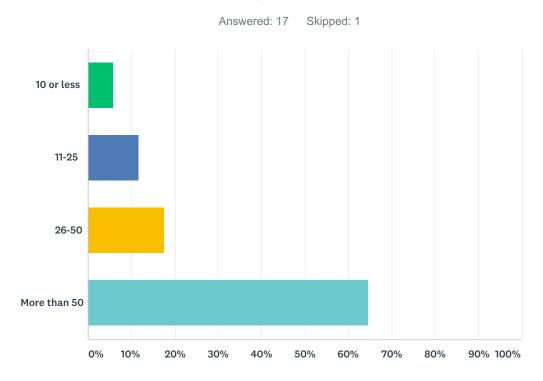
Q1 Please enter your I-PWG Survey Monkey code provided to you by Julian Arbuckle:

Answered: 18 Skipped: 0

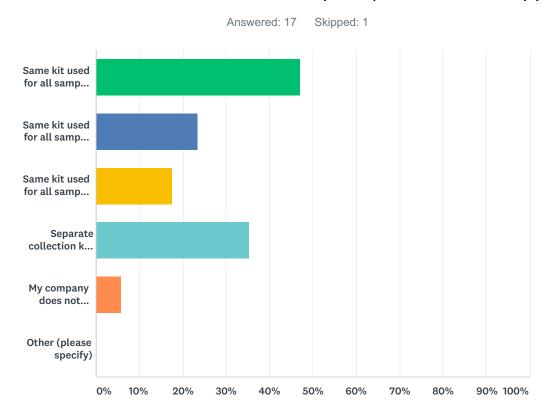
#	RESPONSES	DATE
1	7755	7/1/2019 10:38 AM
2	2910	6/28/2019 9:20 PM
3	8354	6/27/2019 7:06 PM
4	7507	6/27/2019 5:40 PM
5	7629	6/26/2019 8:39 PM
6	6920	6/26/2019 1:21 PM
7	3309	6/26/2019 9:55 AM
8	2276	6/25/2019 6:23 PM
9	2900	6/24/2019 7:41 AM
10	4099	6/21/2019 2:53 PM
11	8008	6/20/2019 3:56 PM
12	7345	6/20/2019 3:25 PM
13	9901	6/20/2019 1:39 AM
14	2531	6/19/2019 9:11 PM
15	2772	6/14/2019 6:17 PM
16	3287	6/11/2019 10:18 PM
17	3444	6/11/2019 5:06 PM
18	I-PWG	6/11/2019 2:16 PM

Q2 Approximately how many clinical trials does your company run in a year?



ANSWER CHOICES	RESPONSES	
10 or less	5.88%	1
11-25	11.76%	2
26-50	17.65%	3
More than 50	64.71%	11
TOTAL		17

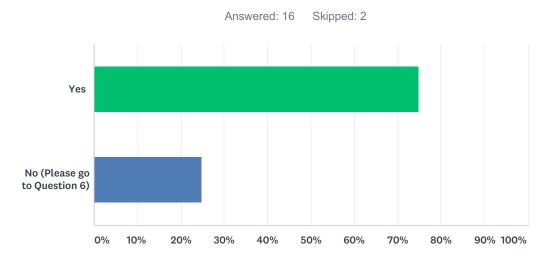
Q3 Please indicate the style of kits your company uses for collection tubes for banked/future use samples (check all that apply).



ANSWER CHOICES	RESPONS	SES
Same kit used for all samples (banked/future use samples and other clinical trial samples) with no special treatment of tubes for banked/future use samples	47.06%	8
Same kit used for all samples (banked/future use samples and other clinical trial samples) with banked/future sample tubes in a separate bag inside the kit to distinguish them	23.53%	4
Same kit used for all samples (banked/future use samples and other clinical trial samples) with warning label on banked/future use sample tubes to distinguish them	17.65%	3
Separate collection kits for banked/future use samples vs other clinical trial samples	35.29%	6
My company does not collect samples for banking/future use (please go to Question 7)	5.88%	1
Other (please specify)	0.00%	0
Total Respondents: 17		

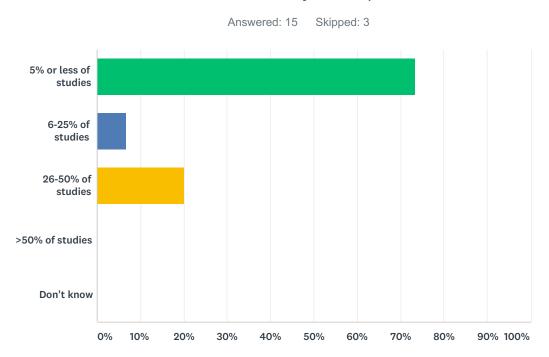
#	OTHER (PLEASE SPECIFY)	DATE
	There are no responses.	

Q4 In multi-site clinical trials, does your company experience the collection of banked/future use specimens at sites where the sampling is not allowed (e.g. due to IRB/EC rejection)?



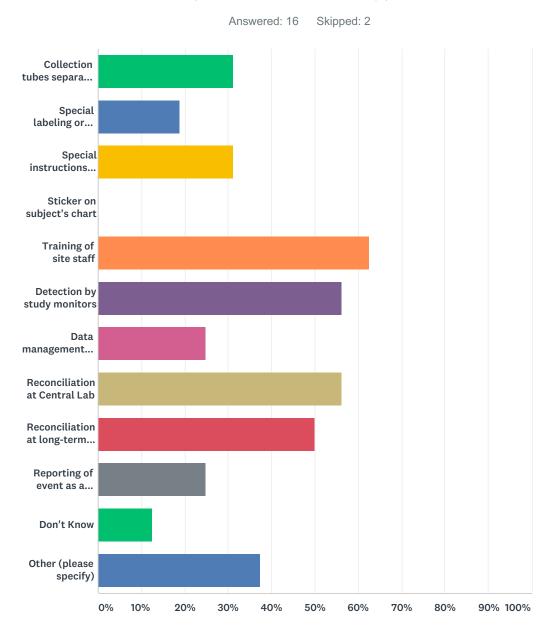
ANSWER CHOICES	RESPONSES	
Yes	75.00%	12
No (Please go to Question 6)	25.00%	4
TOTAL		16

Q5 Please indicate the approximate percentage of your multi-site clinical trials with banking/future use sampling that experience the collection of such specimens at sites where sampling is not allowed (e.g. due to IRB/EC rejection).



ANSWER CHOICES	RESPONSES	
5% or less of studies	73.33%	11
6-25% of studies	6.67%	1
26-50% of studies	20.00%	3
>50% of studies	0.00%	0
Don't know	0.00%	0
TOTAL		15

Q6 What steps do you take to address the collection of banked/future use samples in multi-site studies at sites where the sampling is not allowed (check all that apply).



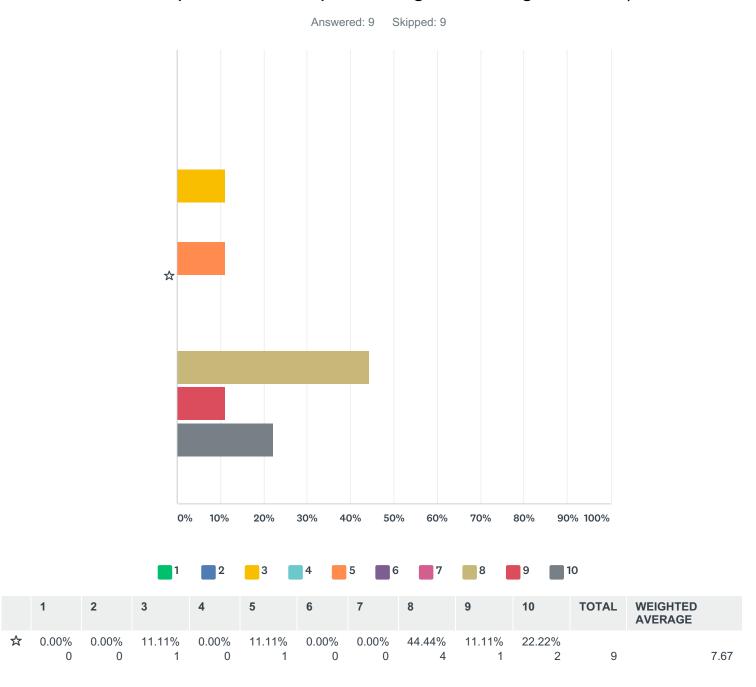
ANSWER CHOICES		RESPONSES	
Collection tubes separated from other tubes (e.g. separate kit; sequestered in separate bag within single kit; etc.)	31.25%	5	
Special labeling or warning on the banked/future use specimen collection tube	18.75%	3	
Special instructions on requisition form	31.25%	5	
Sticker on subject's chart	0.00%	0	
Training of site staff	62.50%	10	
Detection by study monitors	56.25%	9	

Erroneous Collection of Samples for Future Use/Banking

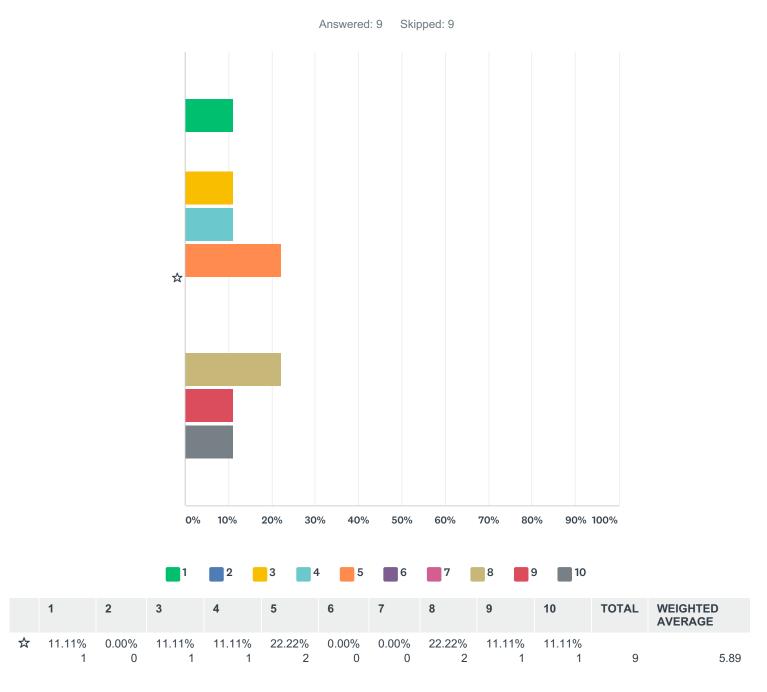
Data management approaches to detect the event in real time and issue queries	25.00%	4
Reconciliation at Central Lab	56.25%	9
Reconciliation at long-term storage facility	50.00%	8
Reporting of event as a protocol deviation or other such status that triggers internal action	25.00%	4
Don't Know	12.50%	2
Other (please specify)	37.50%	6
Total Respondents: 16		

#	OTHER (PLEASE SPECIFY)	DATE
1	Clinical CRO responsibility to tackle this	7/1/2019 10:38 AM
2	review of ICF for research use of samples is very reliable to detect erroneous samples, but this is not necessarily happening during the active study	6/26/2019 8:39 PM
3	It is not put in place at that site.	6/20/2019 1:39 AM
4	not applicable	6/19/2019 9:11 PM
5	Sample reconciliation against consent status.	6/11/2019 10:18 PM
6	kit specific per country regulations	6/11/2019 2:16 PM

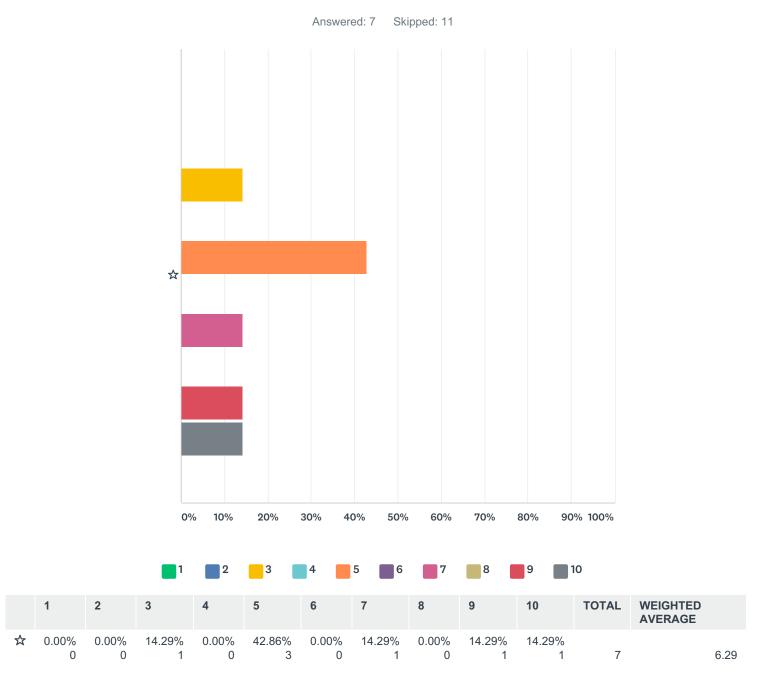
Q7 Considering all experience (including any experience acquired prior to role(s) at your current company), please rate the following steps on a scale of 1-10 for addressing the collection of banked/future use samples in multi-sites studies at sites at which sampling is not allowed. Rating Scale: 1 star = Not At All Effective and 10 stars = Extremely Effective. Please leave the answer blank if you do not have experience with this step. Step - Collection tubes separated from other tubes (e.g. separate kit; sequestered in separate bag within single kit; etc.)



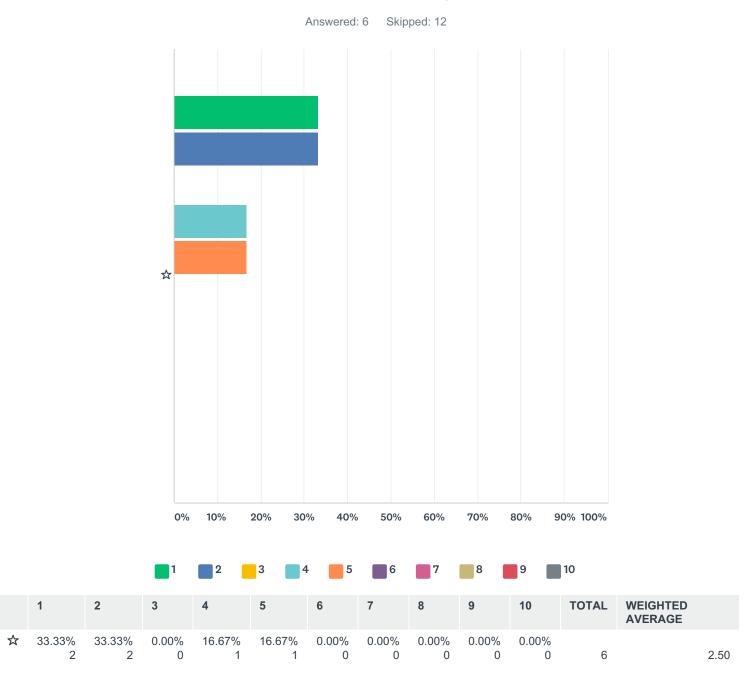
Q8 Considering all experience (including any experience acquired prior to role(s) at your current company), please rate the following steps on a scale of 1-10 for addressing the collection of banked/future use samples in multi-sites studies at sites at which sampling is not allowed. Rating Scale: 1 star = Not At All Effective and 10 stars = Extremely Effective. Please leave the answer blank if you do not have experience with this step. Step - Special labelling or warning on the banked/future use collection tube



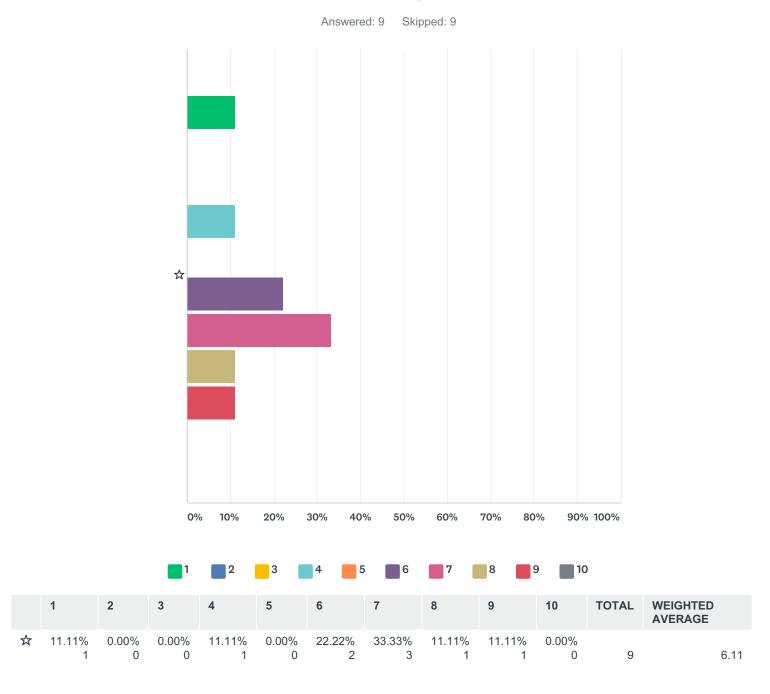
Q9 Considering all experience (including any experience acquired prior to role(s) at your current company), please rate the following steps on a scale of 1-10 for addressing the collection of banked/future use samples in multi-sites studies at sites at which sampling is not allowed. Rating Scale: 1 star = Not At All Effective and 10 stars = Extremely Effective. Please leave the answer blank if you do not have experience with this step. Step - Special instructions on requisition form



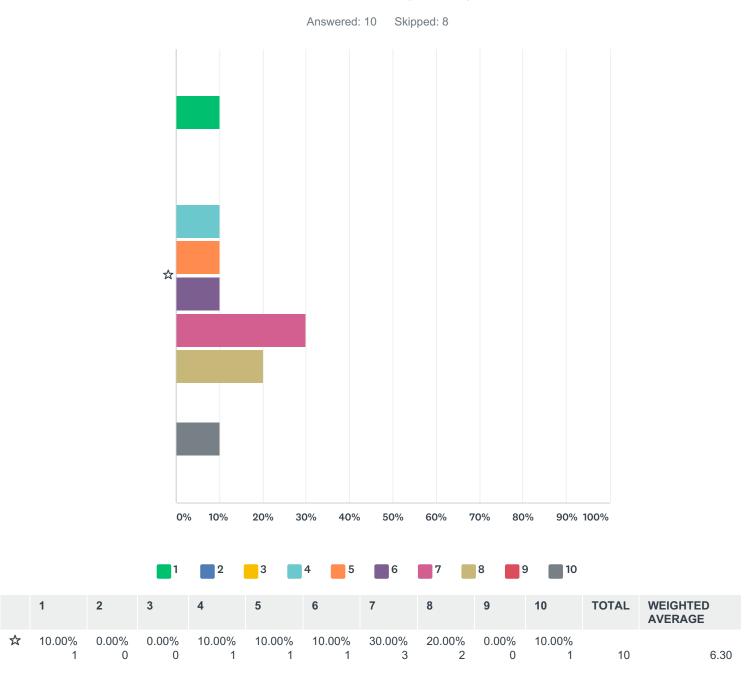
Q10 Considering all experience (including any experience acquired prior to role(s) at your current company), please rate the following steps on a scale of 1-10 for addressing the collection of banked/future use samples in multi-sites studies at sites at which sampling is not allowed. Rating Scale: 1 star = Not At All Effective and 10 stars = Extremely Effective. Please leave the answer blank if you do not have experience with this step. Step - Sticker on subject's chart



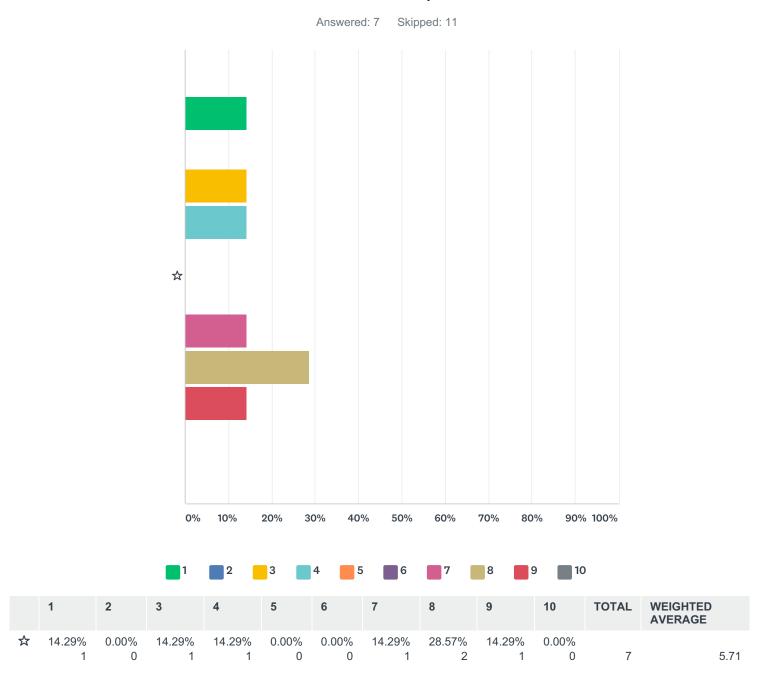
Q11 Considering all experience (including any experience acquired prior to role(s) at your current company), please rate the following steps on a scale of 1-10 for addressing the collection of banked/future use samples in multi-sites studies at sites at which sampling is not allowed. Rating Scale: 1 star = Not At All Effective and 10 stars = Extremely Effective. Please leave the answer blank if you do not have experience with this step. Step - Training of site staff



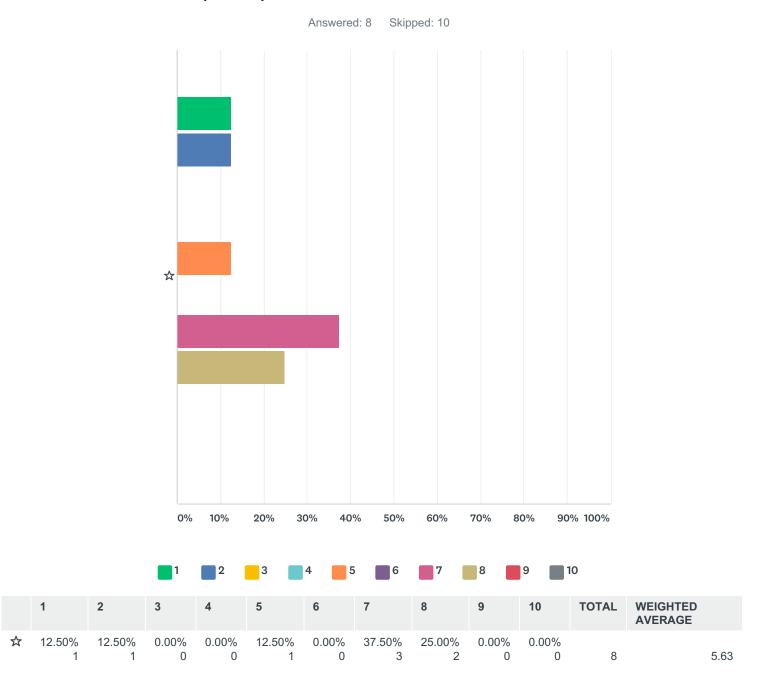
Q12 Considering all experience (including any experience acquired prior to role(s) at your current company), please rate the following steps on a scale of 1-10 for addressing the collection of banked/future use samples in multi-sites studies at sites at which sampling is not allowed. Rating Scale: 1 star = Not At All Effective and 10 stars = Extremely Effective. Please leave the answer blank if you do not have experience with this step. Step - Detection by study monitors



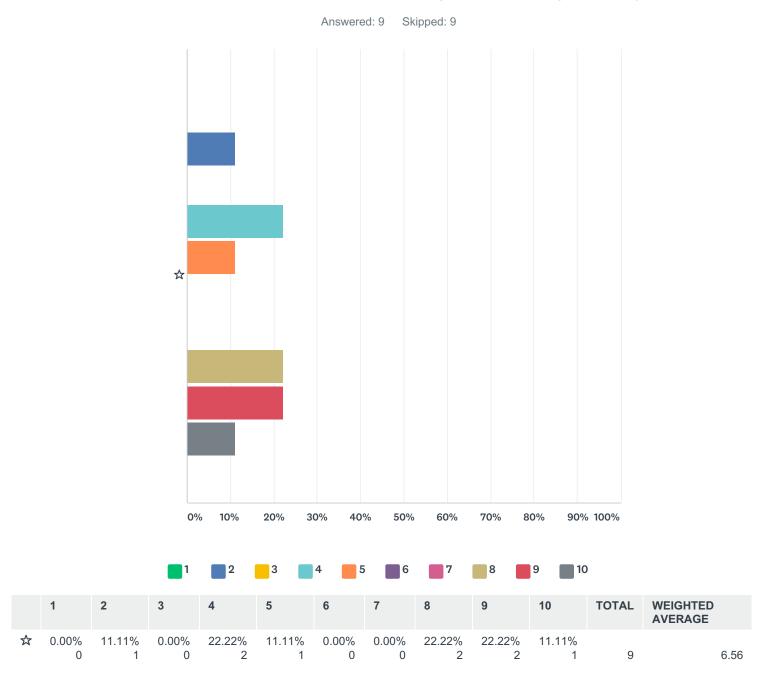
Q13 Considering all experience (including any experience acquired prior to role(s) at your current company), please rate the following steps on a scale of 1-10 for addressing the collection of banked/future use samples in multi-sites studies at sites at which sampling is not allowed. Rating Scale: 1 star = Not At All Effective and 10 stars = Extremely Effective. Please leave the answer blank if you do not have experience with this step. Step - Data management approaches to detect the event in real time and issue queries



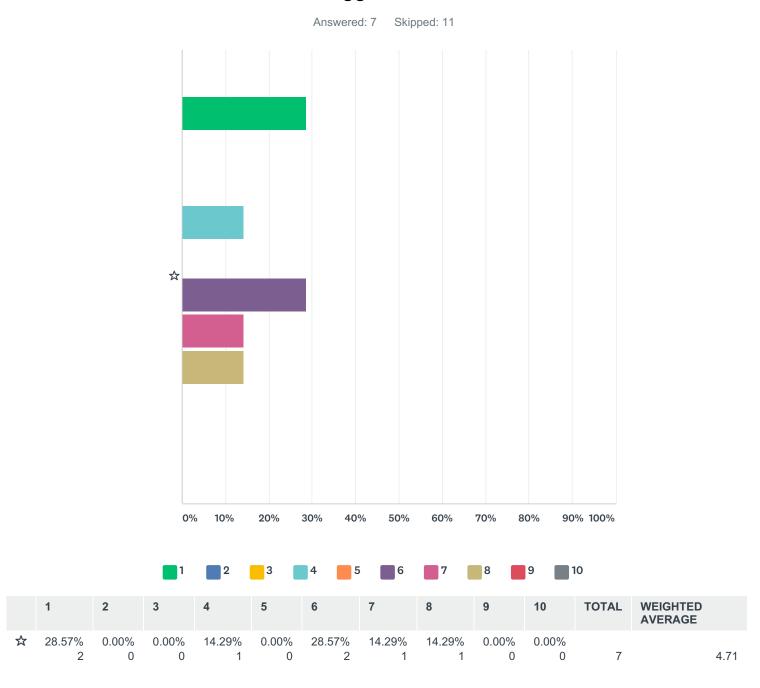
Q14 Considering all experience (including any experience acquired prior to role(s) at your current company), please rate the following steps on a scale of 1-10 for addressing the collection of banked/future use samples in multi-sites studies at sites at which sampling is not allowed. Rating Scale: 1 star = Not At All Effective and 10 stars = Extremely Effective. Please leave the answer blank if you do not have experience with this step. Step - Reconciliation at Central Lab



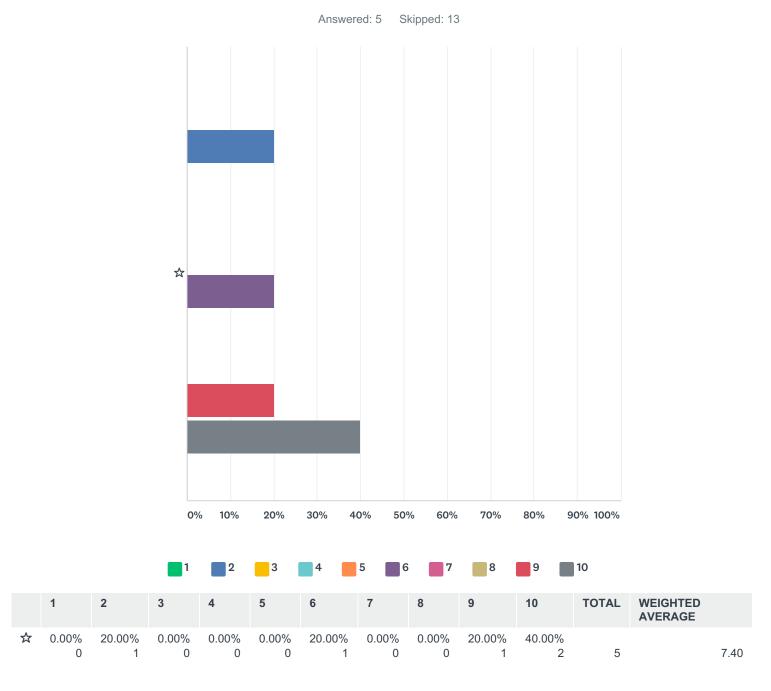
Q15 Considering all experience (including any experience acquired prior to role(s) at your current company), please rate the following steps on a scale of 1-10 for addressing the collection of banked/future use samples in multi-sites studies at sites at which sampling is not allowed. Rating Scale: 1 star = Not At All Effective and 10 stars = Extremely Effective. Please leave the answer blank if you do not have experience with this step. Step - Reconciliation at long-term storage facility



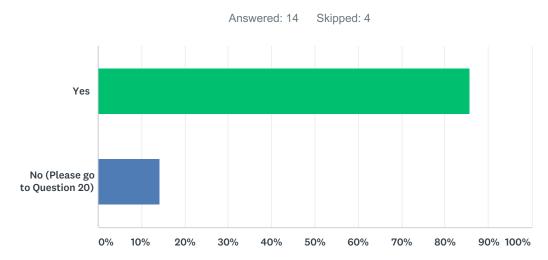
Q16 Considering all experience (including any experience acquired prior to role(s) at your current company), please rate the following steps on a scale of 1-10 for addressing the collection of banked/future use samples in multi-sites studies at sites at which sampling is not allowed. Rating Scale: 1 star = Not At All Effective and 10 stars = Extremely Effective. Please leave the answer blank if you do not have experience with this step. Step - Reporting of event as a protocol deviation or other such status that triggers internal action



Q17 If you selected "Other" in Question 6 and specified a step that was not listed, please rate that step here on a 1 (Not At All Effective) - 10 (Extremely Effective) scale. Otherwise, please go to Question 18.

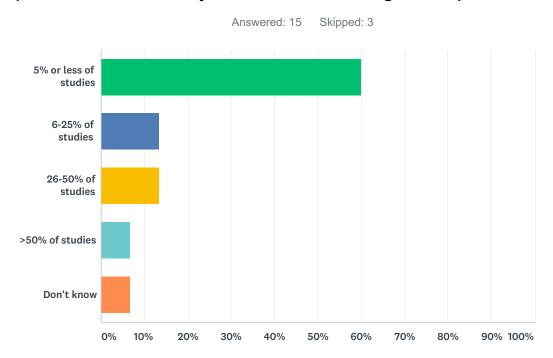


Q18 When the collection of banked/future use specimens is optional, does your company experience the collection of such specimens from subjects who did not agree to provide them?



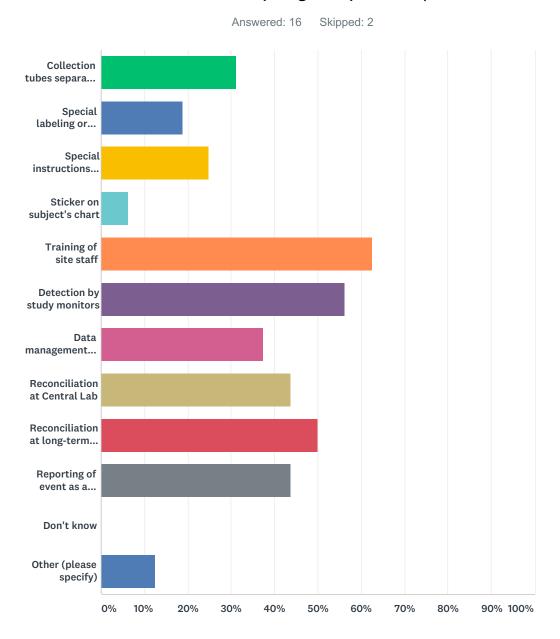
ANSWER CHOICES	RESPONSES	
Yes	85.71%	12
No (Please go to Question 20)	14.29%	2
TOTAL		14

Q19 Please indicate the approximate percentage of your clinical trials with banking/future use sampling that experience the collection of such specimens from subjects who did not agree to provide them.



ANSWER CHOICES	RESPONSES	
5% or less of studies	60.00%	9
6-25% of studies	13.33%	2
26-50% of studies	13.33%	2
>50% of studies	6.67%	1
Don't know	6.67%	1
TOTAL		15

Q20 What steps does/did your company take to address the collection of banked/future use samples from subjects who did not agree to provide them at sites at which the sampling is optional (check all that apply).



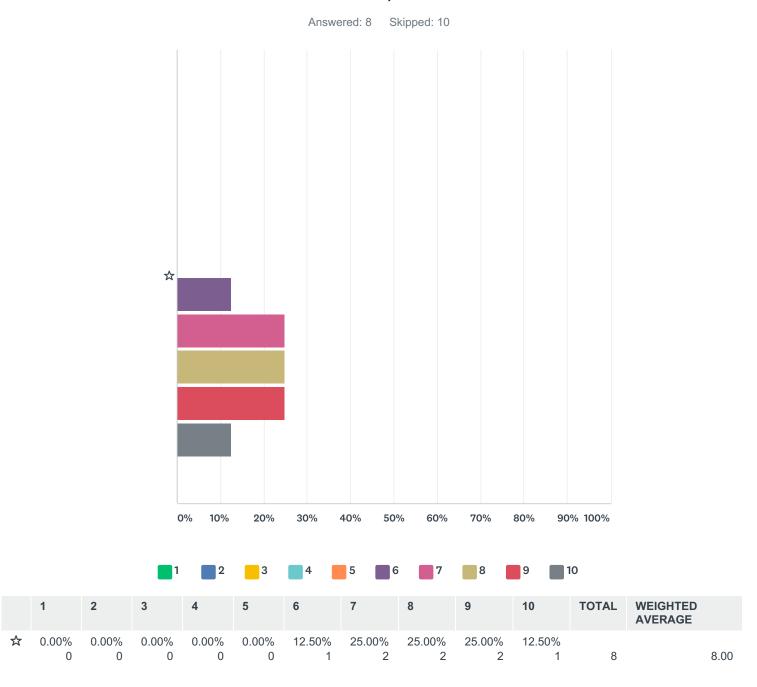
ANSWER CHOICES		RESPONSES	
Collection tubes separated from other tubes (e.g. separate kit; sequestered in separate bag within single kit; etc.)	31.25%	5	
Special labeling or warning on the banked/future use specimen collection tube	18.75%	3	
Special instructions on the requisition form	25.00%	4	
Sticker on subject's chart	6.25%	1	
Training of site staff	62.50%	10	
Detection by study monitors	56.25%	9	

Erroneous Collection of Samples for Future Use/Banking

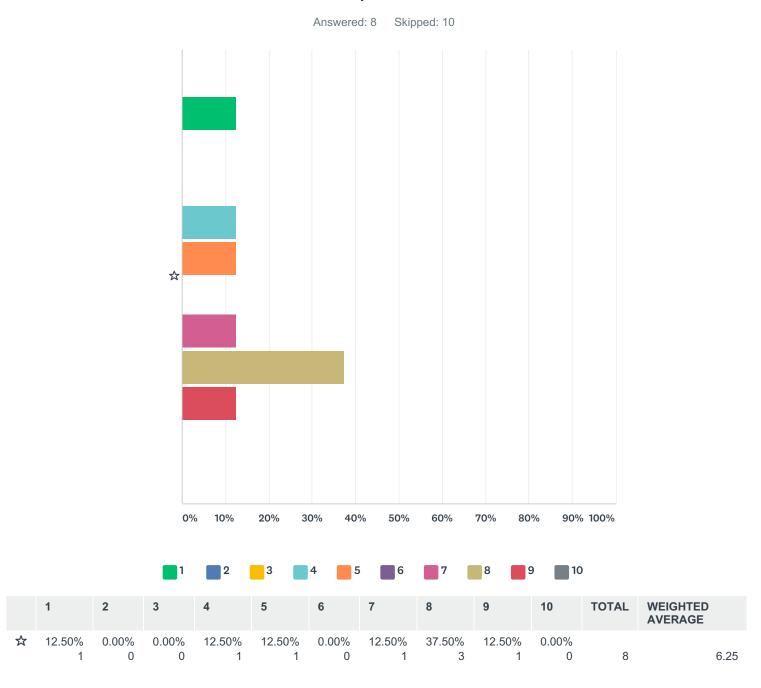
Data management approaches to detect the event in real time and issue queries	37.50%	6
Reconciliation at Central Lab	43.75%	7
Reconciliation at long-term storage facility	50.00%	8
Reporting of event as a protocol deviation or other such status that triggers internal action	43.75%	7
Don't know	0.00%	0
Other (please specify)	12.50%	2
Total Respondents: 16		

#	OTHER (PLEASE SPECIFY)	DATE
1	Reconciliation against consent status.	6/11/2019 10:18 PM
2	reconciliation prior to storage	6/11/2019 2:16 PM

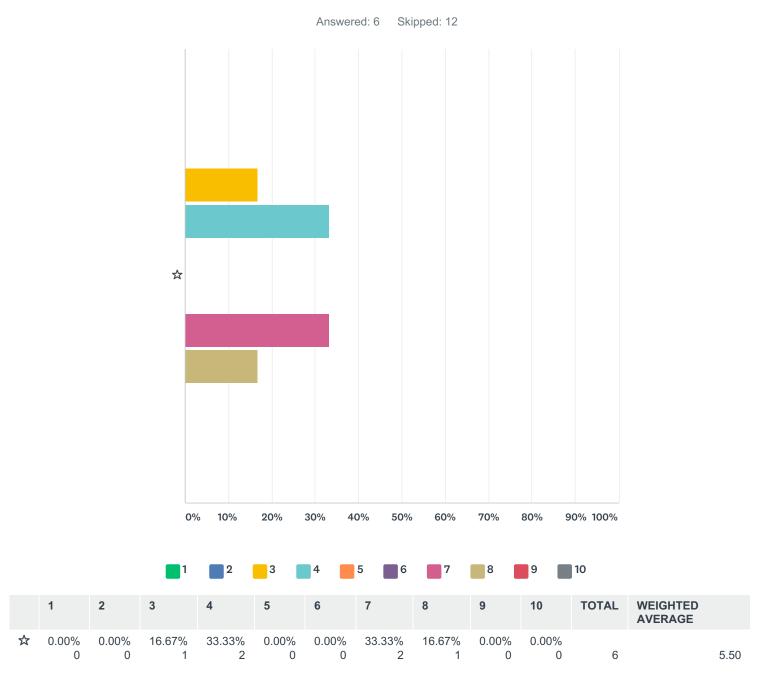
Q21 Considering all experience (including any experience acquired prior to role(s) at your current company), please rate the following steps on a scale of 1-10 for addressing the collection of banked/future use samples from subjects who do not agree to provide them at sites at which the sampling is optional. Scale: 1 Star = Not At All Effective and 10 Stars = Extremely Effective. Please leave the answer blank if you do not have experience with this step. Step - Collection tubes separated from other tubes (e.g. separate kit; sequestered in separate bag within single kit; etc.)



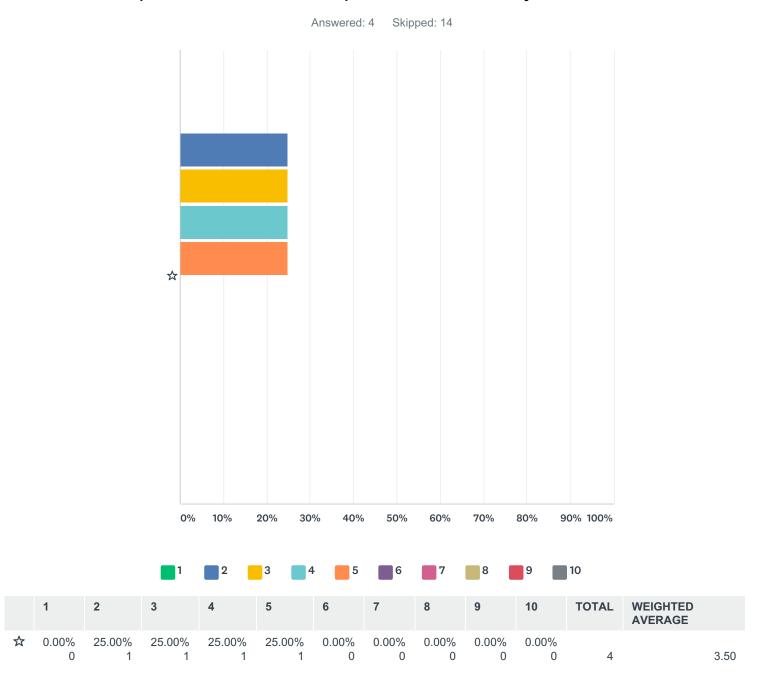
Q22 Considering all experience (including any experience acquired prior to role(s) at your current company), please rate the following steps on a scale of 1-10 for addressing the collection of banked/future use samples from subjects who do not agree to provide them at sites at which the sampling is optional. Scale: 1 Star = Not At All Effective and 10 Stars = Extremely Effective. Please leave the answer blank if you do not have experience with this step. Step - Special labelling or warning on the banked/future use specimen collection tube



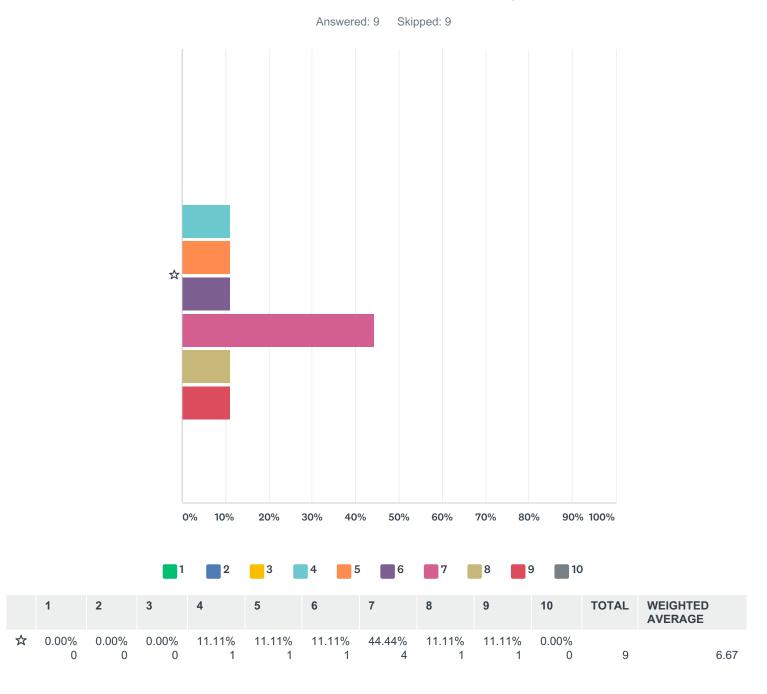
Q23 Considering all experience (including any experience acquired prior to role(s) at your current company), please rate the following steps on a scale of 1-10 for addressing the collection of banked/future use samples from subjects who do not agree to provide them at sites at which the sampling is optional. Scale: 1 Star = Not At All Effective and 10 Stars = Extremely Effective. Please leave the answer blank if you do not have experience with this step. Step - Special instructions on requisition form



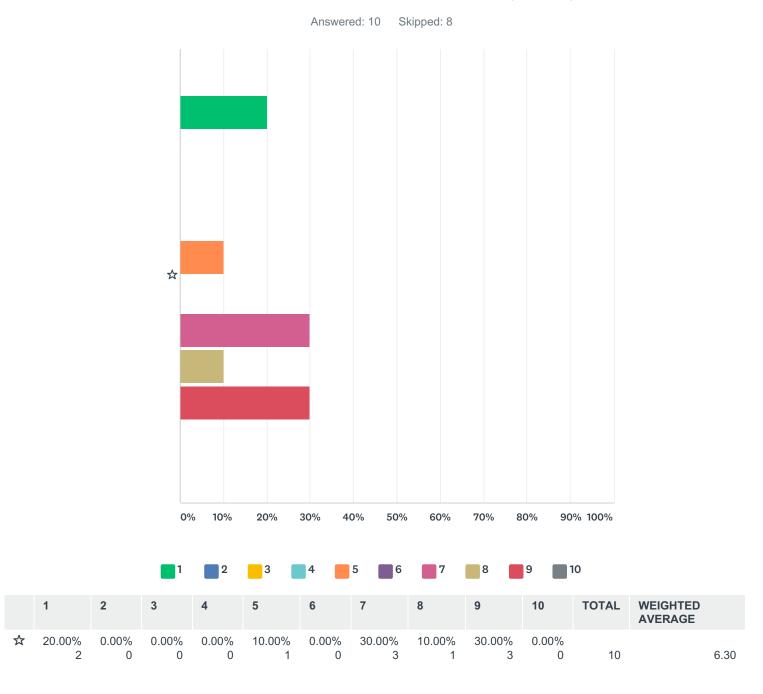
Q24 Considering all experience (including any experience acquired prior to role(s) at your current company), please rate the following steps on a scale of 1-10 for addressing the collection of banked/future use samples from subjects who do not agree to provide them at sites at which the sampling is optional. Scale: 1 Star = Not At All Effective and 10 Stars = Extremely Effective. Please leave the answer blank if you do not have experience with this step. Sticker on a subject's chart.



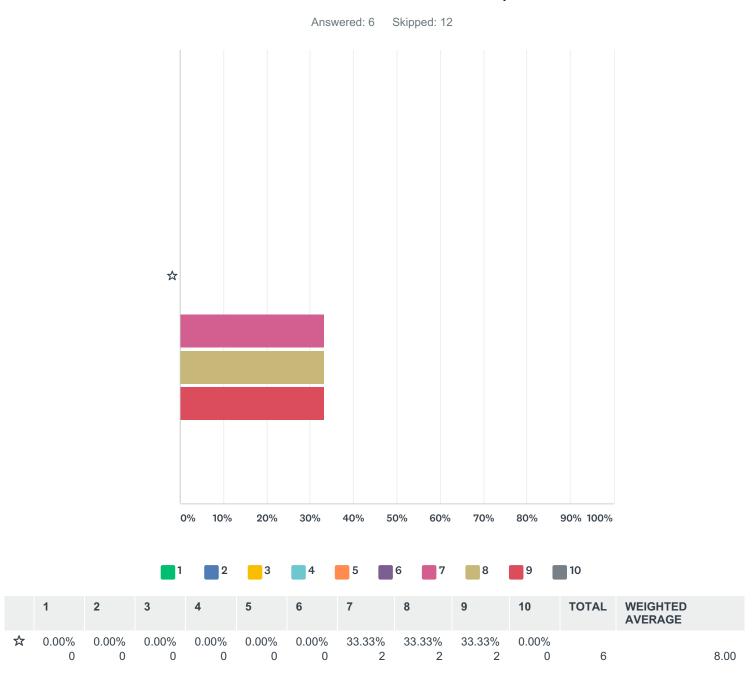
Q25 Considering all experience (including any experience acquired prior to role(s) at your current company), please rate the following steps on a scale of 1-10 for addressing the collection of banked/future use samples from subjects who do not agree to provide them at sites at which the sampling is optional. Scale: 1 Star = Not At All Effective and 10 Stars = Extremely Effective. Please leave the answer blank if you do not have experience with this step. Step - Training of site staff



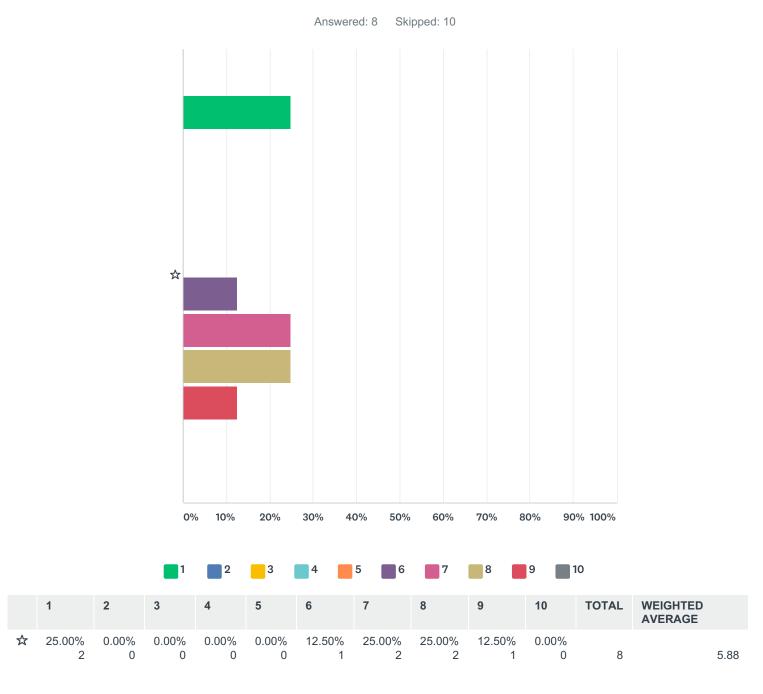
Q26 Considering all experience (including any experience acquired prior to role(s) at your current company), please rate the following steps on a scale of 1-10 for addressing the collection of banked/future use samples from subjects who do not agree to provide them at sites at which the sampling is optional. Scale: 1 Star = Not At All Effective and 10 Stars = Extremely Effective. Please leave the answer blank if you do not have experience with this step. Step - Detection by study monitors



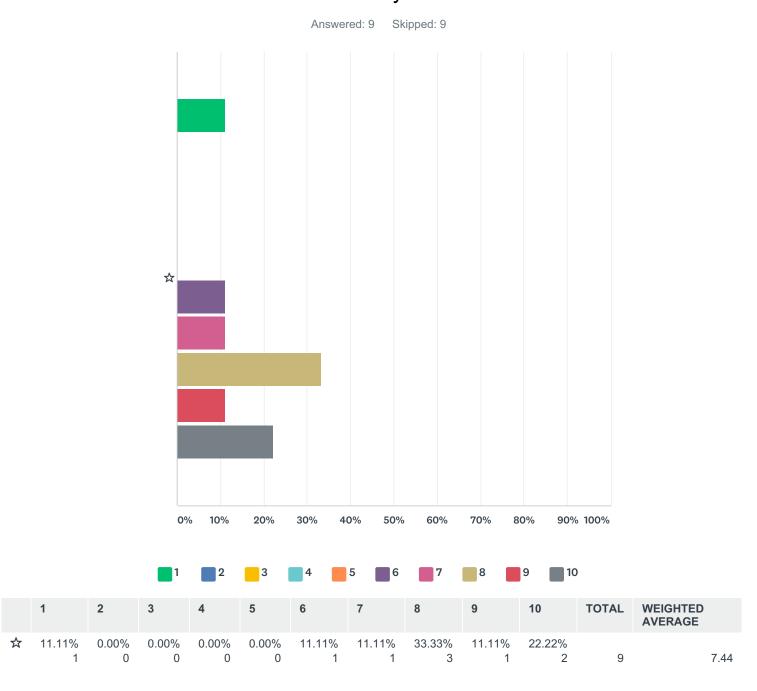
Q27 Considering all experience (including any experience acquired prior to role(s) at your current company), please rate the following steps on a scale of 1-10 for addressing the collection of banked/future use samples from subjects who do not agree to provide them at sites at which the sampling is optional. Scale: 1 Star = Not At All Effective and 10 Stars = Extremely Effective. Please leave the answer blank if you do not have experience with this step. Step - Data management approaches to detect the event in real time and issue queries



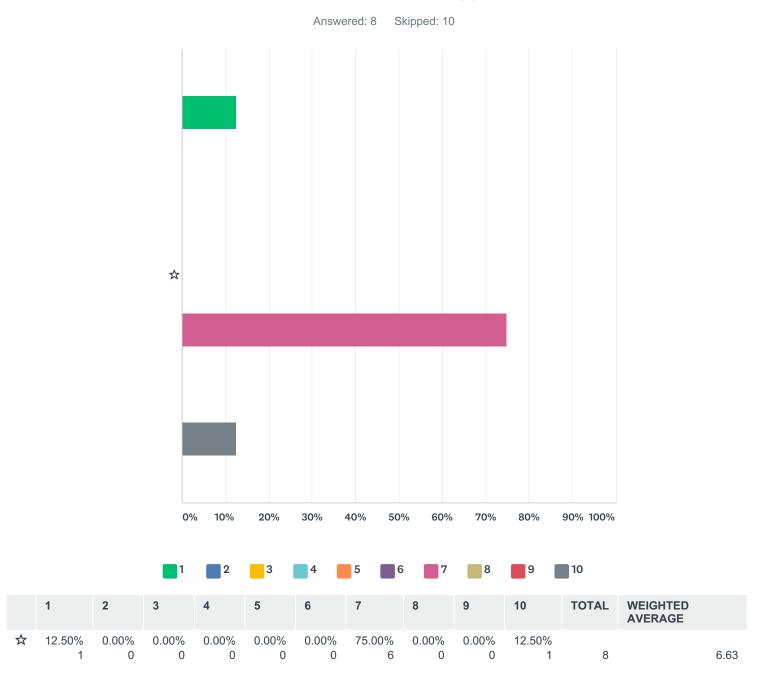
Q28 Considering all experience (including any experience acquired prior to role(s) at your current company), please rate the following steps on a scale of 1-10 for addressing the collection of banked/future use samples from subjects who do not agree to provide them at sites at which the sampling is optional. Scale: 1 Star = Not At All Effective and 10 Stars = Extremely Effective. Please leave the answer blank if you do not have experience with this step. Step - Reconciliation at Central Lab



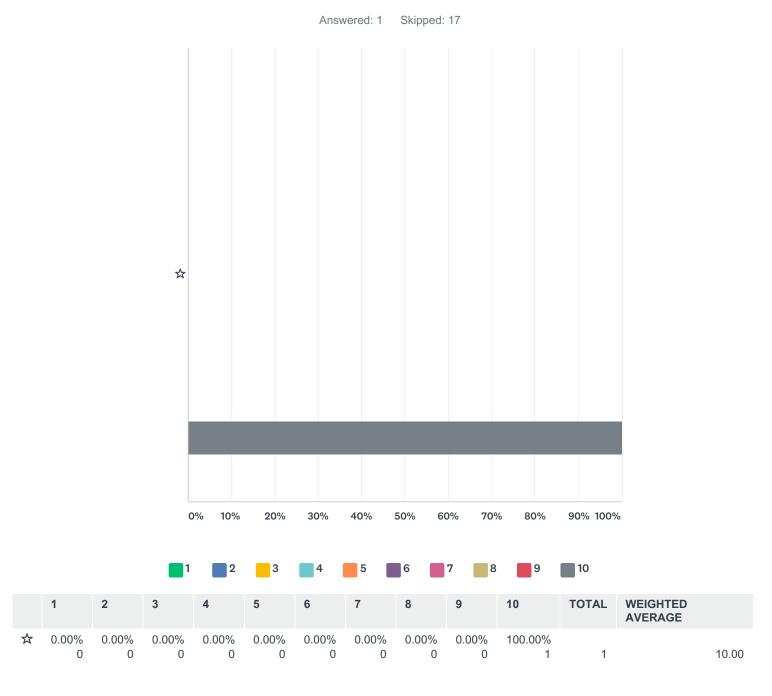
Q29 Considering all experience (including any experience acquired prior to role(s) at your current company), please rate the following steps on a scale of 1-10 for addressing the collection of banked/future use samples from subjects who do not agree to provide them at sites at which the sampling is optional. Scale: 1 Star = Not At All Effective and 10 Stars = Extremely Effective. Please leave the answer blank if you do not have experience with this step. Step - Reconciliation at long-term storage facility



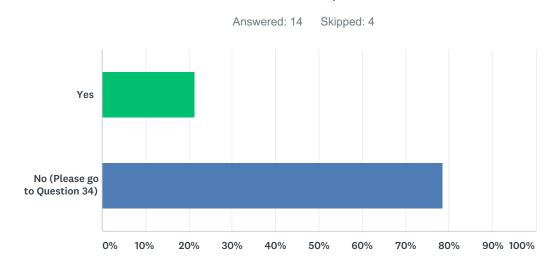
Q30 Considering all experience (including any experience acquired prior to role(s) at your current company), please rate the following steps on a scale of 1-10 for addressing the collection of banked/future use samples from subjects who do not agree to provide them at sites at which the sampling is optional. Scale: 1 Star = Not At All Effective and 10 Stars = Extremely Effective. Please leave the answer blank if you do not have experience with this step. Step - Reporting of an event as a protocol deviation or other such status that triggers internal action



Q31 If you selected "Other" in Question 20 and specified a step that was not listed, please rate that step here on a 1 (Not At All Effective) - 10 (Extremely Effective) scale. Otherwise, please go to Question 32.



Q32 Considering all experience (including any experience acquired prior to role(s) at your current company), are there any approaches that are associated with an unacceptable number of missed banked/future use samples (i.e. samples not collected when they should have been collected)?



ANSWER CHOICES	RESPONSES	
Yes	21.43%	3
No (Please go to Question 34)	78.57%	11
TOTAL		14

Q33 If you answered "Yes" to Question 32 please specify these approaches:

Answered: 3 Skipped: 15

#	RESPONSES	DATE
1	Sample reconciliation	6/24/2019 7:41 AM
2	If a "nice-to-have" mentality exists with these samples, then there should be retraining of staff to ensure they understand why it is important to collect these future use/research samples.	6/21/2019 2:53 PM
3	Retraining of site staff	6/20/2019 3:56 PM

Q34 Please provide any other comments that you think are informative, including information to clarify your responses to Questions 2 - 33:

Answered: 9 Skipped: 9

#	RESPONSES	DATE
1	It was rather difficult to answer the detailed questions since there are lot of variation between clinical CRO practices and study sites.	7/1/2019 10:38 AM
2	Any samples collected but not consented are destroyed	6/27/2019 7:06 PM
3	Most processes are standard, and others may be study specific and implemented at the discretion of the functional area responsible for requisitions. I am not confident that requisitions are read completely prior to collections.	6/26/2019 8:39 PM
4	The company is about to collect samples for whole genome sequencing in wholly owned programs moving forward but hasn't done so systematically until now.	6/25/2019 6:23 PM
5	The purpose of this survey seemed confusing. It seemed the designers were more focused on liability issues when samples were collected when they shouldn't have been and not best practices of how best to collect future research samples or how to address site's or IRB concerns. Also many of the questions were logistical/operational preferences and somewhat common sense, so not sure how this survey will really help the I-PWG membership.	6/21/2019 2:53 PM
6	We are curious if other companies require a separate FBR consent or if it is a check box on the main ICF	6/20/2019 3:56 PM
7	We have answered this survey for broad use genomic samples - these are all optional and under a separated consent addendum	6/20/2019 3:25 PM
8	Most of the time we are not collecting new samples specifically for future use but asking to use any leftover samples.	6/20/2019 1:39 AM
9	Focus on finding samples we should not have does not allow adequate resources to track down samples we should have.	6/11/2019 10:18 PM