

#1

COMPLETE

Collector: Email Invitation 1 (Email)
Started: Tuesday, June 11, 2019 2:10:02 PM
Last Modified: Tuesday, June 11, 2019 2:15:50 PM
Time Spent: 00:05:48
Email:
IP Address:

Page 1: This anonymous survey is about the erroneous collection of samples for future use/banking.

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

I-PWG

Q2 Approximately how many clinical trials does your company run in a year? **More than 50**

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

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

,

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

,

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

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)? **No (Please go to Question 6)**

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). **26-50% of studies**

Erroneous Collection of Samples for Future Use/Banking

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).

Other (please specify):
kit specific per country regulations

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.)

Respondent skipped this question

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

Respondent skipped this question

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

Respondent skipped this question

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

Respondent skipped this question

Erroneous Collection of Samples for Future Use/Banking

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

Respondent skipped this question

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

Respondent skipped this question

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

Respondent skipped this question

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

Respondent skipped this question

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

Respondent skipped this question

Erroneous Collection of Samples for Future Use/Banking

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

Respondent skipped this question

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.

Respondent skipped this question

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?

Respondent skipped this question

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.

26-50% of studies

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).

Other (please specify):
reconciliation prior to storage

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.)

Respondent skipped this question

Erroneous Collection of Samples for Future Use/Banking

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

Respondent skipped this question

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

Respondent skipped this question

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.

Respondent skipped this question

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

Respondent skipped this question

Erroneous Collection of Samples for Future Use/Banking

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

Respondent skipped this question

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

Respondent skipped this question

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

Respondent skipped this question

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

Respondent skipped this question

Erroneous Collection of Samples for Future Use/Banking

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

Respondent skipped this question

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.

Respondent skipped this question

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)?

No (Please go to Question 34)

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

Respondent skipped this question

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

Respondent skipped this question

#2

COMPLETE

Collector: Email Invitation 1 (Email)
Started: Tuesday, June 11, 2019 4:51:43 PM
Last Modified: Tuesday, June 11, 2019 5:06:01 PM
Time Spent: 00:14:18
Email:
IP Address:

Page 1: This anonymous survey is about the erroneous collection of samples for future use/banking.

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

3444

Q2 Approximately how many clinical trials does your company run in a year? **More than 50**

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

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)? **Yes**

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). **5% or less of studies**

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). **Training of site staff, Detection by study monitors, Reconciliation at Central Lab, Reconciliation at long-term storage facility**

Erroneous Collection of Samples for Future Use/Banking

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.)

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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

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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

Respondent skipped this question

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

Respondent skipped this question

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

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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

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Erroneous Collection of Samples for Future Use/Banking

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

Respondent skipped this question

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

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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

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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

Respondent skipped this question

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.

Respondent skipped this question

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?

Yes

Erroneous Collection of Samples for Future Use/Banking

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.

6-25% of studies

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).

Training of site staff ,
Detection by study monitors ,
Data management approaches to detect the event in real time and issue queries ,
Reconciliation at Central Lab ,
Reconciliation at long-term storage facility ,
Reporting of event as a protocol deviation or other such status that triggers internal action

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.)

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9

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

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9

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

Respondent skipped this question

Erroneous Collection of Samples for Future Use/Banking

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.

Respondent skipped this question

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

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7

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

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9

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

☆

9

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

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6

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

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10

Erroneous Collection of Samples for Future Use/Banking

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

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7

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.

Respondent skipped this question

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)?

No (Please go to Question 34)

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

Respondent skipped this question

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

Respondent skipped this question

#3

COMPLETE

Collector: Email Invitation 1 (Email)
Started: Tuesday, June 11, 2019 8:58:28 PM
Last Modified: Tuesday, June 11, 2019 10:18:18 PM
Time Spent: 01:19:50
Email:
IP Address:

Page 1: This anonymous survey is about the erroneous collection of samples for future use/banking.

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

3287

Q2 Approximately how many clinical trials does your company run in a year? **More than 50**

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

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)? **Yes**

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). **5% or less of studies**

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). **Training of site staff**, **Detection by study monitors**, **Special instructions on requisition form**, Other (please specify): **Sample reconciliation against consent status.**

Erroneous Collection of Samples for Future Use/Banking

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.)

Respondent skipped this question

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

Respondent skipped this question

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

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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

Respondent skipped this question

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

☆ 4

Erroneous Collection of Samples for Future Use/Banking

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

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10

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

Respondent skipped this question

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

Respondent skipped this question

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

Respondent skipped this question

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

Respondent skipped this question

Erroneous Collection of Samples for Future Use/Banking

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.

☆

10

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? **Yes**

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. **>50% of studies**

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).

Training of site staff ,

Detection by study monitors ,

Special instructions on the requisition form ,

Other (please specify):
Reconciliation against consent status.

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.)

Respondent skipped this question

Erroneous Collection of Samples for Future Use/Banking

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

Respondent skipped this question

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

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4

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.

Respondent skipped this question

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

☆

4

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

☆

8

Erroneous Collection of Samples for Future Use/Banking

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

Respondent skipped this question

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

Respondent skipped this question

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

Respondent skipped this question

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

Respondent skipped this question

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.

☆

10

Erroneous Collection of Samples for Future Use/Banking

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)?

No (Please go to Question 34)

Q33 If you answered "Yes" to Question 32 please specify these approaches: **Respondent skipped this question**

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

Focus on finding samples we should not have does not allow adequate resources to track down samples we should have.

#4

COMPLETE

Collector: Email Invitation 1 (Email)
Started: Friday, June 14, 2019 6:12:10 PM
Last Modified: Friday, June 14, 2019 6:16:43 PM
Time Spent: 00:04:33
Email:
IP Address:

Page 1: This anonymous survey is about the erroneous collection of samples for future use/banking.

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

2772

Q2 Approximately how many clinical trials does your company run in a year? **More than 50**

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

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)? **Yes**

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). **26-50% of studies**

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). **Detection by study monitors, Reconciliation at long-term storage facility, Reporting of event as a protocol deviation or other such status that triggers internal action**

Erroneous Collection of Samples for Future Use/Banking

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.)

Respondent skipped this question

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

Respondent skipped this question

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

Respondent skipped this question

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

Respondent skipped this question

Erroneous Collection of Samples for Future Use/Banking

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

Respondent skipped this question

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

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1

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

Respondent skipped this question

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

Respondent skipped this question

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

☆

8

Erroneous Collection of Samples for Future Use/Banking

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

☆

6

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. **Respondent skipped this question**

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? **Yes**

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. **26-50% of studies**

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). **Detection by study monitors**, **Reconciliation at long-term storage facility**

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.) **Respondent skipped this question**

Erroneous Collection of Samples for Future Use/Banking

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

Respondent skipped this question

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

Respondent skipped this question

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.

Respondent skipped this question

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

Respondent skipped this question

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

☆

1

Erroneous Collection of Samples for Future Use/Banking

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

Respondent skipped this question

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

Respondent skipped this question

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

☆

8

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

Respondent skipped this question

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.

Respondent skipped this question

Erroneous Collection of Samples for Future Use/Banking

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)?

No (Please go to Question 34)

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

Respondent skipped this question

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

Respondent skipped this question

#5

COMPLETE

Collector: Email Invitation 1 (Email)
Started: Wednesday, June 19, 2019 8:59:49 PM
Last Modified: Wednesday, June 19, 2019 9:11:25 PM
Time Spent: 00:11:36
Email:
IP Address:

Page 1: This anonymous survey is about the erroneous collection of samples for future use/banking.

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

2531

Q2 Approximately how many clinical trials does your company run in a year? **26-50**

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

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)? **No (Please go to Question 6)**

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). **Respondent skipped this question**

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). **Don't Know, Other (please specify): not applicable**

Erroneous Collection of Samples for Future Use/Banking

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.)

Respondent skipped this question

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

Respondent skipped this question

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

Respondent skipped this question

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

Respondent skipped this question

Erroneous Collection of Samples for Future Use/Banking

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

Respondent skipped this question

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

Respondent skipped this question

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

Respondent skipped this question

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

Respondent skipped this question

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

Respondent skipped this question

Erroneous Collection of Samples for Future Use/Banking

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

Respondent skipped this question

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.

Respondent skipped this question

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?

Yes

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.

5% or less of studies

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).

Special instructions on the requisition form ,
Sticker on subject's chart

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.)

Respondent skipped this question

Erroneous Collection of Samples for Future Use/Banking

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

Respondent skipped this question

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

Respondent skipped this question

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.

Respondent skipped this question

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

Respondent skipped this question

Erroneous Collection of Samples for Future Use/Banking

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

Respondent skipped this question

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

Respondent skipped this question

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

Respondent skipped this question

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

Respondent skipped this question

Erroneous Collection of Samples for Future Use/Banking

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

Respondent skipped this question

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.

Respondent skipped this question

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)?

Respondent skipped this question

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

Respondent skipped this question

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

Respondent skipped this question

#6

COMPLETE

Collector: Email Invitation 1 (Email)
Started: Thursday, June 20, 2019 1:33:45 AM
Last Modified: Thursday, June 20, 2019 1:38:45 AM
Time Spent: 00:05:00
Email:
IP Address:

Page 1: This anonymous survey is about the erroneous collection of samples for future use/banking.

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

9901

Q2 Approximately how many clinical trials does your company run in a year? **More than 50**

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

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)? **Yes**

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). **5% or less of studies**

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). **Other (please specify): It is not put in place at that site.**

Erroneous Collection of Samples for Future Use/Banking

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.)

Respondent skipped this question

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

Respondent skipped this question

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

Respondent skipped this question

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

Respondent skipped this question

Erroneous Collection of Samples for Future Use/Banking

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

Respondent skipped this question

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

Respondent skipped this question

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

Respondent skipped this question

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

Respondent skipped this question

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

Respondent skipped this question

Erroneous Collection of Samples for Future Use/Banking

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

Respondent skipped this question

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.

☆

9

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?

No (Please go to Question 20)

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.

Don't know

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).

Training of site staff ,

Reconciliation at long-term storage facility ,

Reporting of event as a protocol deviation or other such status that triggers internal action

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.)

Respondent skipped this question

Erroneous Collection of Samples for Future Use/Banking

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

Respondent skipped this question

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

Respondent skipped this question

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.

Respondent skipped this question

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

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5

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

Respondent skipped this question

Erroneous Collection of Samples for Future Use/Banking

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

Respondent skipped this question

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

Respondent skipped this question

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

☆

8

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

☆

7

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.

Respondent skipped this question

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)?

No (Please go to Question 34)

Erroneous Collection of Samples for Future Use/Banking

Q33 If you answered "Yes" to Question 32 please specify these approaches: **Respondent skipped this question**

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

Most of the time we are not collecting new samples specifically for future use but asking to use any leftover samples.

#7

COMPLETE

Collector: Email Invitation 1 (Email)
Started: Thursday, June 20, 2019 3:04:02 PM
Last Modified: Thursday, June 20, 2019 3:25:20 PM
Time Spent: 00:21:18
Email:
IP Address:

Page 1: This anonymous survey is about the erroneous collection of samples for future use/banking.

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

7345

Q2 Approximately how many clinical trials does your company run in a year? **More than 50**

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

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)? **Yes**

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). **5% or less of studies**

Erroneous Collection of Samples for Future Use/Banking

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).

Collection tubes separated from other tubes (e.g. separate kit; sequestered in separate bag within single kit; etc.)

,

Special labeling or warning on the banked/future use specimen collection tube

,

Training of site staff

Reconciliation at Central Lab

Reconciliation at long-term storage facility

Reporting of event as a protocol deviation or other such status that triggers internal action

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.)

☆

8

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

☆

8

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

☆

7

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

☆

5

Erroneous Collection of Samples for Future Use/Banking

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

☆ 8

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

☆ 4

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

☆ 4

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

☆ 8

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

☆ 4

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

☆ 4

Erroneous Collection of Samples for Future Use/Banking

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.	Respondent skipped this question
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?	Yes
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.	5% or less of studies
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).	Collection tubes separated from other tubes (e.g. separate kit; sequestered in separate bag within single kit; etc.) , Special labeling or warning on the banked/future use specimen collection tube , Training of site staff , Detection by study monitors , Data management approaches to detect the event in real time and issue queries , Reconciliation at Central Lab , Reconciliation at long-term storage facility , Reporting of event as a protocol deviation or other such status that triggers internal action
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.)	

☆

8

Erroneous Collection of Samples for Future Use/Banking

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

☆

8

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

☆

7

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.

☆

5

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

☆

7

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

☆

5

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

☆

7

Erroneous Collection of Samples for Future Use/Banking

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

☆

9

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

☆

6

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

☆

7

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.

Respondent skipped this question

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)?

No (Please go to Question 34)

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

Respondent skipped this question

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

We have answered this survey for broad use genomic samples - these are all optional and under a separated consent addendum

#8

COMPLETE

Collector: Email Invitation 1 (Email)
Started: Thursday, June 20, 2019 3:45:31 PM
Last Modified: Thursday, June 20, 2019 3:55:34 PM
Time Spent: 00:10:03
Email:
IP Address:

Page 1: This anonymous survey is about the erroneous collection of samples for future use/banking.

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

8008

Q2 Approximately how many clinical trials does your company run in a year? **More than 50**

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

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)? **Yes**

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). **5% or less of studies**

Erroneous Collection of Samples for Future Use/Banking

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).

Collection tubes separated from other tubes (e.g. separate kit; sequestered in separate bag within single kit; etc.)

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Training of site staff

Detection by study monitors

Data management approaches to detect the event in real time and issue queries

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.)

☆

5

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

☆

5

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

☆

5

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

☆

1

Erroneous Collection of Samples for Future Use/Banking

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

☆

6

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

☆

5

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

☆

8

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

☆

2

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

☆

2

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

Respondent skipped this question

Erroneous Collection of Samples for Future Use/Banking

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. **Respondent skipped this question**

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? **Yes**

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. **5% or less of studies**

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). **Collection tubes separated from other tubes (e.g. separate kit; sequestered in separate bag within single kit; etc.)**,
Training of site staff,
Detection by study monitors

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.)

☆ 7

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

☆ 1

Erroneous Collection of Samples for Future Use/Banking

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

Respondent skipped this question

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.

Respondent skipped this question

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

☆

9

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

☆

9

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

☆

7

Erroneous Collection of Samples for Future Use/Banking

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

☆

1

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

☆

1

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

Respondent skipped this question

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.

Respondent skipped this question

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)?

Yes

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

Retraining of site staff

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

We are curious if other companies require a separate FBR consent or if it is a check box on the main ICF

#9

COMPLETE

Collector: Email Invitation 1 (Email)
Started: Friday, June 21, 2019 2:20:26 PM
Last Modified: Friday, June 21, 2019 2:53:00 PM
Time Spent: 00:32:34
Email:
IP Address:

Page 1: This anonymous survey is about the erroneous collection of samples for future use/banking.

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

4099

Q2 Approximately how many clinical trials does your company run in a year? **26-50**

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

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)? **Yes**

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). **26-50% of studies**

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). **Don't Know**

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.)

☆

9

Erroneous Collection of Samples for Future Use/Banking

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

☆

9

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

Respondent skipped this question

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

Respondent skipped this question

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

Respondent skipped this question

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

Respondent skipped this question

Erroneous Collection of Samples for Future Use/Banking

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

Respondent skipped this question

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

Respondent skipped this question

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

Respondent skipped this question

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

Respondent skipped this question

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.

☆

2

Erroneous Collection of Samples for Future Use/Banking

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? **No (Please go to Question 20)**

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. **Respondent skipped this question**

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). **Data management approaches to detect the event in real time and issue queries**

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.)

☆

6

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

☆

8

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 **Respondent skipped this question**

Erroneous Collection of Samples for Future Use/Banking

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.

Respondent skipped this question

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

Respondent skipped this question

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

Respondent skipped this question

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

Respondent skipped this question

Erroneous Collection of Samples for Future Use/Banking

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

Respondent skipped this question

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

Respondent skipped this question

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

Respondent skipped this question

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.

Respondent skipped this question

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)?

Yes

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

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.

Erroneous Collection of Samples for Future Use/Banking

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

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.

#10

COMPLETE

Collector: Email Invitation 1 (Email)
Started: Monday, June 24, 2019 7:27:34 AM
Last Modified: Monday, June 24, 2019 7:40:51 AM
Time Spent: 00:13:17
Email:
IP Address:

Page 1: This anonymous survey is about the erroneous collection of samples for future use/banking.

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

2900

Q2 Approximately how many clinical trials does your company run in a year? **26-50**

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

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)? **Yes**

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). **5% or less of studies**

Erroneous Collection of Samples for Future Use/Banking

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).

Collection tubes separated from other tubes (e.g. separate kit; sequestered in separate bag within single kit; etc.)

,

Special labeling or warning on the banked/future use specimen collection tube

,

Training of site staff

Data management approaches to detect the event in real time and issue queries

,

Reconciliation at Central Lab

Reporting of event as a protocol deviation or other such status that triggers internal action

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.)

☆

8

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

☆

3

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

Respondent skipped this question

Erroneous Collection of Samples for Future Use/Banking

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

☆ 2

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

☆ 7

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

☆ 6

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

☆ 7

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

☆ 7

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

☆ 4

Erroneous Collection of Samples for Future Use/Banking

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

☆

8

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.

Respondent skipped this question

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?

Yes

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.

5% or less of studies

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).

Collection tubes separated from other tubes (e.g. separate kit; sequestered in separate bag within single kit; etc.)

,

Special labeling or warning on the banked/future use specimen collection tube

,

Training of site staff

Data management approaches to detect the event in real time and issue queries

,

Reconciliation at Central Lab

Reporting of event as a protocol deviation or other such status that triggers internal action

Erroneous Collection of Samples for Future Use/Banking

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.)

☆

8

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

☆

8

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

☆

4

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.

☆

3

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

☆

6

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

☆

7

Erroneous Collection of Samples for Future Use/Banking

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

☆

8

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

☆

8

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

☆

7

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

☆

7

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.

Respondent skipped this question

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)?

Yes

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

Sample reconciliation

Erroneous Collection of Samples for Future Use/Banking

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

Respondent skipped this question

#11

COMPLETE

Collector: Email Invitation 1 (Email)
Started: Tuesday, June 25, 2019 6:18:45 PM
Last Modified: Tuesday, June 25, 2019 6:22:30 PM
Time Spent: 00:03:45
Email:
IP Address:

Page 1: This anonymous survey is about the erroneous collection of samples for future use/banking.

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

2276

Q2 Approximately how many clinical trials does your company run in a year? **11-25**

Q3 Please indicate the style of kits your company uses for collection tubes for banked/future use samples (check all that apply). **My company does not collect samples for banking/future use (please go to Question 7)**

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)? **Respondent skipped this question**

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). **Respondent skipped this question**

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). **Respondent skipped this question**

Erroneous Collection of Samples for Future Use/Banking

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.)

Respondent skipped this question

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

Respondent skipped this question

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

Respondent skipped this question

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

Respondent skipped this question

Erroneous Collection of Samples for Future Use/Banking

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

Respondent skipped this question

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

Respondent skipped this question

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

Respondent skipped this question

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

Respondent skipped this question

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

Respondent skipped this question

Erroneous Collection of Samples for Future Use/Banking

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

Respondent skipped this question

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.

Respondent skipped this question

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?

Respondent skipped this question

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.

Respondent skipped this question

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).

Respondent skipped this question

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.)

Respondent skipped this question

Erroneous Collection of Samples for Future Use/Banking

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

Respondent skipped this question

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

Respondent skipped this question

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.

Respondent skipped this question

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

Respondent skipped this question

Erroneous Collection of Samples for Future Use/Banking

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

Respondent skipped this question

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

Respondent skipped this question

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

Respondent skipped this question

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

Respondent skipped this question

Erroneous Collection of Samples for Future Use/Banking

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

Respondent skipped this question

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.

Respondent skipped this question

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)?

Respondent skipped this question

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

Respondent skipped this question

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

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.

#12

COMPLETE

Collector: Email Invitation 1 (Email)
Started: Wednesday, June 26, 2019 9:47:34 AM
Last Modified: Wednesday, June 26, 2019 9:55:28 AM
Time Spent: 00:07:54
Email:
IP Address:

Page 1: This anonymous survey is about the erroneous collection of samples for future use/banking.

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

3309

Q2 Approximately how many clinical trials does your company run in a year? **More than 50**

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

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)? **Yes**

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). **6-25% of studies**

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). **Reconciliation at Central Lab**

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.)

☆ **3**

Erroneous Collection of Samples for Future Use/Banking

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

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1

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

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3

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

☆

1

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

☆

1

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

☆

7

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

☆

3

Erroneous Collection of Samples for Future Use/Banking

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

☆

8

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

☆

8

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

☆

1

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. **Respondent skipped this question**

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? **Yes**

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. **6-25% of studies**

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). **Reconciliation at Central Lab**

Erroneous Collection of Samples for Future Use/Banking

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.)

Respondent skipped this question

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

Respondent skipped this question

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

Respondent skipped this question

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.

Respondent skipped this question

Erroneous Collection of Samples for Future Use/Banking

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

Respondent skipped this question

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

Respondent skipped this question

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

Respondent skipped this question

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

☆

7

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

Respondent skipped this question

Erroneous Collection of Samples for Future Use/Banking

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

Respondent skipped this question

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.

Respondent skipped this question

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)?

No (Please go to Question 34)

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

Respondent skipped this question

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

Respondent skipped this question

#13

COMPLETE

Collector: Email Invitation 1 (Email)
Started: Wednesday, June 26, 2019 1:17:03 PM
Last Modified: Wednesday, June 26, 2019 1:21:25 PM
Time Spent: 00:04:22
Email:
IP Address:

Page 1: This anonymous survey is about the erroneous collection of samples for future use/banking.

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

6920

Q2 Approximately how many clinical trials does your company run in a year? **More than 50**

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

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)? **Yes**

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). **5% or less of studies**

Erroneous Collection of Samples for Future Use/Banking

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).

Collection tubes separated from other tubes (e.g. separate kit; sequestered in separate bag within single kit; etc.)

,

Training of site staff

Detection by study monitors

Data management approaches to detect the event in real time and issue queries

,

Reconciliation at Central Lab

Reconciliation at long-term storage facility

Reporting of event as a protocol deviation or other such status that triggers internal action

,

Special instructions on requisition form

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.)

☆

8

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

☆

4

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

☆

9

Erroneous Collection of Samples for Future Use/Banking

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

☆ 4

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

☆ 9

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

☆ 8

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

☆ 8

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

☆ 7

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

☆ 9

Erroneous Collection of Samples for Future Use/Banking

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

☆

6

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.

Respondent skipped this question

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?

Yes

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.

5% or less of studies

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).

Collection tubes separated from other tubes (e.g. separate kit; sequestered in separate bag within single kit; etc.)

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Training of site staff

Detection by study monitors

Data management approaches to detect the event in real time and issue queries

,

Reconciliation at Central Lab

Reconciliation at long-term storage facility

Reporting of event as a protocol deviation or other such status that triggers internal action

,

Special instructions on the requisition form

Erroneous Collection of Samples for Future Use/Banking

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.)

☆

9

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

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4

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

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8

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.

☆

4

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

☆

8

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

☆

7

Erroneous Collection of Samples for Future Use/Banking

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

☆

8

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

☆

7

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

☆

9

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

☆

7

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.

Respondent skipped this question

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)?

Respondent skipped this question

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

Respondent skipped this question

Erroneous Collection of Samples for Future Use/Banking

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

Respondent skipped this question

#14

COMPLETE

Collector: Email Invitation 2 (Email)
Started: Wednesday, June 26, 2019 8:20:08 PM
Last Modified: Wednesday, June 26, 2019 8:39:01 PM
Time Spent: 00:18:53
Email:
IP Address:

Page 1: This anonymous survey is about the erroneous collection of samples for future use/banking.

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

7629

Q2 Approximately how many clinical trials does your company run in a year? **More than 50**

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

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)? **No (Please go to Question 6)**

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). **5% or less of studies**

Erroneous Collection of Samples for Future Use/Banking

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).

Collection tubes separated from other tubes (e.g. separate kit; sequestered in separate bag within single kit; etc.)

,

Special labeling or warning on the banked/future use specimen collection tube

,

Training of site staff

Detection by study monitors

Reconciliation at Central Lab

Reconciliation at long-term storage facility

Special instructions on requisition form

Other (please specify):

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

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.)

☆

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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

☆

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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

☆

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Erroneous Collection of Samples for Future Use/Banking

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

Respondent skipped this question

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

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6

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

☆

7

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

☆

1

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

☆

7

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

☆

5

Erroneous Collection of Samples for Future Use/Banking

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

☆

7

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.

☆

10

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? **Yes**

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. **5% or less of studies**

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). **Collection tubes separated from other tubes (e.g. separate kit; sequestered in separate bag within single kit; etc.)**,
Special labeling or warning on the banked/future use specimen collection tube,
Training of site staff,
Detection by study monitors,
Reporting of event as a protocol deviation or other such status that triggers internal action

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.)

☆

7

Erroneous Collection of Samples for Future Use/Banking

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

☆

7

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

☆

7

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.

Respondent skipped this question

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

☆

7

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

☆

7

Erroneous Collection of Samples for Future Use/Banking

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

Respondent skipped this question

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

Respondent skipped this question

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

Respondent skipped this question

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

☆

7

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.

Respondent skipped this question

Erroneous Collection of Samples for Future Use/Banking

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)?

No (Please go to Question 34)

Q33 If you answered "Yes" to Question 32 please specify these approaches: **Respondent skipped this question**

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

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.

#15

COMPLETE

Collector: Email Invitation 1 (Email)
Started: Thursday, June 27, 2019 5:13:28 PM
Last Modified: Thursday, June 27, 2019 5:40:23 PM
Time Spent: 00:26:55
Email:
IP Address:

Page 1: This anonymous survey is about the erroneous collection of samples for future use/banking.

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

7507

Q2 Approximately how many clinical trials does your company run in a year? **11-25**

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

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)? **Yes**

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). **5% or less of studies**

Erroneous Collection of Samples for Future Use/Banking

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).

Training of site staff ,
Detection by study monitors ,
Data management approaches to detect the event in real time and issue queries ,
Reconciliation at Central Lab ,
Reconciliation at long-term storage facility ,
Special instructions on requisition form

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.)

Respondent skipped this question

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

Respondent skipped this question

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

Respondent skipped this question

Erroneous Collection of Samples for Future Use/Banking

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

Respondent skipped this question

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

Respondent skipped this question

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

Respondent skipped this question

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

Respondent skipped this question

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

Respondent skipped this question

Erroneous Collection of Samples for Future Use/Banking

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

Respondent skipped this question

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

Respondent skipped this question

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.

Respondent skipped this question

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?

Respondent skipped this question

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.

5% or less of studies

Erroneous Collection of Samples for Future Use/Banking

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).

Training of site staff ,
Detection by study monitors ,
Data management approaches to detect the event in real time and issue queries ,
Reconciliation at Central Lab ,
Reconciliation at long-term storage facility ,
Special instructions on the requisition form

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.)

Respondent skipped this question

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

Respondent skipped this question

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

Respondent skipped this question

Erroneous Collection of Samples for Future Use/Banking

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.

Respondent skipped this question

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

Respondent skipped this question

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

Respondent skipped this question

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

Respondent skipped this question

Erroneous Collection of Samples for Future Use/Banking

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

Respondent skipped this question

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

Respondent skipped this question

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

Respondent skipped this question

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.

Respondent skipped this question

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)?

No (Please go to Question 34)

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

Respondent skipped this question

Erroneous Collection of Samples for Future Use/Banking

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

Respondent skipped this question

#16

COMPLETE

Collector: Email Invitation 1 (Email)
Started: Thursday, June 27, 2019 6:11:40 PM
Last Modified: Thursday, June 27, 2019 7:05:41 PM
Time Spent: 00:54:01
Email:
IP Address:

Page 1: This anonymous survey is about the erroneous collection of samples for future use/banking.

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

8354

Q2 Approximately how many clinical trials does your company run in a year? **More than 50**

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

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)? **Yes**

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). **5% or less of studies**

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). **Training of site staff, Detection by study monitors, Reconciliation at Central Lab, Reconciliation at long-term storage facility**

Erroneous Collection of Samples for Future Use/Banking

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.)

☆

10

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

☆

5

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

☆

5

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

☆

2

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

☆

7

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

☆

7

Erroneous Collection of Samples for Future Use/Banking

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

☆

9

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

☆

1

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

☆

10

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

☆

1

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. **Respondent skipped this question**

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? **Yes**

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. **5% or less of studies**

Erroneous Collection of Samples for Future Use/Banking

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).

Training of site staff

Reconciliation at long-term storage facility

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.)

☆

10

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

☆

5

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

☆

3

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.

☆

2

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

☆

7

Erroneous Collection of Samples for Future Use/Banking

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

☆

1

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

☆

9

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

☆

1

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

☆

10

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

☆

1

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.

Respondent skipped this question

Erroneous Collection of Samples for Future Use/Banking

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)?

No (Please go to Question 34)

Q33 If you answered "Yes" to Question 32 please specify these approaches: **Respondent skipped this question**

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

Any samples collected but not consented are destroyed

#17

COMPLETE

Collector: Email Invitation 1 (Email)
Started: Friday, June 28, 2019 9:19:32 PM
Last Modified: Friday, June 28, 2019 9:19:42 PM
Time Spent: 00:00:10
Email:
IP Address:

Page 1: This anonymous survey is about the erroneous collection of samples for future use/banking.

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

2910

Q2 Approximately how many clinical trials does your company run in a year? **Respondent skipped this question**

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

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)? **Respondent skipped this question**

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). **Respondent skipped this question**

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). **Respondent skipped this question**

Erroneous Collection of Samples for Future Use/Banking

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.)

Respondent skipped this question

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

Respondent skipped this question

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

Respondent skipped this question

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

Respondent skipped this question

Erroneous Collection of Samples for Future Use/Banking

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

Respondent skipped this question

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

Respondent skipped this question

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

Respondent skipped this question

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

Respondent skipped this question

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

Respondent skipped this question

Erroneous Collection of Samples for Future Use/Banking

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

Respondent skipped this question

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.

Respondent skipped this question

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?

Respondent skipped this question

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.

Respondent skipped this question

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).

Respondent skipped this question

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.)

Respondent skipped this question

Erroneous Collection of Samples for Future Use/Banking

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

Respondent skipped this question

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

Respondent skipped this question

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.

Respondent skipped this question

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

Respondent skipped this question

Erroneous Collection of Samples for Future Use/Banking

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

Respondent skipped this question

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

Respondent skipped this question

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

Respondent skipped this question

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

Respondent skipped this question

Erroneous Collection of Samples for Future Use/Banking

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

Respondent skipped this question

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.

Respondent skipped this question

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)?

Respondent skipped this question

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

Respondent skipped this question

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

Respondent skipped this question

#18

COMPLETE

Collector: Email Invitation 1 (Email)
Started: Monday, July 01, 2019 9:52:38 AM
Last Modified: Monday, July 01, 2019 10:38:13 AM
Time Spent: 00:45:35
Email:
IP Address:

Page 1: This anonymous survey is about the erroneous collection of samples for future use/banking.

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

7755

Q2 Approximately how many clinical trials does your company run in a year? **10 or less**

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

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

,

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

,

Separate collection kits for banked/future use samples vs other clinical trial samples

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)? **No (Please go to Question 6)**

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). **5% or less of studies**

Erroneous Collection of Samples for Future Use/Banking

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).

Training of site staff ,

Detection by study monitors ,

Reconciliation at Central Lab ,

Reconciliation at long-term storage facility ,

Special instructions on requisition form ,

Other (please specify):

Clinical CRO responsibility to tackle this

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.)

Respondent skipped this question

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

Respondent skipped this question

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

Respondent skipped this question

Erroneous Collection of Samples for Future Use/Banking

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

Respondent skipped this question

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

Respondent skipped this question

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

Respondent skipped this question

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

Respondent skipped this question

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

Respondent skipped this question

Erroneous Collection of Samples for Future Use/Banking

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

Respondent skipped this question

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

Respondent skipped this question

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.

☆

6

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?

Yes

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.

5% or less of studies

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).

Detection by study monitors ,

Reconciliation at Central Lab ,

Reconciliation at long-term storage facility ,

Reporting of event as a protocol deviation or other such status that triggers internal action

Erroneous Collection of Samples for Future Use/Banking

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.)

Respondent skipped this question

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

Respondent skipped this question

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

Respondent skipped this question

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.

Respondent skipped this question

Erroneous Collection of Samples for Future Use/Banking

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

Respondent skipped this question

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

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9

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

Respondent skipped this question

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

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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

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Erroneous Collection of Samples for Future Use/Banking

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

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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.

Respondent skipped this question

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)?

No (Please go to Question 34)

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

Respondent skipped this question

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

It was rather difficult to answer the detailed questions since there are lot of variation between clinical CRO practices and study sites.
