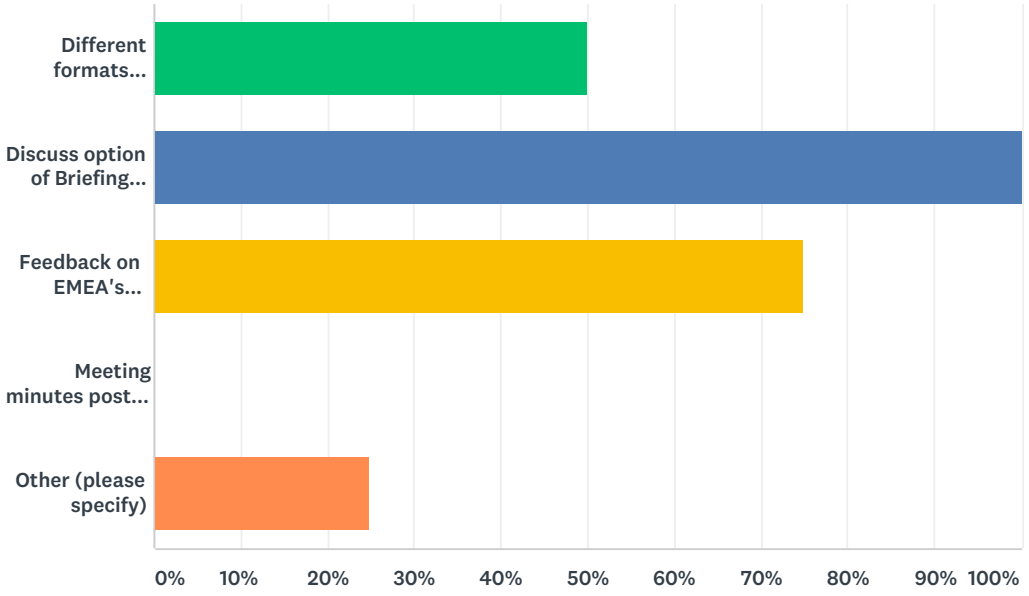
Answered: 3 Skipped: 22



ANSWER CHOICES	RESPONSES	
Yes	100.00%	3
No	0.00%	0
TOTAL		3

Q31 What could be done to enhance the interest in Briefing Meetings in your company (Select all that apply)

Answered: 4 Skipped: 21



ANSWER CHOICES	RESPONSES	
Different formats allowed: VC/net meeting, webinars instead of traditional face-to-face	50.00%	2
Discuss option of Briefing Meeting during routine Agency interactions with reviewing division	100.00%	4
Feedback on EMEA's advice/experience more routinely/widely available	75.00%	3
Meeting minutes posted (redacted) on EMEA website	0.00%	0
Other (please specify)	25.00%	1
Total Respondents: 4		

Q32 How can benefits of Briefing Meetings be further increased?

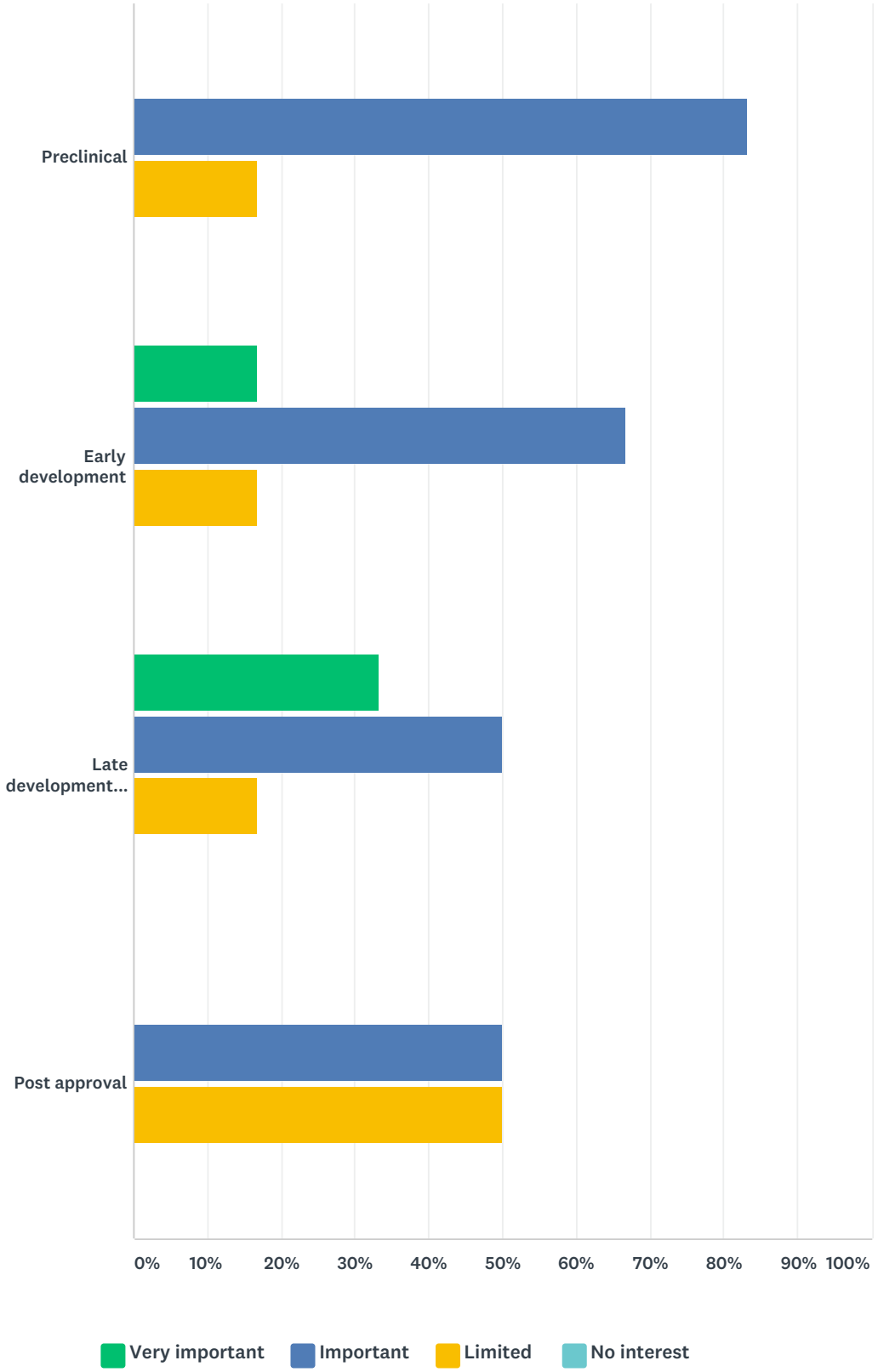
Answered: 3 Skipped: 22

Q33 What would be good additions/modifications to Briefing Meetings in the future?

Answered: 3 Skipped: 22

Q34 What is the view of your company on seeking input on biomarkers from Health Authorities?

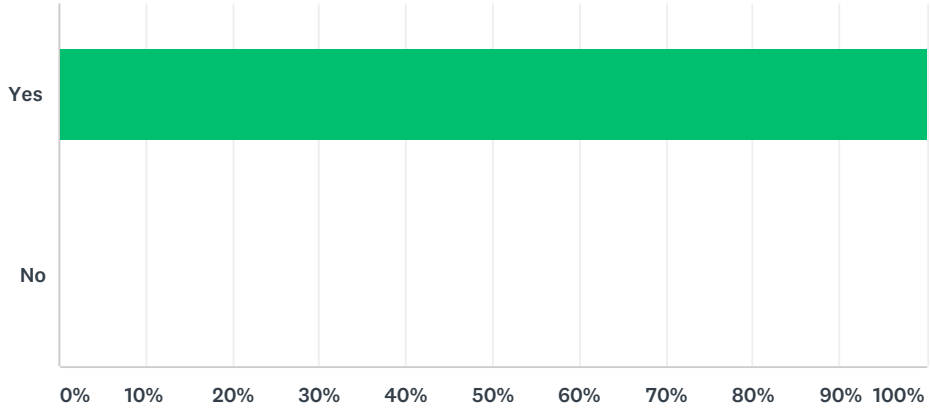
Answered: 6 Skipped: 19



	VERY IMPORTANT	IMPORTANT	LIMITED	NO INTEREST	TOTAL
Preclinical	0.00% 0	83.33% 5	16.67% 1	0.00% 0	6
Early development	16.67% 1	66.67% 4	16.67% 1	0.00% 0	6
Late development (after POC)	33.33% 2	50.00% 3	16.67% 1	0.00% 0	6
Post approval	0.00% 0	50.00% 3	50.00% 3	0.00% 0	6

Q35 Does your company request Scientific Advice from EMEA?

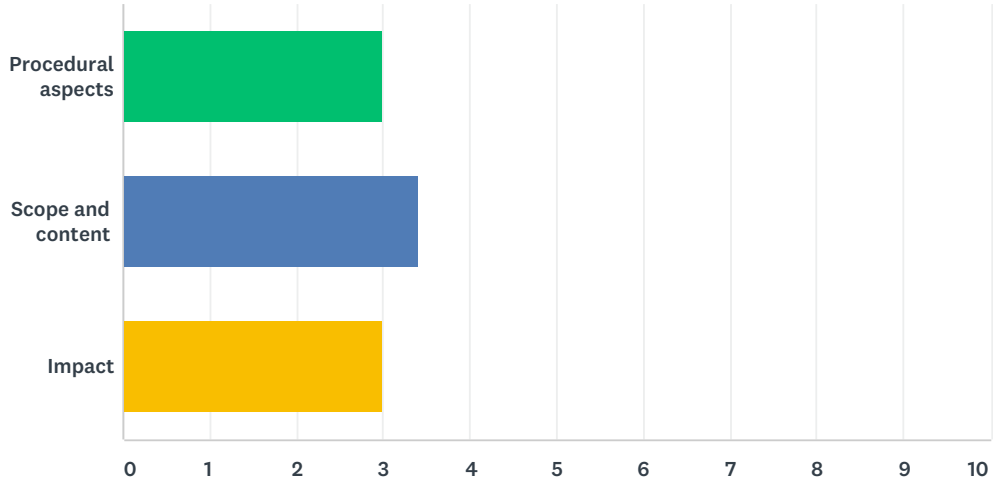
Answered: 4 Skipped: 21



ANSWER CHOICES	RESPONSES	
Yes	100.00%	4
No	0.00%	0
TOTAL		4

Q36 FDA's VXDS meetings are viewed favorably for (Please rate on scale 1 to 5)

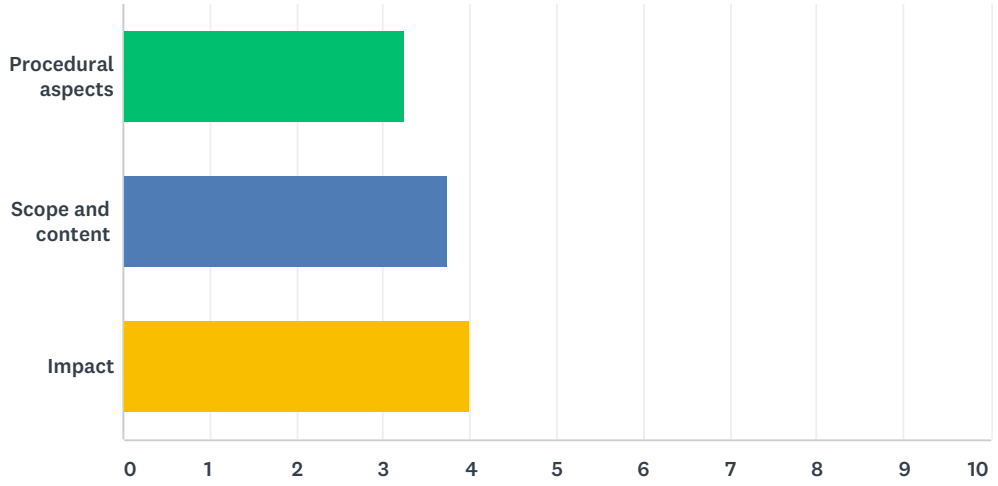
Answered: 5 Skipped: 20



	LEAST -1	2	3	4	MOST - 5	N/A	TOTAL	WEIGHTED AVERAGE
Procedural aspects	0.00% 0	40.00% 2	40.00% 2	0.00% 0	20.00% 1	0.00% 0	5	3.00
Scope and content	0.00% 0	20.00% 1	20.00% 1	60.00% 3	0.00% 0	0.00% 0	5	3.40
Impact	0.00% 0	60.00% 3	0.00% 0	20.00% 1	20.00% 1	0.00% 0	5	3.00

Q37 EMEA's Scientific Advice meetings are viewed favorably for (Please rate on scale of 1 to 5)

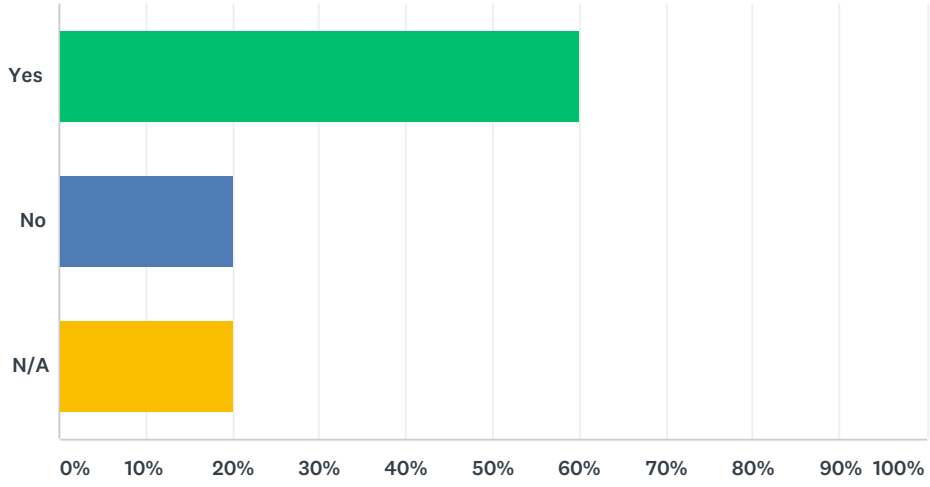
Answered: 4 Skipped: 21



	LEAST -1	2	3	4	MOST - 5	N/A	TOTAL	WEIGHTED AVERAGE
Procedural aspects	0.00% 0	25.00% 1	25.00% 1	50.00% 2	0.00% 0	0.00% 0	4	3.25
Scope and content	0.00% 0	0.00% 0	25.00% 1	75.00% 3	0.00% 0	0.00% 0	4	3.75
Impact	0.00% 0	25.00% 1	0.00% 0	25.00% 1	50.00% 2	0.00% 0	4	4.00

Q38 FDA and EMEA meetings have (often) similar outcomes

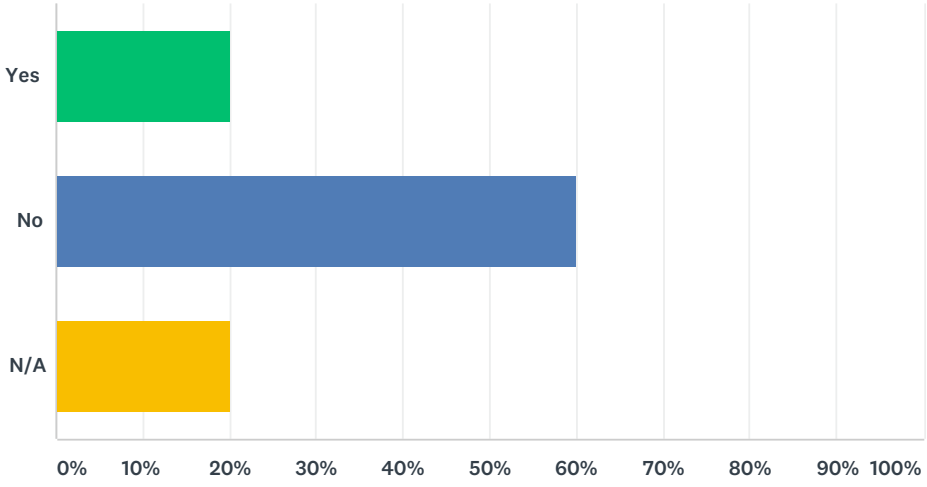
Answered: 5 Skipped: 20



ANSWER CHOICES	RESPONSES	
Yes	60.00%	3
No	20.00%	1
N/A	20.00%	1
TOTAL		5

Q39 FDA and EMEA meetings have (often) divergent outcomes

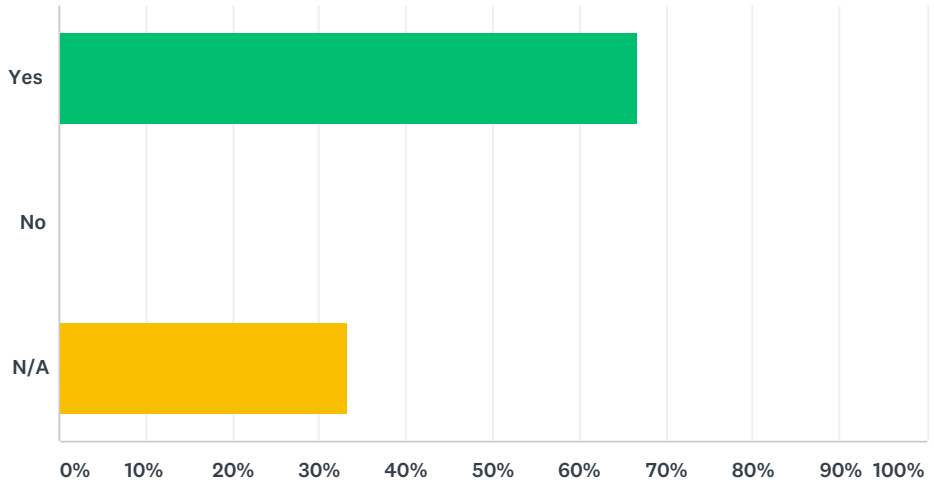
Answered: 5 Skipped: 20



ANSWER CHOICES	RESPONSES	
Yes	20.00%	1
No	60.00%	3
N/A	20.00%	1
TOTAL		5

Q40 FDA and EMEA officials gave (often) similar advice

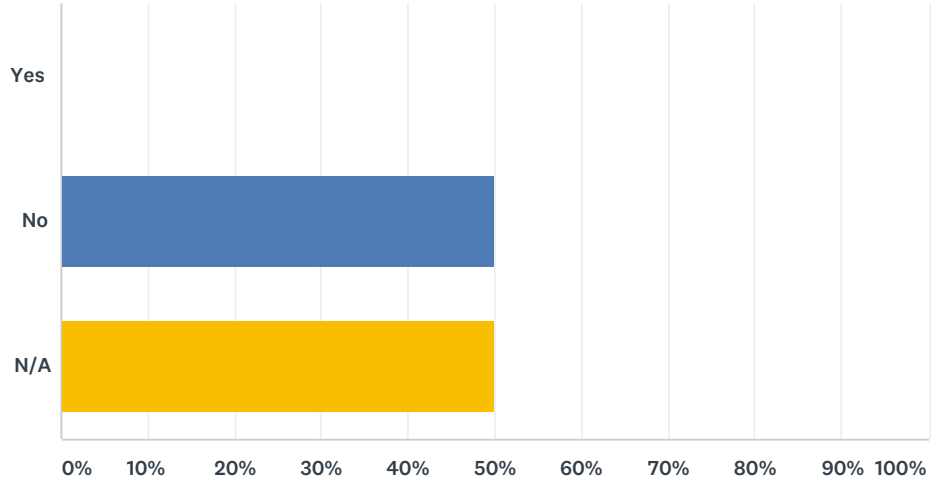
Answered: 6 Skipped: 19



ANSWER CHOICES	RESPONSES	
Yes	66.67%	4
No	0.00%	0
N/A	33.33%	2
TOTAL		6

Q41 FDA and EMEA officials gave (often) divergent advice

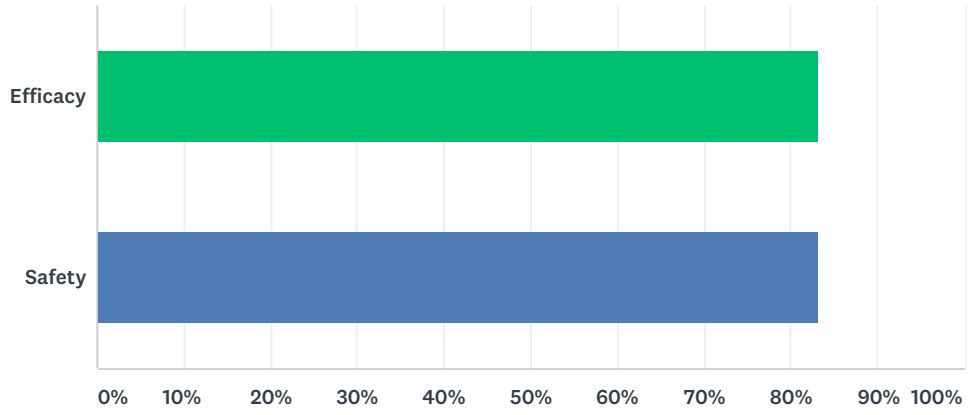
Answered: 6 Skipped: 19



ANSWER CHOICES	RESPONSES	
Yes	0.00%	0
No	50.00%	3
N/A	50.00%	3
TOTAL		6

Q42 Discussion on biomarkers

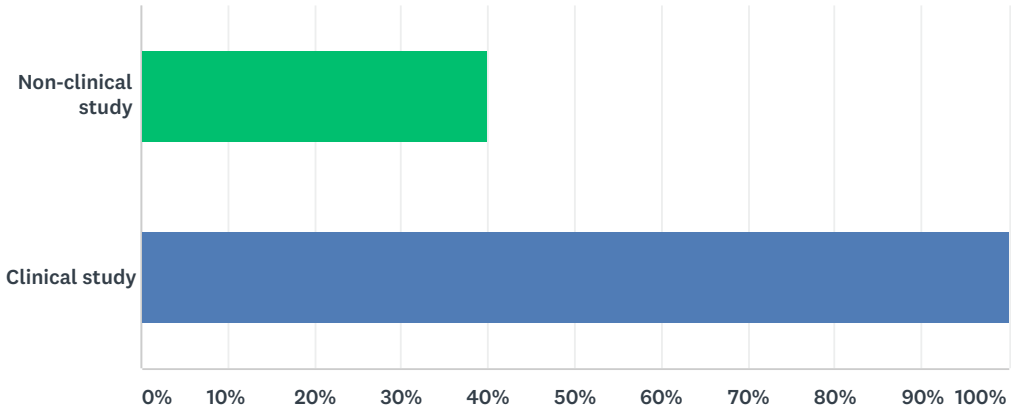
Answered: 6 Skipped: 19



ANSWER CHOICES	RESPONSES	
Efficacy	83.33%	5
Safety	83.33%	5
Total Respondents: 6		

Q43 Discussion on biomarker study design

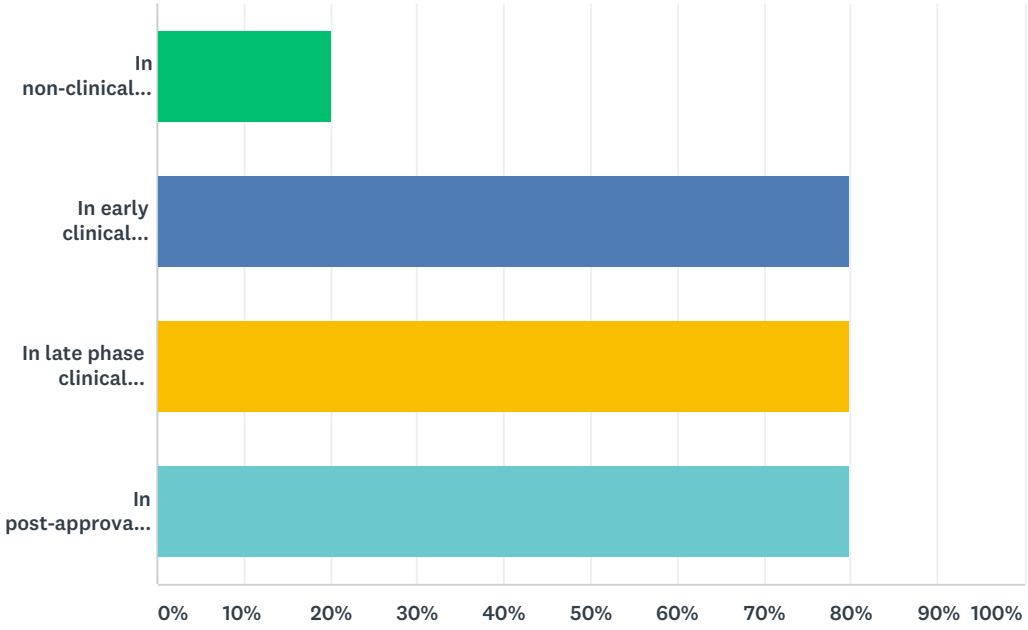
Answered: 5 Skipped: 20



ANSWER CHOICES	RESPONSES	
Non-clinical study	40.00%	2
Clinical study	100.00%	5
Total Respondents: 5		

Q44 Discussion on use of biomarkers in development programs

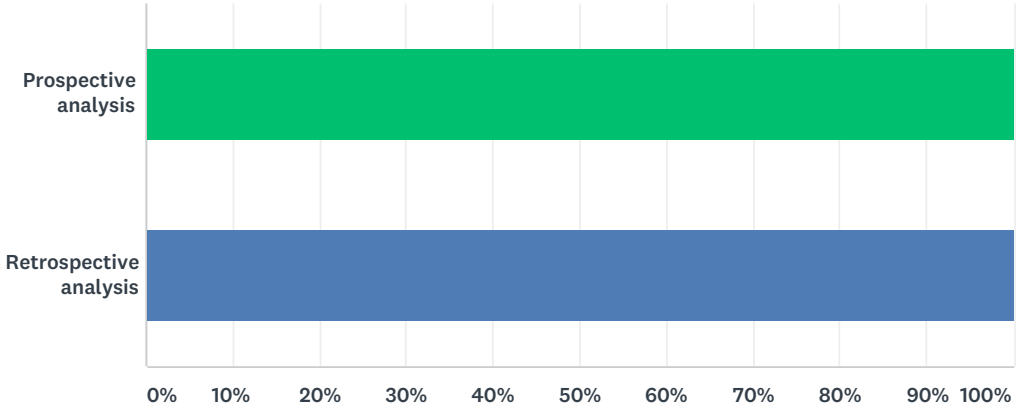
Answered: 5 Skipped: 20



ANSWER CHOICES	RESPONSES	
In non-clinical studies	20.00%	1
In early clinical studies	80.00%	4
In late phase clinical studies (Phase 2b or Phase 3)	80.00%	4
In post-approval studies	80.00%	4
Total Respondents: 5		

Q45 Discussion on biomarker data analysis

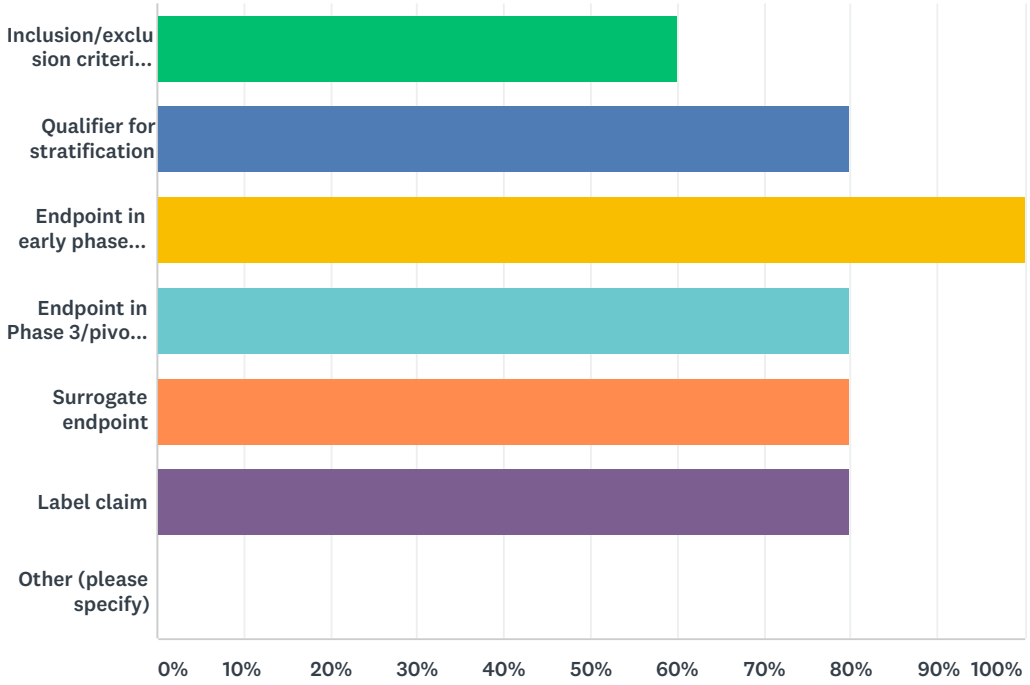
Answered: 4 Skipped: 21



ANSWER CHOICES	RESPONSES	
Prospective analysis	100.00%	4
Retrospective analysis	100.00%	4
Total Respondents: 4		

Q46 Discussion on use and/or regulatory qualification of biomarkers for:

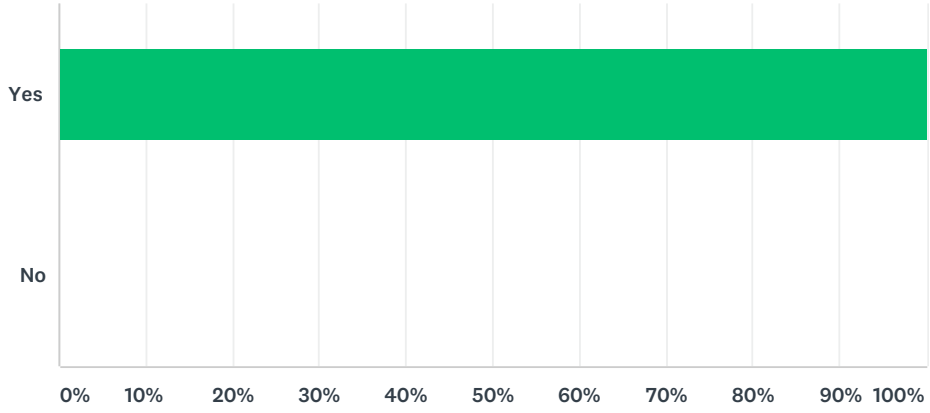
Answered: 5 Skipped: 20



ANSWER CHOICES	RESPONSES	
Inclusion/exclusion criteria in clinical studies	60.00%	3
Qualifier for stratification	80.00%	4
Endpoint in early phase clinical trial	100.00%	5
Endpoint in Phase 3/pivotal study	80.00%	4
Surrogate endpoint	80.00%	4
Label claim	80.00%	4
Other (please specify)	0.00%	0
Total Respondents: 5		

Q47 Discussion on co-development diagnostic test

Answered: 4 Skipped: 21



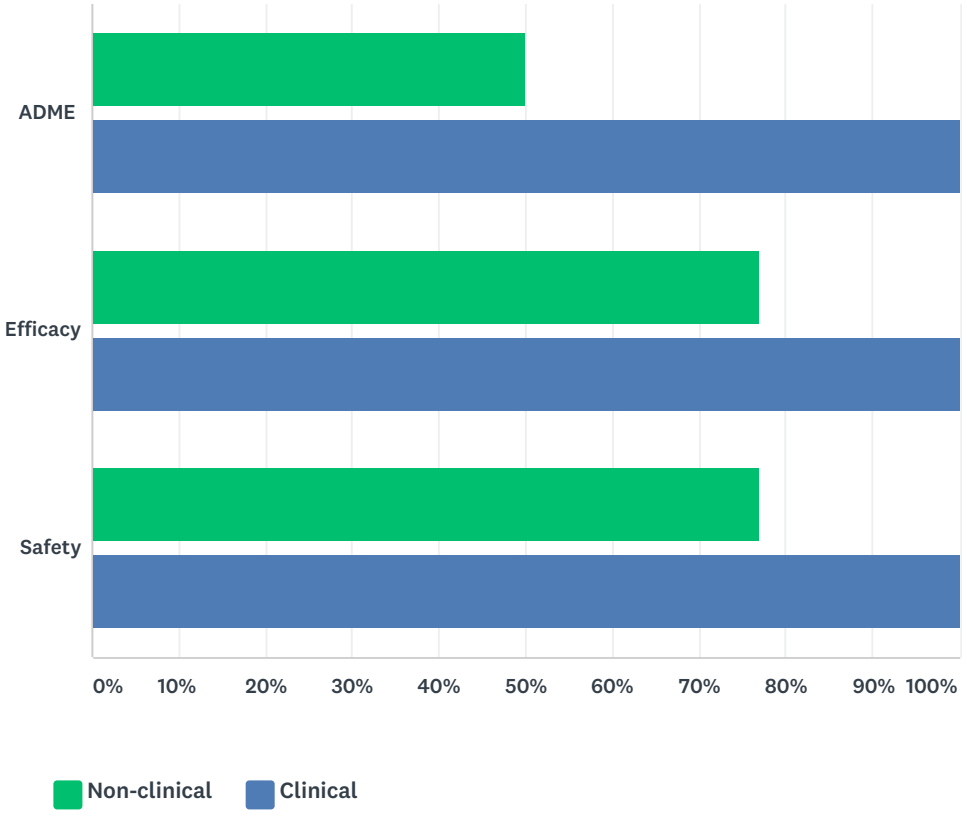
ANSWER CHOICES	RESPONSES	
Yes	100.00%	4
No	0.00%	0
Total Respondents: 4		

Q48 Discussion on other Topics (Describe):

Answered: 1 Skipped: 24

Q49 In what areas are biomarkers employed in your clinical studies? (Select all that apply)

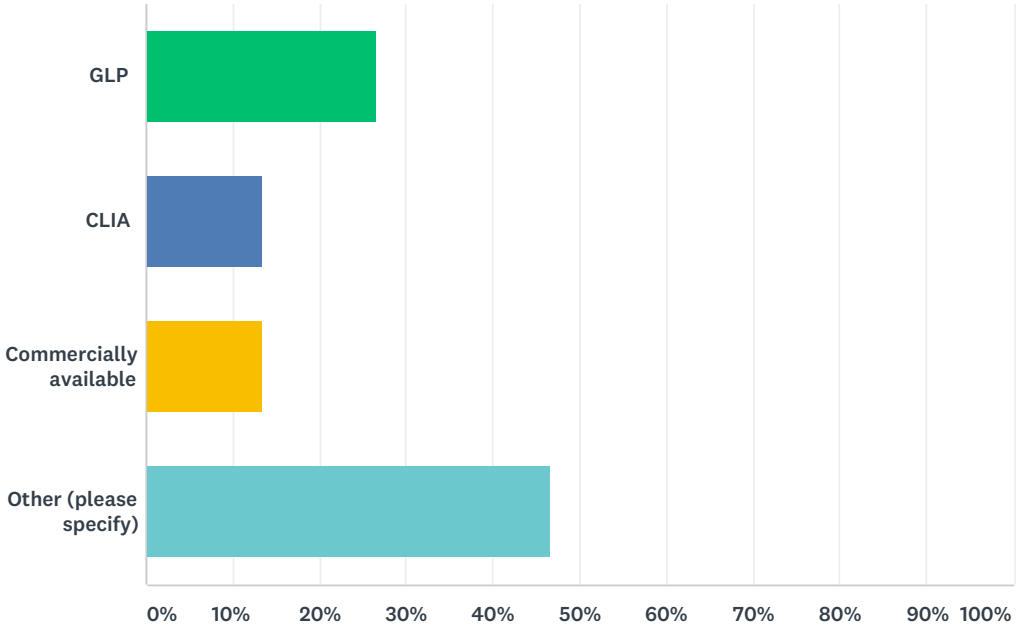
Answered: 13 Skipped: 12



	NON-CLINICAL	CLINICAL	TOTAL RESPONDENTS
ADME	50.00% 6	100.00% 12	12
Efficacy	76.92% 10	100.00% 13	13
Safety	76.92% 10	100.00% 13	13

Q50 Under what laboratory conditions (GLP, CLIA, etc.) are biomarkers in clinical studies analyzed?

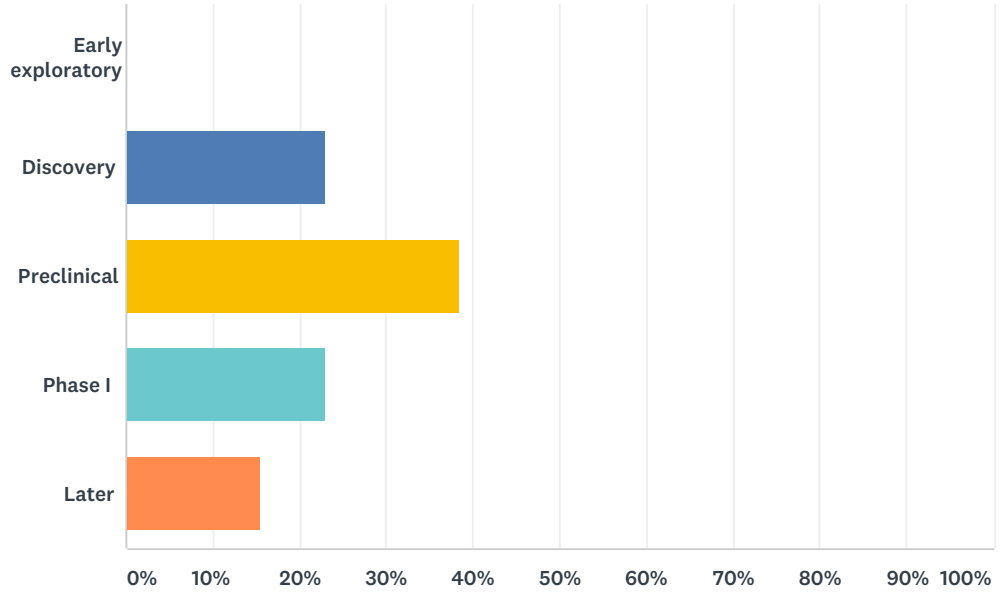
Answered: 15 Skipped: 10



ANSWER CHOICES	RESPONSES	
GLP	26.67%	4
CLIA	13.33%	2
Commercially available	13.33%	2
Other (please specify)	46.67%	7
TOTAL		15

Q51 At what point in drug development are biomarker strategies most commonly developed?

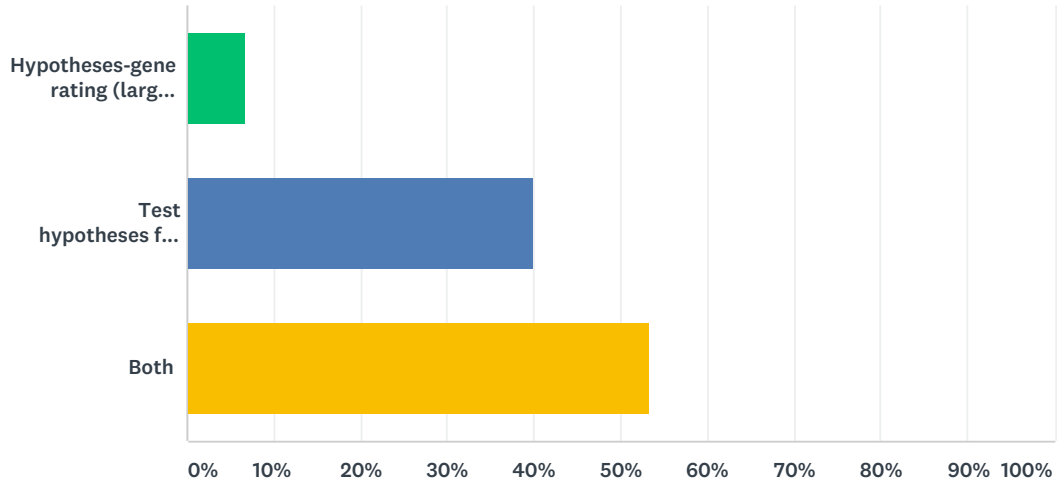
Answered: 13 Skipped: 12



ANSWER CHOICES	RESPONSES	
Early exploratory	0.00%	0
Discovery	23.08%	3
Preclinical	38.46%	5
Phase I	23.08%	3
Later	15.38%	2
TOTAL		13

Q52 Are your biomarker studies in phase 3 clinical trials designed to be:

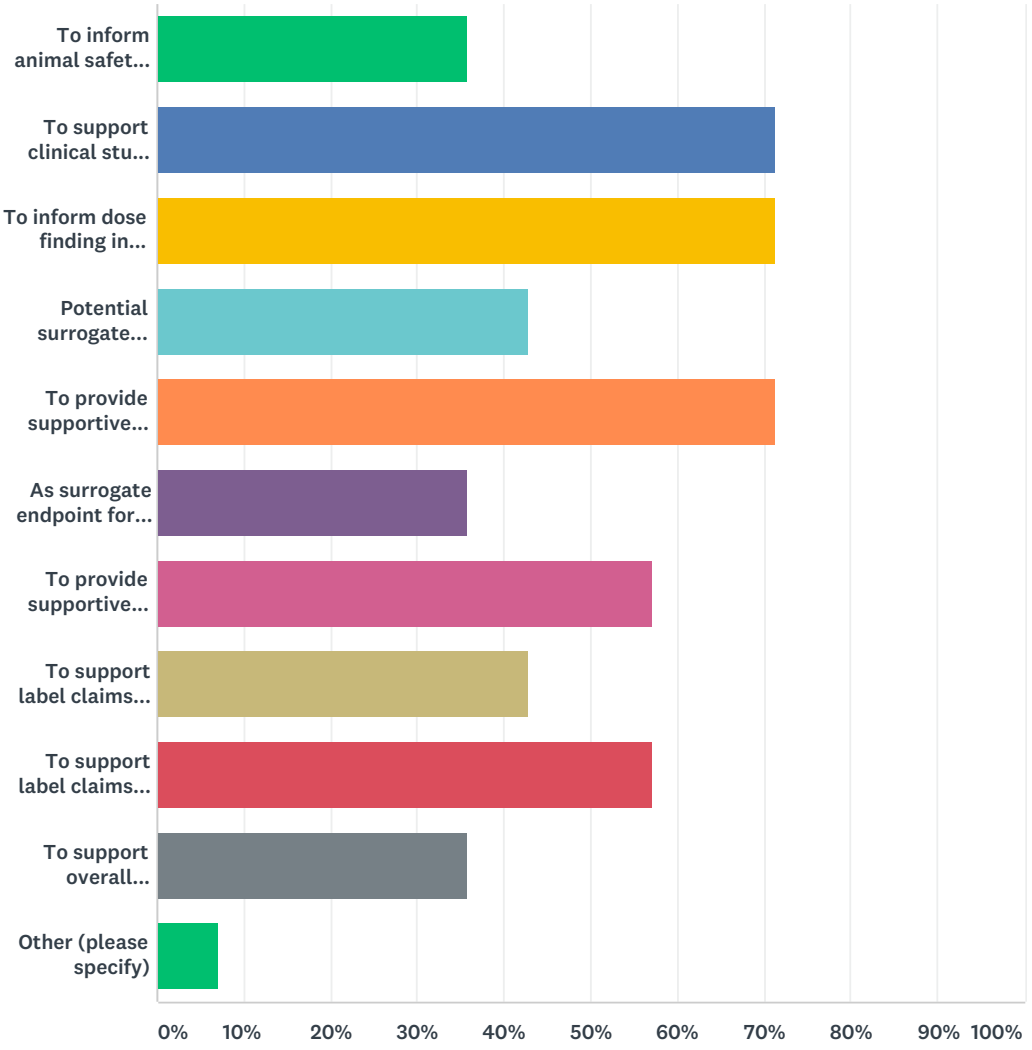
Answered: 15 Skipped: 10



ANSWER CHOICES	RESPONSES	
Hypotheses-generating (large scale profiling approaches)	6.67%	1
Test hypotheses for one or a few biomarkers	40.00%	6
Both	53.33%	8
TOTAL		15

Q53 How are biomarker study results used in regulatory submissions? (Select all that apply)

Answered: 14 Skipped: 11

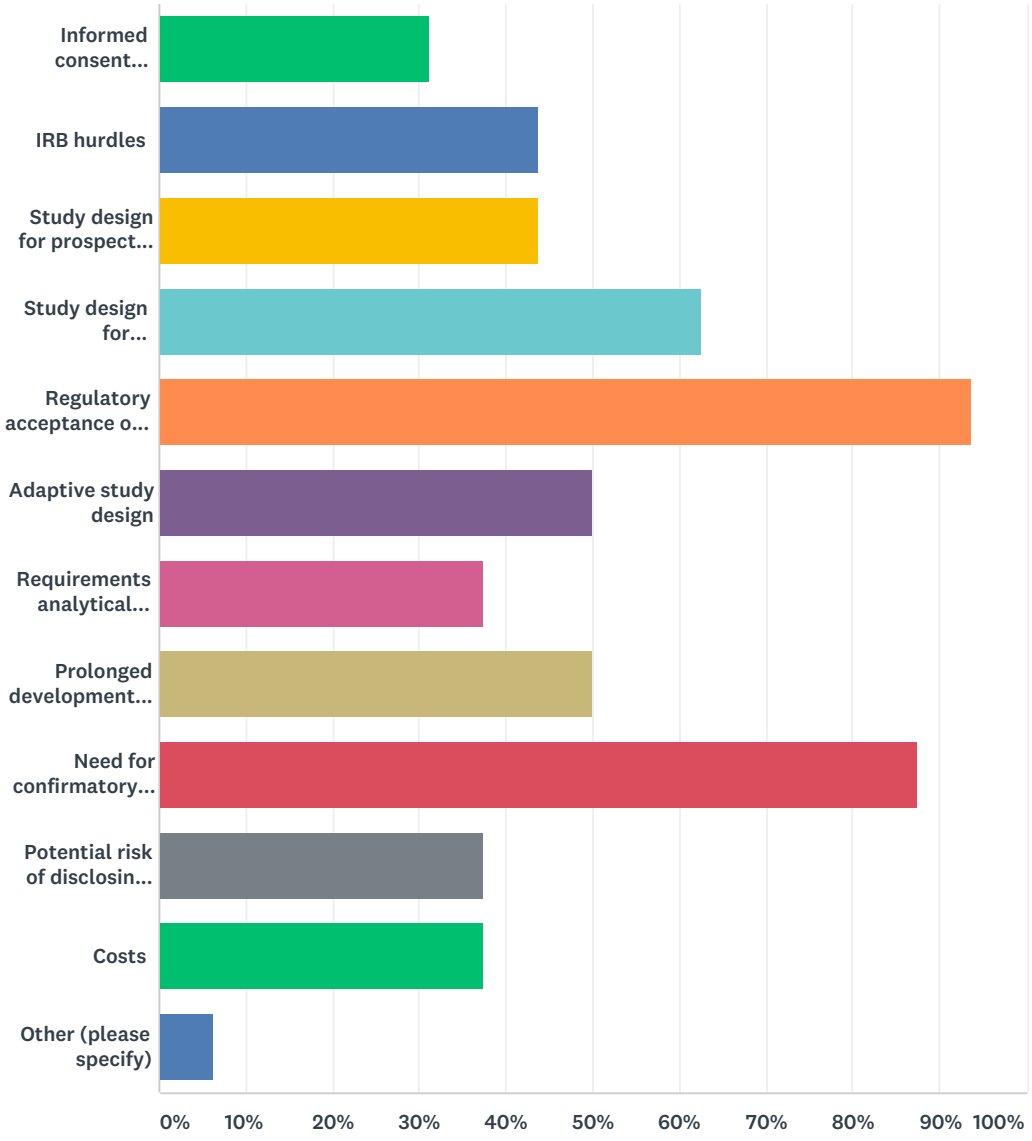


ANSWER CHOICES	RESPONSES	
To inform animal safety studies	35.71%	5
To support clinical study design (e.g. inclusion/exclusion, prognosis)	71.43%	10
To inform dose finding in clinical trials	71.43%	10
Potential surrogate endpoint for long-term efficacy outcomes	42.86%	6
To provide supportive evidence for efficacy	71.43%	10
As surrogate endpoint for efficacy in accelerated approval (when reasonably predictive of clinical benefit)	35.71%	5
To provide supportive evidence and rationale for adverse event/laboratory changes	57.14%	8
To support label claims: Clinical decision making (Indications, dosing recommendations/modifications)	42.86%	6
To support label claims: Descriptive sections (clinical pharmacology, clinical studies)	57.14%	8

To support overall benefit-risk assessments with ability to identify "extreme responder" and/or "non-responder" populations	35.71%	5
Other (please specify)	7.14%	1
Total Respondents: 14		

Q54 What do you think are the most important unresolved issues facing biomarker use in drug development today? (Select all that apply)

Answered: 16 Skipped: 9



ANSWER CHOICES	RESPONSES	
Informed consent harmonization	31.25%	5
IRB hurdles	43.75%	7
Study design for prospective analysis	43.75%	7
Study design for retrospective analysis	62.50%	10
Regulatory acceptance of retrospective data analysis	93.75%	15
Adaptive study design	50.00%	8
Requirements analytical validation	37.50%	6

Prolonged development programs	50.00%	8
Need for confirmatory/additional clinical studies	87.50%	14
Potential risk of disclosing exploratory data i.e. no "safe harbor"	37.50%	6
Costs	37.50%	6
Other (please specify)	6.25%	1
Total Respondents: 16		

Q55 Additional comments and thoughts

Answered: 3 Skipped: 22