Q1 Please enter your company specific code as provided by Jenny Green. Please note that each company will submit responses for this general questionnaire only once.

Answered: 14 Skipped: 0

ANSWER CHOICES	RESPONSES	
Name:	0.00%	0
Code Number	100.00%	14
Address 1:	0.00%	0
Address 2:	0.00%	0
City/Town:	0.00%	0
State/Province:	0.00%	0
ZIP/Postal Code:	0.00%	0
Country:	0.00%	0
Email Address:	0.00%	0
Phone Number:	0.00%	0

#	NAME:	DATE
	There are no responses.	

#	CODE NUMBER	DATE
1	3263	3/20/2015 2:31 PM
2	5836	3/2/2015 6:32 PM
3	1687	11/26/2014 12:02 AM
4	9502	11/13/2014 10:31 AM
5	9876	10/29/2014 2:58 AM
6	4037	10/22/2014 5:49 AM
7	6145	10/21/2014 10:57 AM
8	7431	10/20/2014 7:45 PM
9	2281	10/20/2014 3:12 PM
10	2281	10/17/2014 7:19 PM
11	9901	10/16/2014 10:07 PM
12	2658	10/15/2014 1:13 PM
13	8074	10/10/2014 6:47 PM
14	4818	10/2/2014 8:06 PM

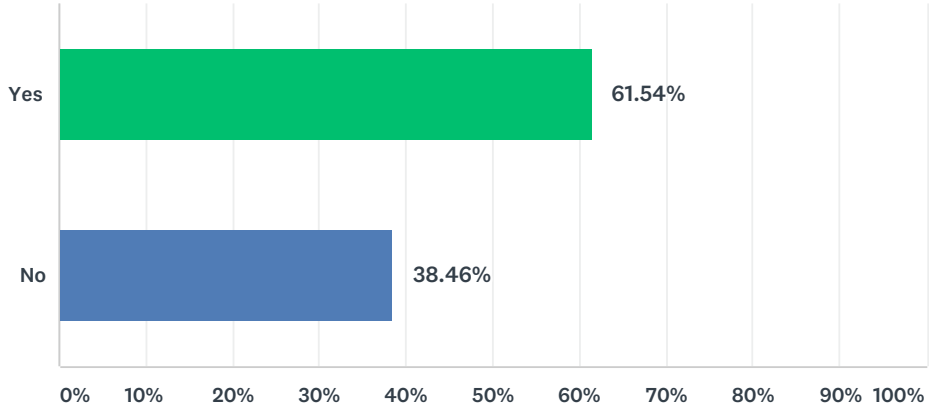
#	ADDRESS 1:	DATE
	There are no responses.	

#	ADDRESS 2:	DATE
	There are no responses.	

#	CITY/TOWN:	DATE
	There are no responses.	
#	STATE/PROVINCE:	DATE
	There are no responses.	
#	ZIP/POSTAL CODE:	DATE
	There are no responses.	
#	COUNTRY:	DATE
	There are no responses.	
#	EMAIL ADDRESS:	DATE
	There are no responses.	
#	PHONE NUMBER:	DATE
	There are no responses.	

Q2 Is DNA collection routine for all phase II clinical studies?

Answered: 13 Skipped: 1



ANSWER CHOICES	RESPONSES	
Yes	61.54%	8
No	38.46%	5
TOTAL		13

#	OTHER (PLEASE SPECIFY)	DATE
1	Routinely in protocol, but can be optional	11/26/2014 12:02 AM
2	Mandatory Phase I Retrospective Sample Collection is implemented in all TAs.	10/20/2014 7:45 PM
3	not mandatory, but in most PH2, we do collect DNA samples; roughly 75% of studies	10/15/2014 1:16 PM

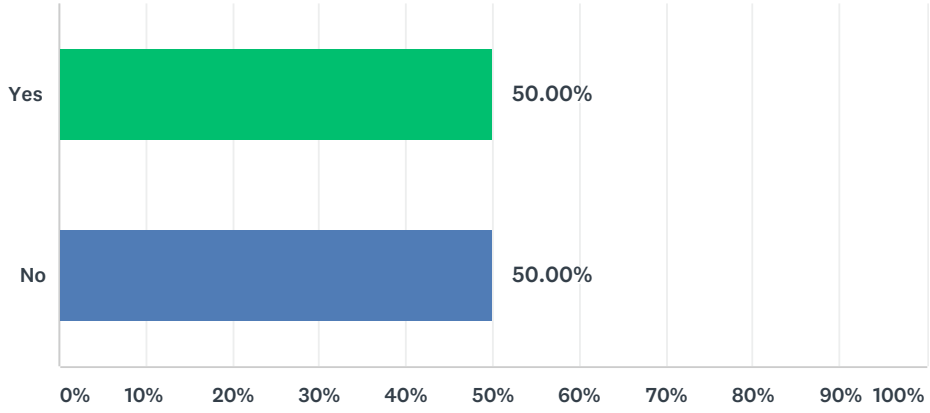
Q3 Which phase II studies do not collect DNA samples and why?

Answered: 6 Skipped: 8

#	RESPONSES	DATE
1	dpends on indication and use of sample	3/2/2015 6:33 PM
2	No specific criteria, depends on drug and indication	11/13/2014 10:32 AM
3	Individual clinical team choice.	10/29/2014 2:59 AM
4	when there is no planned biomarker program associated to the compound	10/22/2014 5:57 AM
5	TAs outside of Oncology are the primary example (infectious diseases, inflammation, CNS). The reason for this is patient accrual speed.	10/20/2014 7:45 PM
6	where the disease indication is not genetically linked or there is no basis for genetic testing	10/15/2014 1:19 PM

Q4 Is DNA collection routine for all phase III clinical studies?

Answered: 14 Skipped: 0



ANSWER CHOICES	RESPONSES	
Yes	50.00%	7
No	50.00%	7
TOTAL		14

#	OTHER (PLEASE SPECIFY)	DATE
1	Routinely in protocol, but can be optional	11/26/2014 12:02 AM
2	DNA would most likely be collected for biomarker elucidation and a Phase III setting really offers no verification of the biomarker derived from DNA exploration.	10/20/2014 7:45 PM

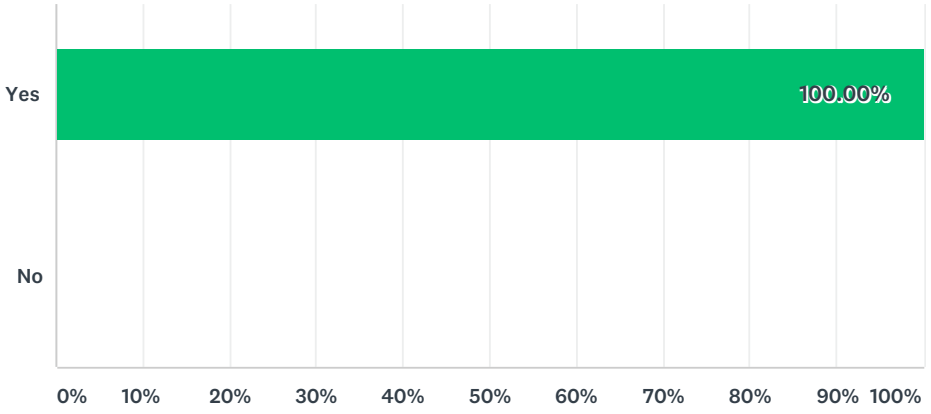
Q5 Which phase III studies do not collect DNA samples and why?

Answered: 7 Skipped: 7

#	RESPONSES	DATE
1	depends on indication and use of sample	3/2/2015 6:33 PM
2	No particular criteria	11/13/2014 10:32 AM
3	Individual clinical team choice.	10/29/2014 2:59 AM
4	when there is no planned biomarker program associated to the compound or when DNA samples were already collected in earlier phases for this compound and analysis did not lead to any hypothesis to validate	10/22/2014 5:59 AM
5	There is no collection at Phase III, regardless of TA.	10/20/2014 7:46 PM
6	CTT decision. See Q16 for specific reasons	10/16/2014 10:09 PM
7	not sure which ones, but size of trial and storage concerns may be an issue	10/15/2014 1:20 PM

Q6 Are collection requirements and processes the same for both phase II and phase III studies (protocol language, consent language,...)?

Answered: 14 Skipped: 0

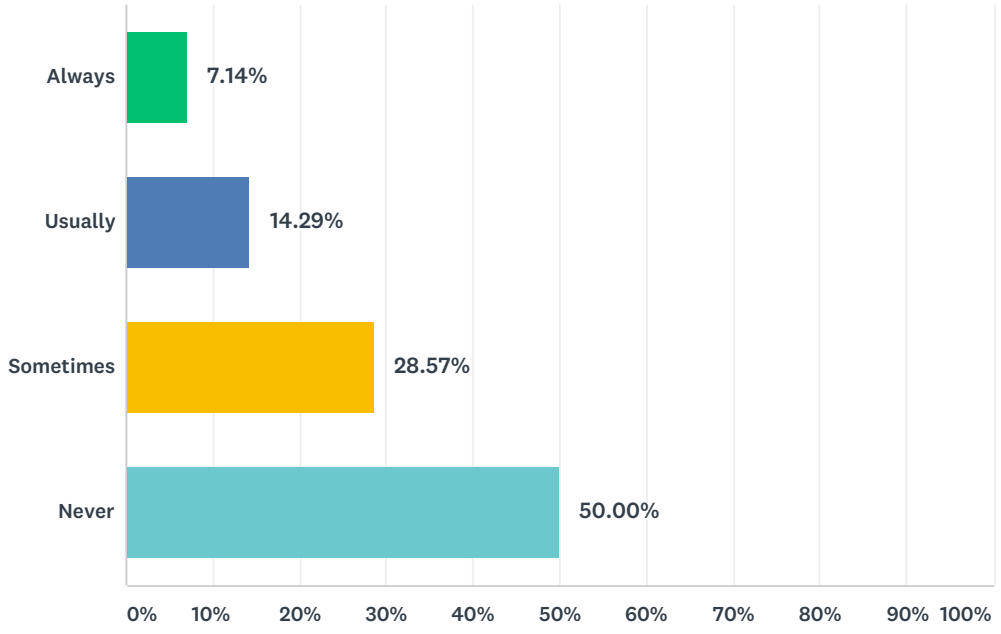


ANSWER CHOICES	RESPONSES	
Yes	100.00%	14
No	0.00%	0
TOTAL		14

#	IF NO, PLEASE DESCRIBE HOW THEY ARE DIFFERENT?	DATE
	There are no responses.	

Q7 When selecting sites for your clinical study do you consider willingness/ability to participate in DNA collection during site feasibility assessment?

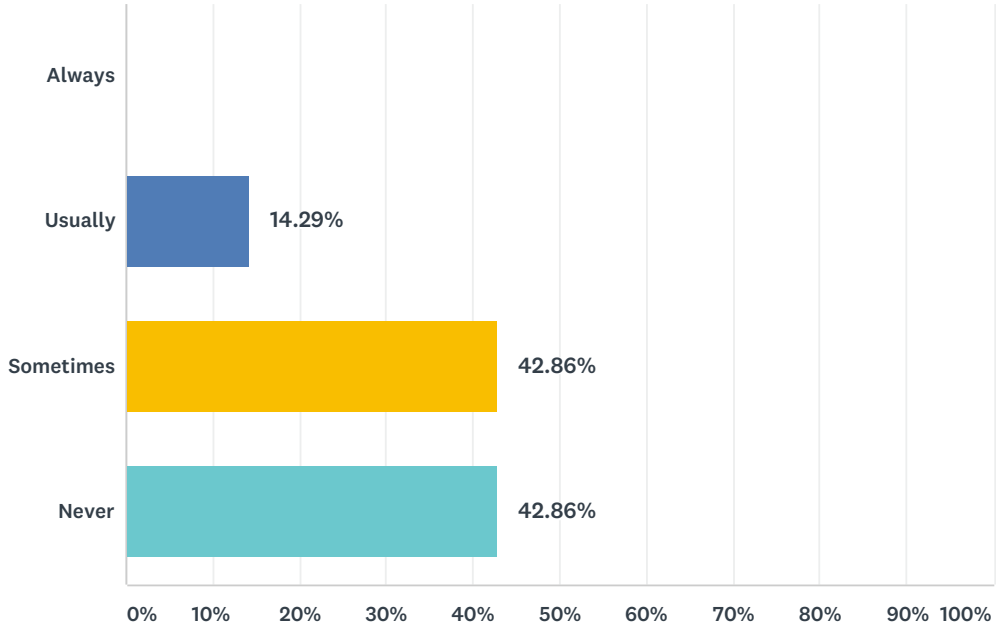
Answered: 14 Skipped: 0



ANSWER CHOICES	RESPONSES	
Always	7.14%	1
Usually	14.29%	2
Sometimes	28.57%	4
Never	50.00%	7
TOTAL		14

Q8 Do you preferentially select sites which you know to approve DNA collection?

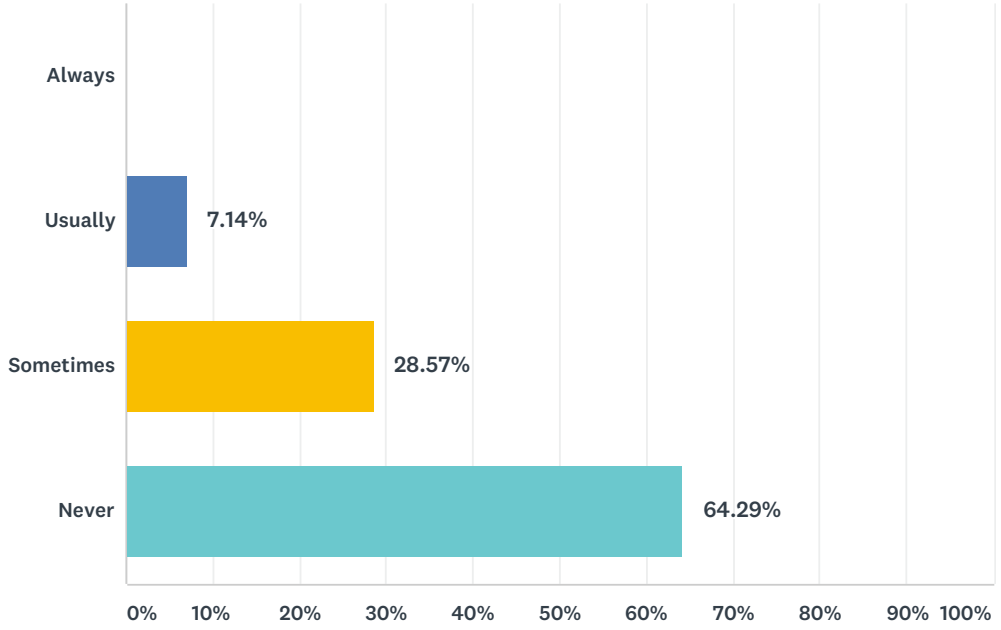
Answered: 14 Skipped: 0



ANSWER CHOICES	RESPONSES	
Always	0.00%	0
Usually	14.29%	2
Sometimes	42.86%	6
Never	42.86%	6
TOTAL		14

Q9 Do you reject sites that do not approve DNA collection?

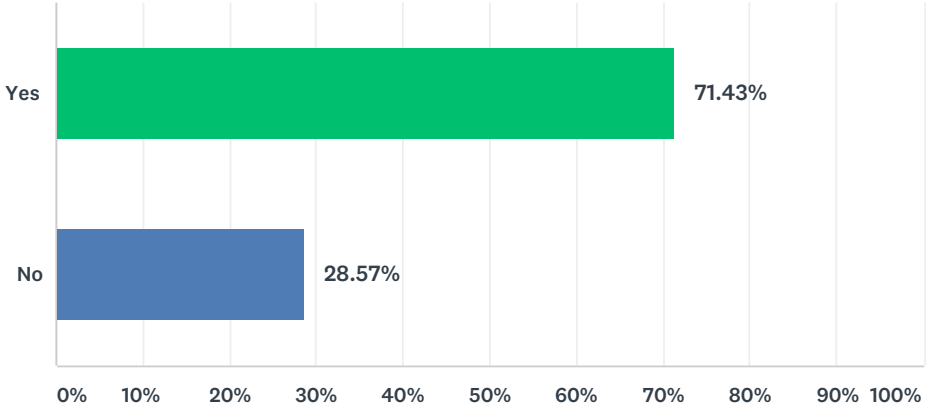
Answered: 14 Skipped: 0



ANSWER CHOICES	RESPONSES	
Always	0.00%	0
Usually	7.14%	1
Sometimes	28.57%	4
Never	64.29%	9
TOTAL		14

Q10 Does your company have a dedicated core team that supports integration of genetics and DNA collection across all clinical development programs?

Answered: 14 Skipped: 0

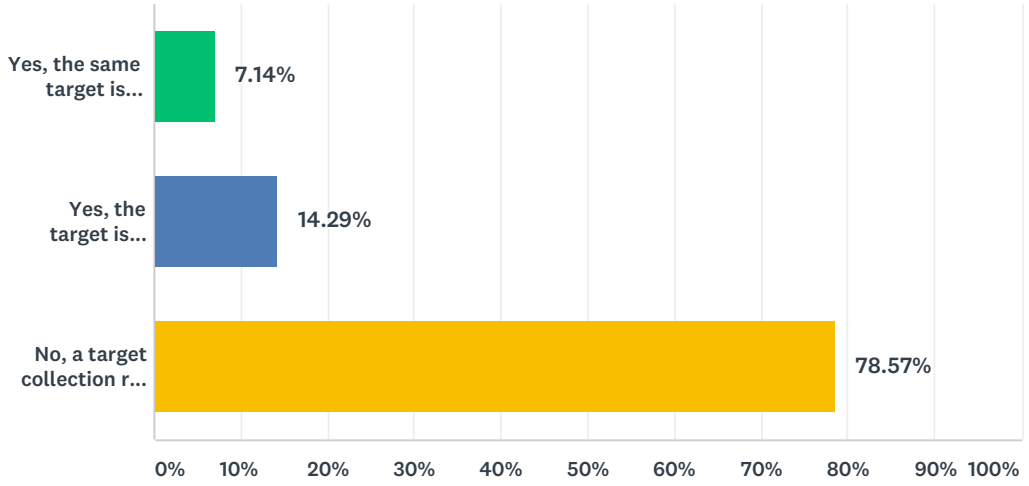


ANSWER CHOICES	RESPONSES	
Yes	71.43%	10
No	28.57%	4
TOTAL		14

#	IF NO, PLEASE DESCRIBE HOW GENETICS/DNA COLLECTION IS INTEGRATED INTO CLINICAL DEVELOPMENT	DATE
1	the clinical team along with biomarker lead determine	3/2/2015 6:34 PM
2	On an ad hoc basis, whenever required to perform a post-hoc analysis this is outsourced to a speciality company	11/13/2014 10:34 AM
3	Template language for protocol and ICD is posted and available for clinical teams to use, if they choose to incorporate sample banking for future genetic analyses in their studies.	10/29/2014 2:59 AM

Q11 Does your company have established DNA collection targets (e.g. goal to achieve 90% collection)?

Answered: 14 Skipped: 0

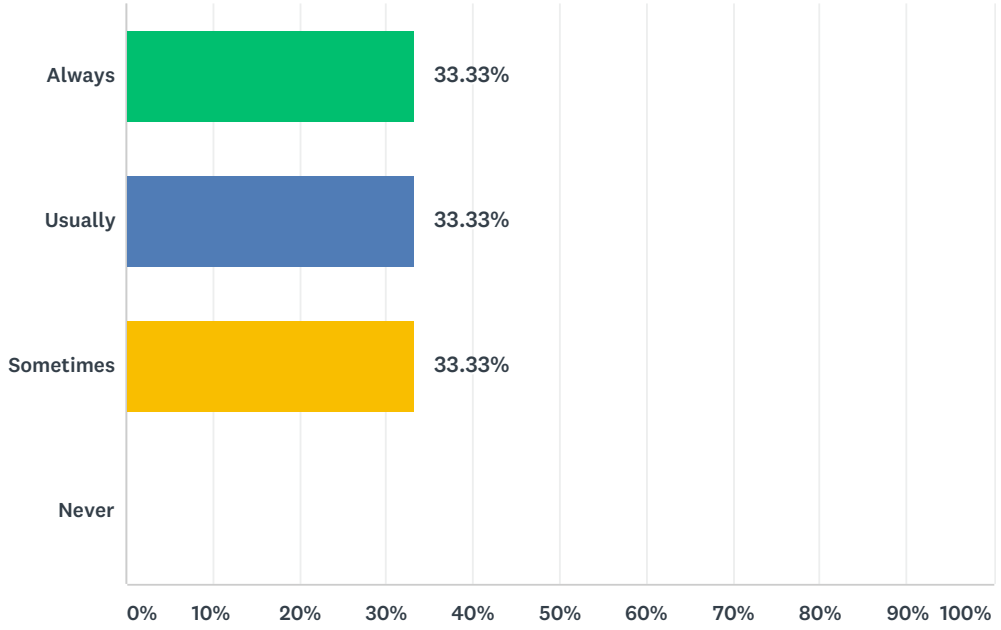


ANSWER CHOICES	RESPONSES	
Yes, the same target is established across all studies	7.14%	1
Yes, the target is established per study	14.29%	2
No, a target collection rate is not established	78.57%	11
TOTAL		14

#	IF YES, PLEASE DESCRIBE AND INCLUDE TARGETED COLLECTION RATE	DATE
1	Aim to collect a sample from all consenting subjects in all arms and all countries. A goal would be achieve 90%.	10/21/2014 11:18 AM
2	100% for Phase I and variable % for Phase II.	10/20/2014 7:46 PM
3	We strive for a high collection rate, but it is not a strict requirement	10/2/2014 8:08 PM

Q12 How often do studies achieve this target?

Answered: 3 Skipped: 11

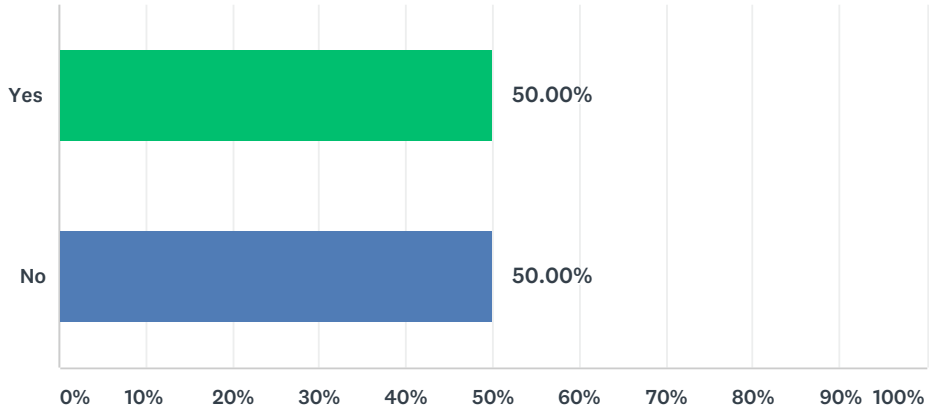


ANSWER CHOICES	RESPONSES	
Always	33.33%	1
Usually	33.33%	1
Sometimes	33.33%	1
Never	0.00%	0
TOTAL		3

#	OPTION TO ADD PERCENTAGE OF STUDIES THAT ACHIEVE TARGET	DATE
1	75%	10/2/2014 8:09 PM

Q13 Do you have a policy or position that all protocols must include DNA collection (without regard to whether subject participation in DNA collection is required or optional)?

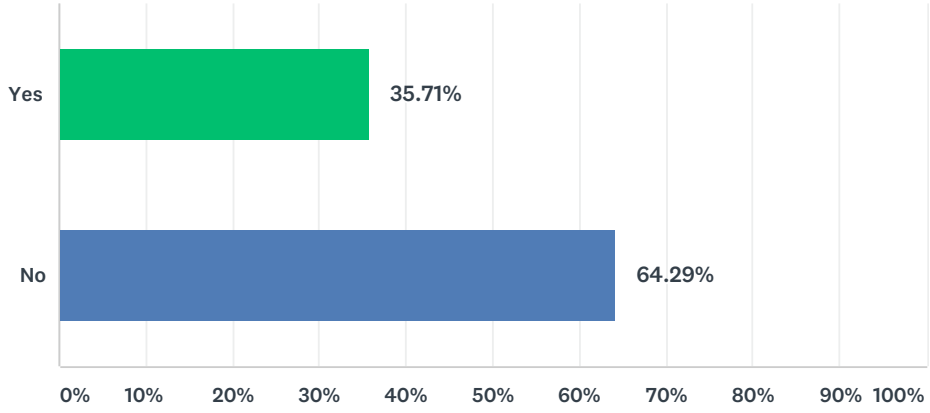
Answered: 14 Skipped: 0



ANSWER CHOICES	RESPONSES	
Yes	50.00%	7
No	50.00%	7
TOTAL		14

Q14 Is DNA collection a requirement in all phase II-III protocols?

Answered: 14 Skipped: 0

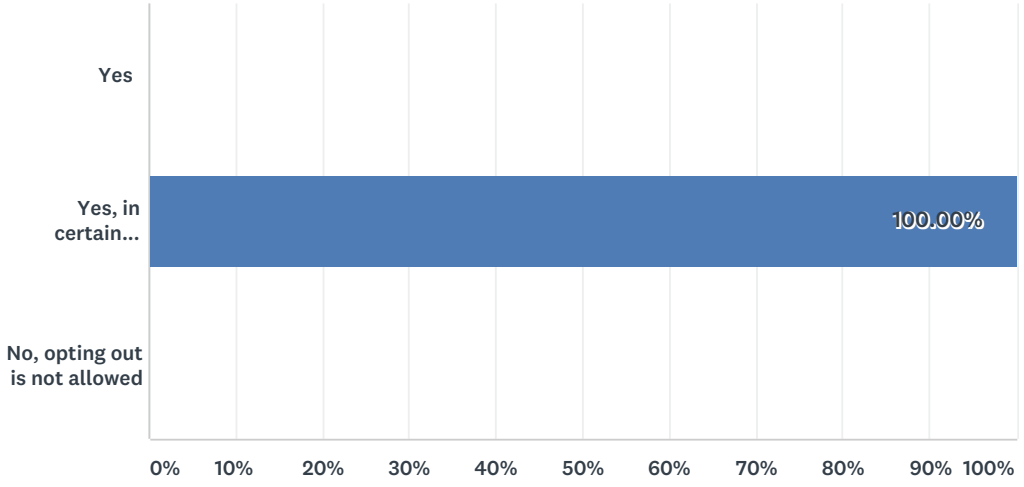


ANSWER CHOICES	RESPONSES	
Yes	35.71%	5
No	64.29%	9
TOTAL		14

#	OTHER (PLEASE SPECIFY)	DATE
1	Unless a companion diagnostic program is driven off the germline DNA outcomes for trial inclusion, a required DNA collection is not mandated.	10/20/2014 7:48 PM
2	optional genomics ICF	10/2/2014 8:09 PM

Q15 Can teams opt out of including DNA collection in the protocol?

Answered: 5 Skipped: 9

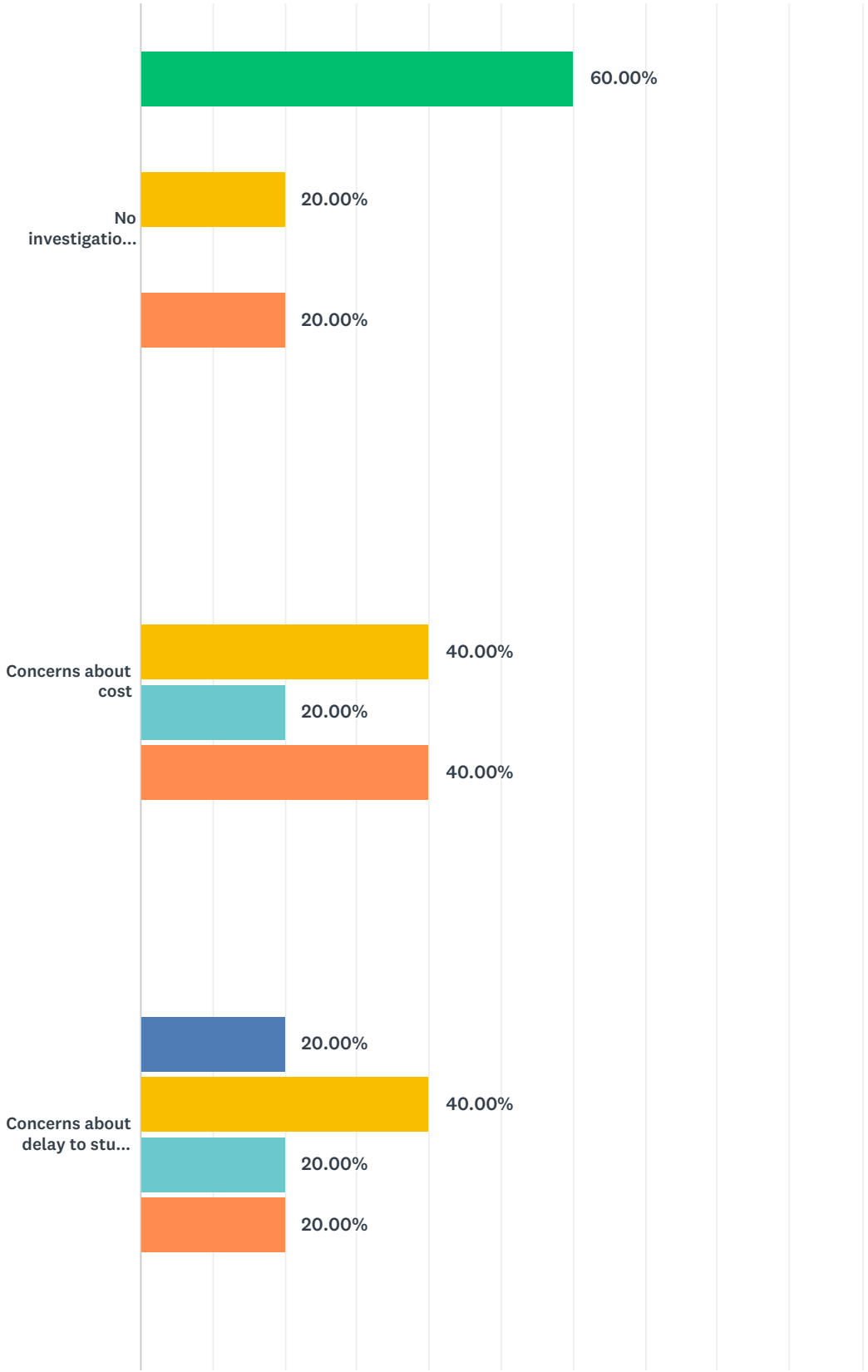


ANSWER CHOICES	RESPONSES	
Yes	0.00%	0
Yes, in certain circumstances	100.00%	5
No, opting out is not allowed	0.00%	0
TOTAL		5

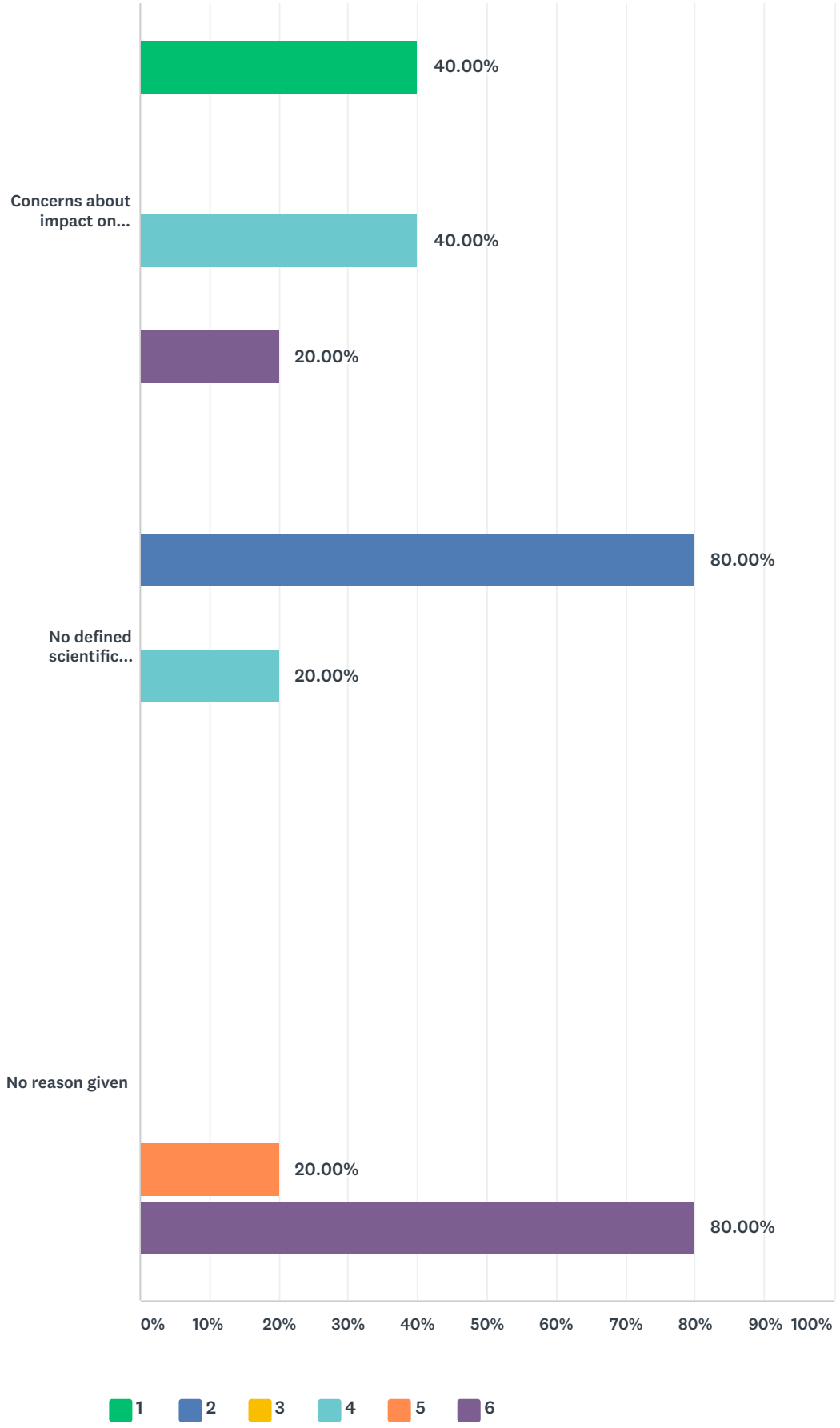
#	OTHER (PLEASE SPECIFY)	DATE
1	We have a waiver process that can be used with a strong business or scientifc rationale	10/20/2014 3:14 PM
2	We require collection in all Phase II and III protocols unless an exemption is approved, based on a strong rationale.	10/17/2014 7:29 PM
3	Pediatrics and PK intensive studies	10/10/2014 6:49 PM

Q16 What are the reasons for why study teams opt out of DNA collection (please place in order by frequency)?

Answered: 5 Skipped: 9



2016 DNA Collection Practices

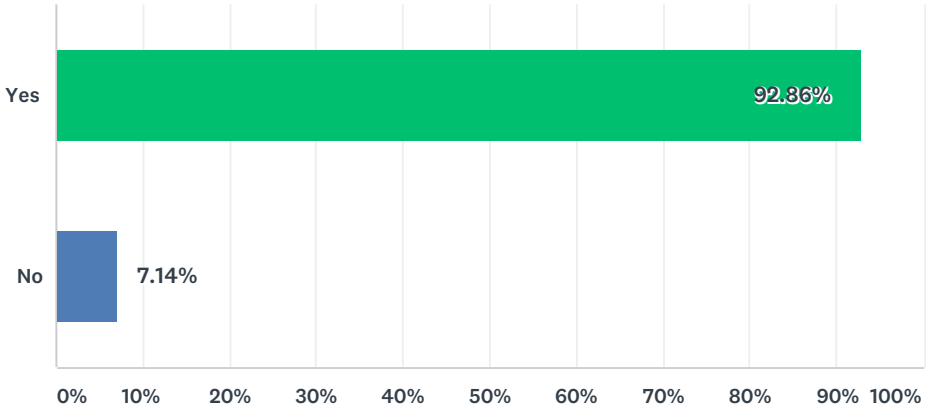


	1	2	3	4	5	6	TOTAL	SCORE

No investigational product in the study	60.00% 3	0.00% 0	20.00% 1	0.00% 0	20.00% 1	0.00% 0	5	4.80
Concerns about cost	0.00% 0	0.00% 0	40.00% 2	20.00% 1	40.00% 2	0.00% 0	5	3.00
Concerns about delay to study start	0.00% 0	20.00% 1	40.00% 2	20.00% 1	20.00% 1	0.00% 0	5	3.60
Concerns about impact on recruitment	40.00% 2	0.00% 0	0.00% 0	40.00% 2	0.00% 0	20.00% 1	5	3.80
No defined scientific rationale or scientific rationale is not strong for DNA analysis	0.00% 0	80.00% 4	0.00% 0	20.00% 1	0.00% 0	0.00% 0	5	4.60
No reason given	0.00% 0	0.00% 0	0.00% 0	0.00% 0	20.00% 1	80.00% 4	5	1.20

Q17 Do you have standardized DNA collection and processing requirements for DNA (i.e. central lab or other collection and processing standards used by all teams versus clinical teams defining their own sample collection and processing requirements?

Answered: 14 Skipped: 0

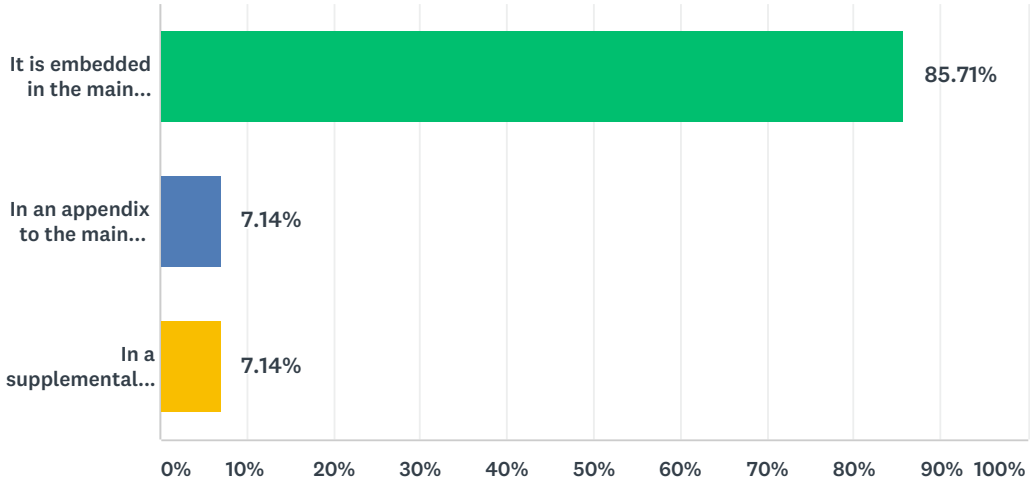


ANSWER CHOICES	RESPONSES	
Yes	92.86%	13
No	7.14%	1
TOTAL		14

#	OTHER (PLEASE SPECIFY)	DATE
1	5 mL EDTA tube of whole blood delivered to our repository.	10/20/2014 7:49 PM

Q18 Where in the clinical study protocol is DNA collection/research described?

Answered: 14 Skipped: 0



ANSWER CHOICES	RESPONSES	
It is embedded in the main study protocol	85.71%	12
In an appendix to the main study protocol	7.14%	1
In a supplemental protocol	7.14%	1
TOTAL		14

#	OTHER (PLEASE SPECIFY)	DATE
1	Appendix will typically have instructions and an ICF.	10/20/2014 7:49 PM
2	there is a section in the appendix with details	10/20/2014 3:16 PM
3	It's both in the main protocol and in a protocol appendix	10/17/2014 7:33 PM

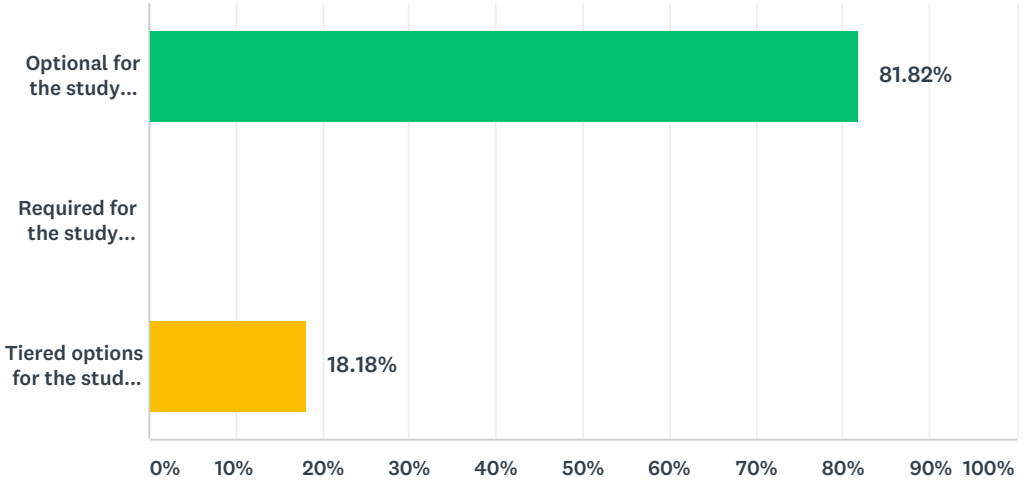
Q19 Regarding your answer to the previous question, what do you consider to be the advantages or disadvantages to the approach?

Answered: 12 Skipped: 2

#	RESPONSES	DATE
1	Trial team is forced to consider sample collection.	3/20/2015 2:34 PM
2	It is always described with the main protocol language. Consistency with the DNA collection language.	11/26/2014 12:19 AM
3	Advantages are a total focus on the main protocol Disadvantages are clear, we may only obtain a subset of DNA samples that, depending on the study size, may be insufficient for exploratory ad-hoc analyses	11/13/2014 10:36 AM
4	Advantages: 1. Simplifies studies materials; 2. By making it part of the clinical trial protocol, this reinforces the position that collecting a sample for drug response research is tightly aligned with the primary goals of clinical trials. Disadvantage: 1. Our tiered approach generates some confusion with clinical teams, CROs, and study sites regarding understanding what is mandatory and what is optional. This can negatively impact the implementation of this aproach and the quality of the data received about individual subject choices regarding whether to provide a sample for drug response research (Tier 1) and whether to allow the sample to also be used for broader additional research (Tier 2).	10/29/2014 3:01 AM
5	advantage: all clinical sites are aware of the collection of DNA. When our company was using a supplement protocol, this separate protocol was not always submitted to some of the sites disadvantage: we tend to get more questions from ECs /IRBs and this may delay approval of study protocol	10/22/2014 6:05 AM
6	Advanatage: All genetic research is described in a single part of the protocol. Disadvantage: not always clear that the section is fully reviewed by authorities.	10/21/2014 11:28 AM
7	The language is embedded in our main study protocol and is an advantage only because we are protocol-bound to collect said sample.	10/20/2014 7:49 PM
8	Appendix provides m alot of details that are not included in teh protocol we use both	10/20/2014 3:16 PM
9	It is an advantage to include DNA collection within the main protocol, because it emphasizes the importance of the collection. The appendix allows for more detail regarding DNA/future use collection than could otherwise be provided in the main body of the protocol.	10/17/2014 7:33 PM
10	It is part of standard global protocol template.	10/16/2014 10:10 PM
11	one document instead of multiple ones for patients to read and sign	10/15/2014 1:25 PM
12	makes it a more integral part of the study	10/10/2014 6:50 PM

Q20 What is your DNA collection strategy?

Answered: 11 Skipped: 3

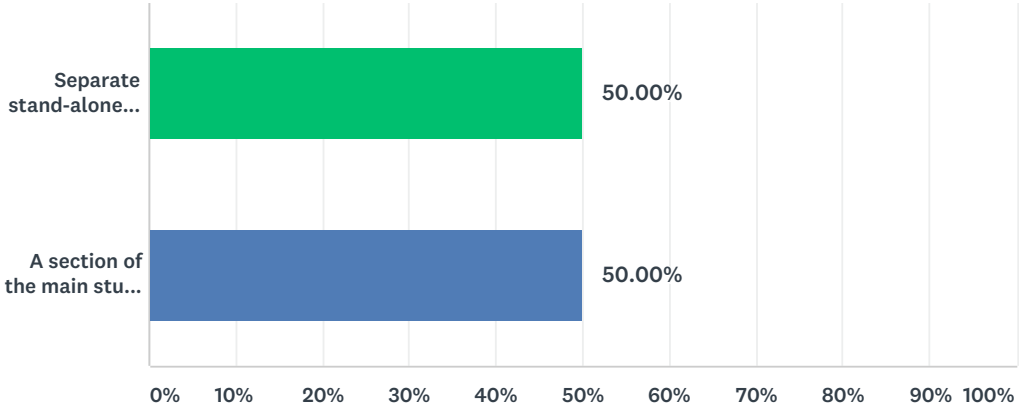


ANSWER CHOICES	RESPONSES	
Optional for the study participant--they can choose not to give a DNA sample and still participate in the main clinical study.	81.82%	9
Required for the study participant--they must agree to give a DNA sample to participate in the main clinical study.	0.00%	0
Tiered options for the study participant--e.g. DNA collection is required for study with option to allow samples to be stored for future use	18.18%	2
TOTAL		11

#	OTHER (PLEASE SPECIFY)	DATE
1	If the clinical team chooses to include the DNA collection in the protocol, there is a tiered consent as follows for the subjects: DNA collection and storage for drug response research is mandatory, with option to allow the sample to be used in research on other, broader topics (disease, use as population controls, use in technology development, etc).	10/29/2014 3:02 AM
2	we actually do potentially a combination of all the above: in some studies, DNA collection is mandatory, in others it is optional. We also have studies where collection is mandatory but storage for future research is optional.	10/22/2014 6:08 AM
3	There may be circumstances where DNA sampling is required, but this is on a limited number of occasions.	10/21/2014 11:32 AM
4	Its is mandatory in Healthy volunteers studies	10/20/2014 3:18 PM
5	Although optional for patient participants, we require DNA collection in healthy volunteers.	10/17/2014 7:34 PM
6	we do a mix of all three approaches depending on the Phase and the indication	10/15/2014 1:28 PM

Q21 Consider that the informed consent form is comprised of two parts: 1) the patient information sheet that describes the purpose and details of the study and 2) a consent/signature page. This question is specific to the PATIENT INFORMATION SHEET only.How is the PATIENT INFORMATION presented to the study participant?

Answered: 14 Skipped: 0

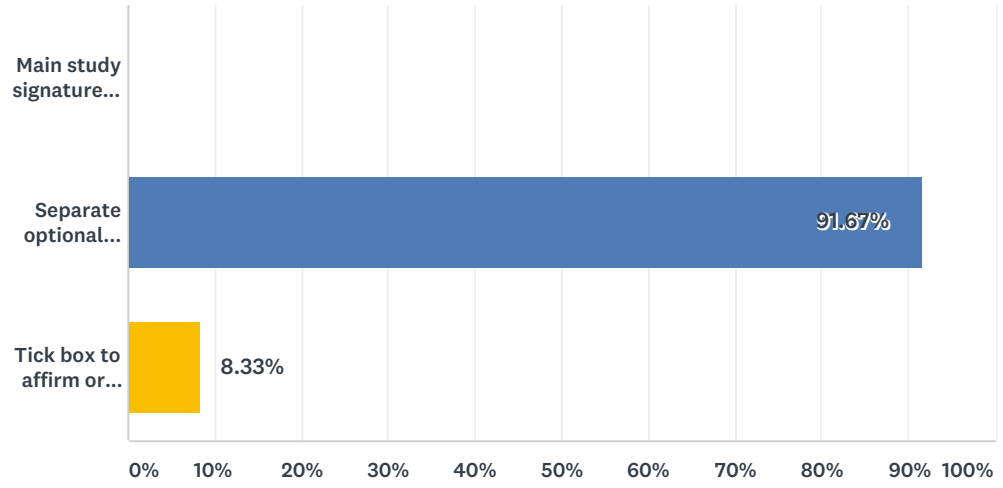


ANSWER CHOICES	RESPONSES	
Separate stand-alone patient information sheet for DNA collection	50.00%	7
A section of the main study patient information sheet	50.00%	7
TOTAL		14

#	OTHER (PLEASE SPECIFY)	DATE
1	part of main consent if it is not optional - if optional sample than seperate consent is used	3/2/2015 6:36 PM
2	There may be circumstances where a stand alone PIS is required by IRB/EC or other authority	10/21/2014 11:32 AM

Q22 Consider that the informed consent form is comprised of two parts: 1) the patient information sheet that describes the purpose and details of the study and 2) a consent/signature page. This question is specific to the CONSENT/SIGNATURE PAGE only.How is the CONSENT/SIGNATURE PAGE presented to the study participant?

Answered: 12 Skipped: 2

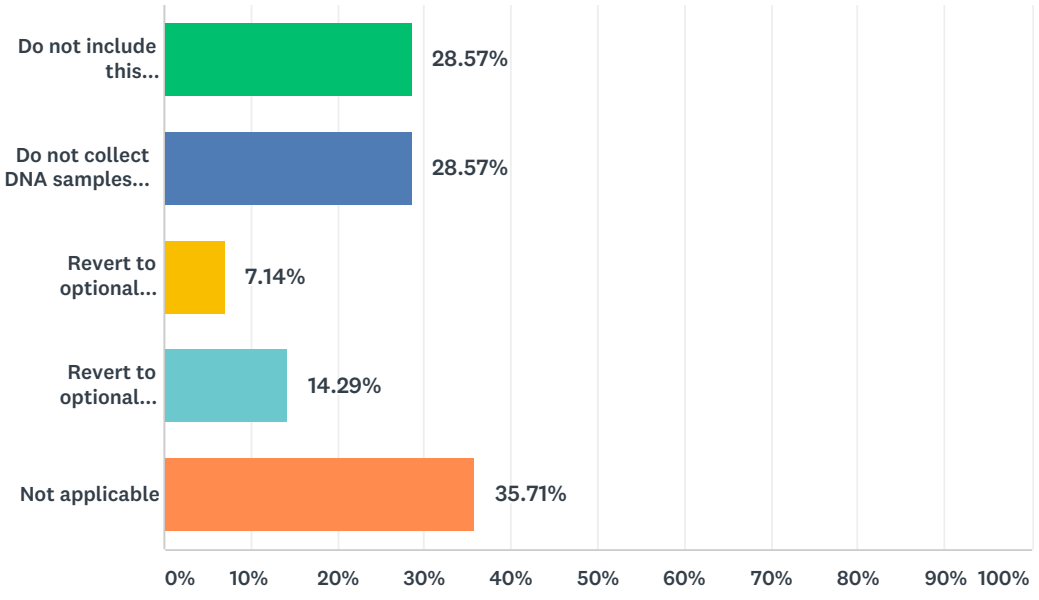


ANSWER CHOICES	RESPONSES	
Main study signature allows for DNA collection (is required for entry to study)	0.00%	0
Separate optional signature page that is stand-alone from main study consent signature	91.67%	11
Tick box to affirm or decline optional participation as part of main study signature page	8.33%	1
TOTAL		12

#	OTHER (PLEASE SPECIFY)	DATE
1	Varies, but typically the main study signature allows for DNA collection & storage for drug response research; same consent page has a place for the subject to check a box/initial their choice about the optional additional research on broader topics using the sample.	10/29/2014 3:02 AM
2	Tick box may be used on rare occasions at request of IRB/EC	10/21/2014 11:32 AM
3	can be both #1 and #2 depending on the phase of the study and indication	10/15/2014 1:28 PM

Q23 When DNA collection is required for all study participants (i.e. they must agree to give a DNA sample to participate in the main clinical study) then what mechanisms do you have in place to manage countries or EC/IRB that do not permit mandating collection of a DNA sample (tick all that apply)?

Answered: 14 Skipped: 0

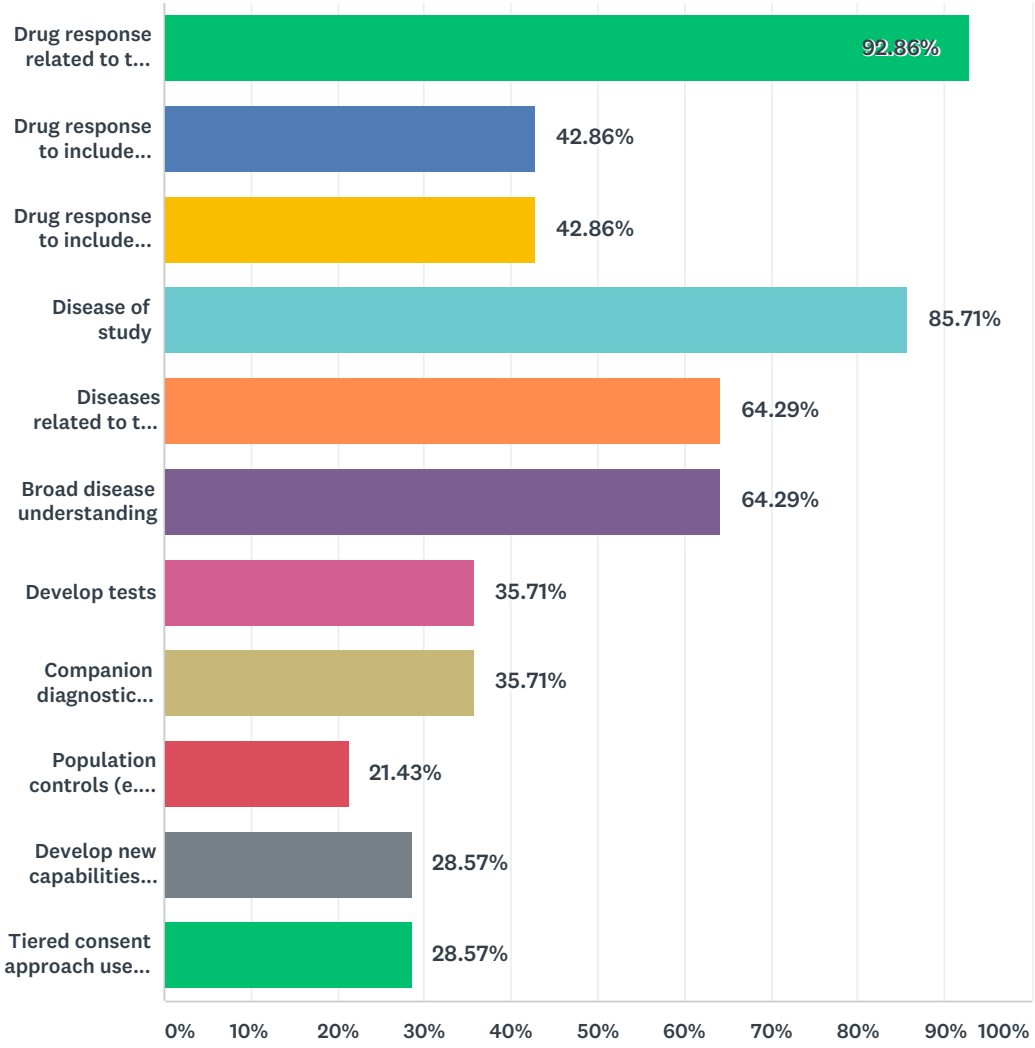


ANSWER CHOICES	RESPONSES	
Do not include this country/site in the study	28.57%	4
Do not collect DNA samples from participants at this site	28.57%	4
Revert to optional participation in DNA sampling by providing a different main consent with an optional signature/tick box for DNA collection	7.14%	1
Revert to optional participation in DNA sampling by providing a separate optional Patient Information Sheet and Consent/Signature document	14.29%	2
Not applicable	35.71%	5
Total Respondents: 14		

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

Q24 In this question we are trying to understand the scope of research to be conducted. If you utilize a tiered consent please indicated "Tiered consent" and describe the Tiering approach in the comments. What do you ask the patient to consent to regarding the collection and use of their DNA specimen? (check all that apply)

Answered: 14 Skipped: 0



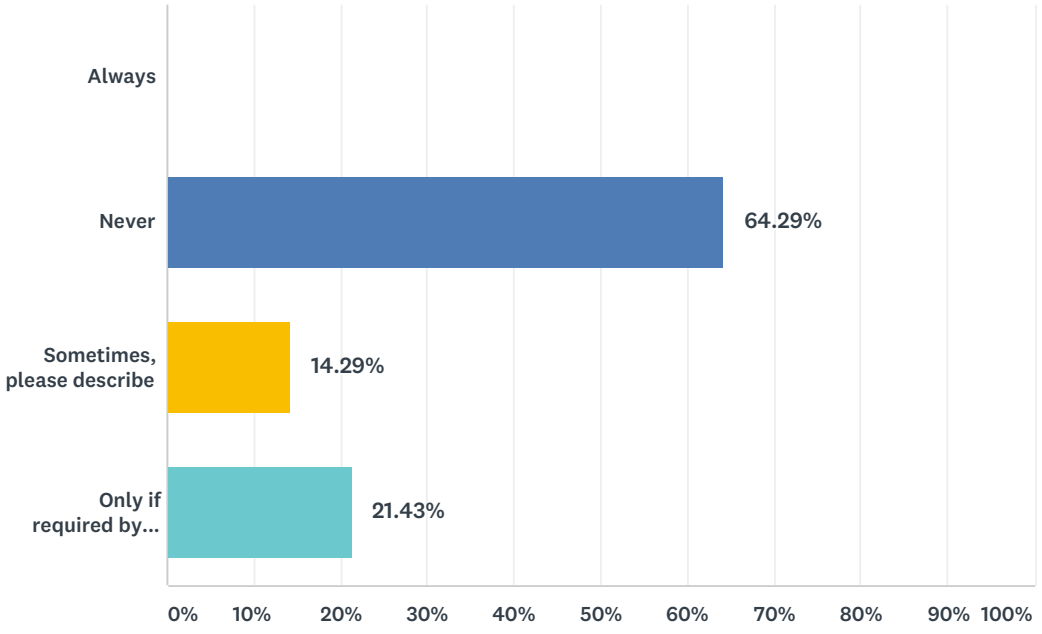
ANSWER CHOICES	RESPONSES	
Drug response related to the investigational product	92.86%	13
Drug response to include comparator drugs	42.86%	6
Drug response to include co-administered drugs	42.86%	6
Disease of study	85.71%	12
Diseases related to the disease of study	64.29%	9
Broad disease understanding	64.29%	9

Develop tests	35.71%	5
Companion diagnostic development	35.71%	5
Population controls (e.g. controls for other diseases)	21.43%	3
Develop new capabilities or methods	28.57%	4
Tiered consent approach used, please describe	28.57%	4
Total Respondents: 14		

#	COMMENT	DATE
1	1st tier: drug response related to the investigational product, co-administered drugs, and comparator drugs. 2nd tier: disease indication in the study, conditions related to the disease, develop tests, companion diagnostics development, develop new capabilities or methods, population controls, and use in studying natural variation.	10/29/2014 3:03 AM
2	mandatory collection of DNA would imply that we would list the genes or pathways that we would look at. Optional collection of DNA is for future research on response to drug, on disease biology and progression and related diseases, and for development of biomarker or diagnostics tests	10/22/2014 6:20 AM
3	We also address safety concerns (ADME).	10/20/2014 7:50 PM
4	consent as part of main trial + optional consent for use of residual samples + optional new sample collection	10/15/2014 1:36 PM

Q25 In your consent template, do you specify the platforms or methods (technologies or analysis methods) that will be used to study genetic variation?

Answered: 14 Skipped: 0

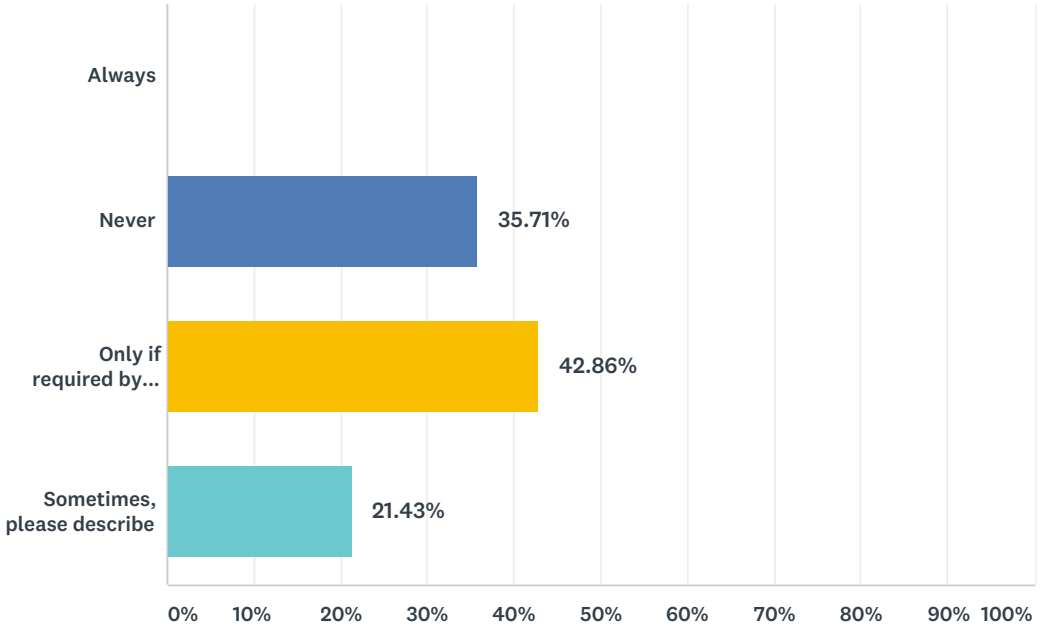


ANSWER CHOICES	RESPONSES	
Always	0.00%	0
Never	64.29%	9
Sometimes, please describe	14.29%	2
Only if required by country regulation or policy, please indicate countries, institutions in comments	21.43%	3
TOTAL		14

#	COMMENTS	DATE
1	If the intent is to run run WGS or exome sequencing, we tend to specify it.	10/22/2014 6:20 AM
2	In some jurisdictions there is a requirement to include this information, e.g., Taiwan.	10/21/2014 11:48 AM
3	For two reasons, this is never specified: 1. We do not know what next generation technologies might be made available to us. 2. Only prospective testing in "difficult" countries might specify technologies used.	10/20/2014 7:50 PM
4	When required by local or regional request e.g Taiwan	10/20/2014 3:21 PM
5	Only if we are absolutely required to identify the exact genes to be investigated, we identify the platform/technology. This has only occurred in Taiwan.	10/17/2014 7:43 PM
6	Technologies change over time	10/16/2014 10:12 PM

Q26 In your consent template, do you specify what genes or genetic variants will be analyzed?

Answered: 14 Skipped: 0

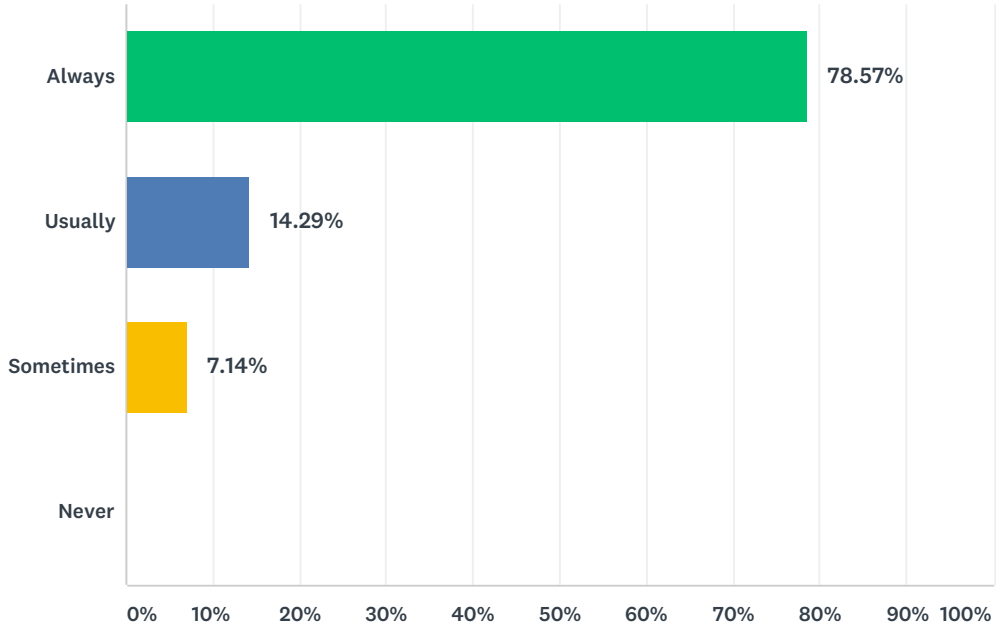


ANSWER CHOICES	RESPONSES	
Always	0.00%	0
Never	35.71%	5
Only if required by country regulation or institution policy, please indicate countries or institutions	42.86%	6
Sometimes, please describe	21.43%	3
TOTAL		14

#	COMMENTS	DATE
1	Taiwan and Brazil. Occasionally requested for some institutes in Spain and Japan.	10/21/2014 11:48 AM
2	This information is only listed in the clinical study protocol during prospective studies only.	10/20/2014 7:50 PM
3	When required by local or regional request e.g Taiwan	10/20/2014 3:21 PM
4	Again, we have only done this for Taiwan.	10/17/2014 7:43 PM
5	eg Japan	10/16/2014 10:12 PM
6	we try and leave the language as flexible as possible, but know certain IRBs will want a list of genes, so sometimes we need to pre-specify	10/15/2014 1:36 PM
7	Only if a prescreening test is required by not for the typical DNA collection	10/10/2014 6:52 PM
8	only if targeted genes are pre-identified.	10/2/2014 8:17 PM

Q27 The next series of questions relates to your company's storage and banking practices to determine how they are described in the informed consent template. Does your company store the sample you collect for DNA analysis beyond the end of the study?

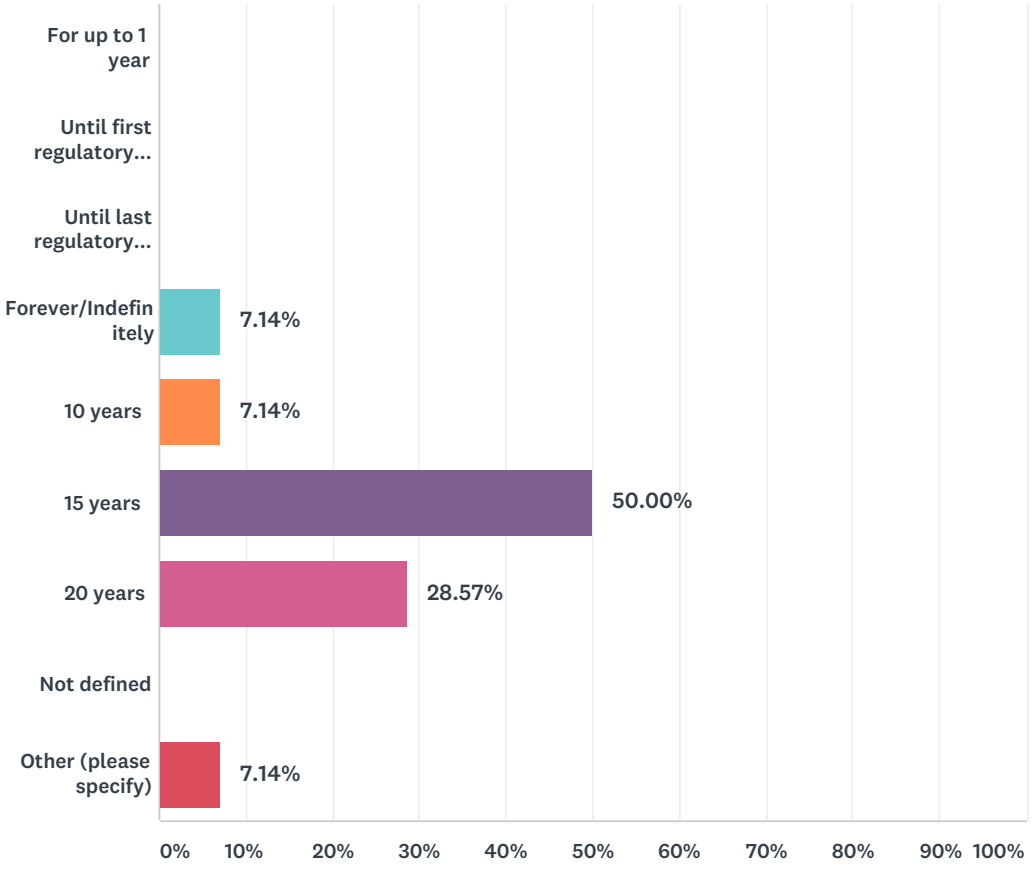
Answered: 14 Skipped: 0



ANSWER CHOICES	RESPONSES	
Always	78.57%	11
Usually	14.29%	2
Sometimes	7.14%	1
Never	0.00%	0
TOTAL		14

Q28 In the informed consent template, which best describes the usual duration of storage for the DNA samples?

Answered: 14 Skipped: 0

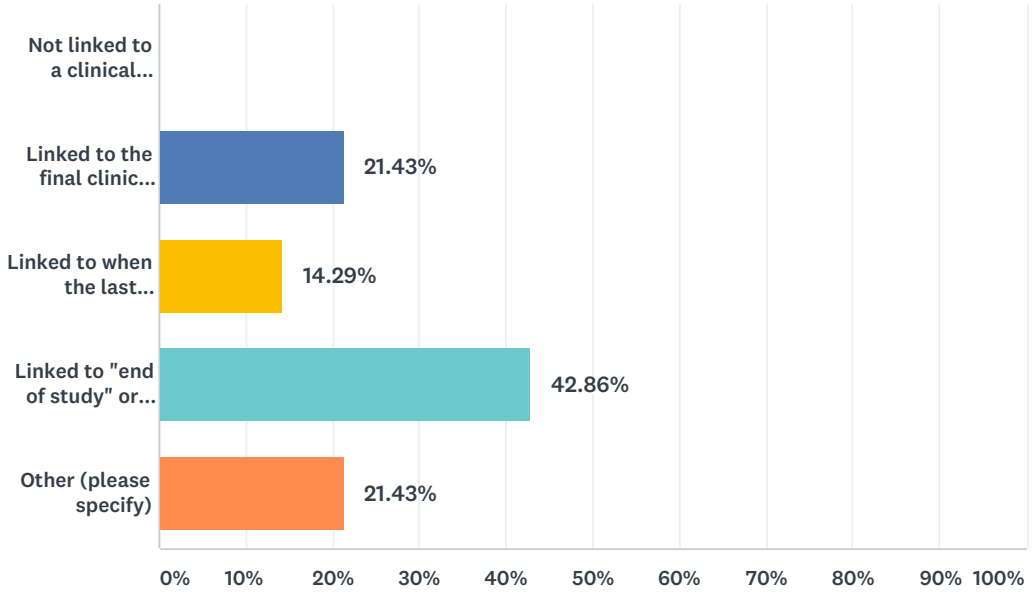


ANSWER CHOICES	RESPONSES	
For up to 1 year	0.00%	0
Until first regulatory approval or termination of the study drug	0.00%	0
Until last regulatory approval	0.00%	0
Forever/Indefinitely	7.14%	1
10 years	7.14%	1
15 years	50.00%	7
20 years	28.57%	4
Not defined	0.00%	0
Other (please specify)	7.14%	1
TOTAL		14

#	OTHER (PLEASE SPECIFY)	DATE
1	for main, 2 years post LPLV and for optional it is indefinite	10/15/2014 1:36 PM

Q29 Is there a clinical study milestone used for triggering the start of the storage duration?

Answered: 14 Skipped: 0



ANSWER CHOICES	RESPONSES	
Not linked to a clinical study milestone	0.00%	0
Linked to the final clinical study report	21.43%	3
Linked to when the last subject completes the study (last subject visit)	14.29%	2
Linked to "end of study" or "completion of study protocol"	42.86%	6
Other (please specify)	21.43%	3
TOTAL		14

#	OTHER (PLEASE SPECIFY)	DATE
1	We use the blood draw collection data	10/20/2014 3:21 PM
2	Linked to date of sample collection	10/17/2014 7:43 PM
3	Linked to collection day	10/16/2014 10:12 PM

Q30 If storage period is not linked to a clinical study milestone then is there a program milestone that triggers the storage duration (e.g. 2 years after initial filing in an ICH region)?

Answered: 0 Skipped: 14

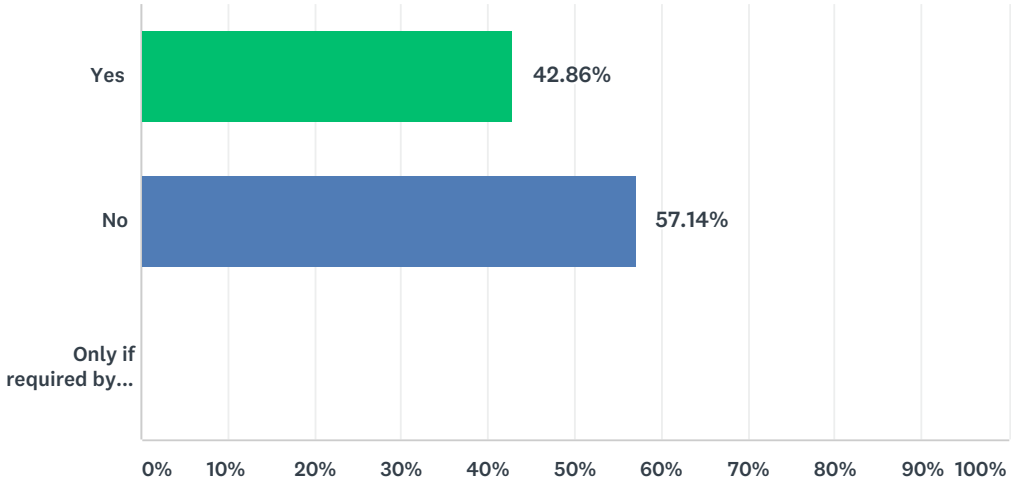
⚠ No matching responses.

ANSWER CHOICES	RESPONSES	
No	0.00%	0
Yes (please specify)	0.00%	0
TOTAL		0

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

Q31 In the informed consent, do you describe the reason for the defined storage duration?

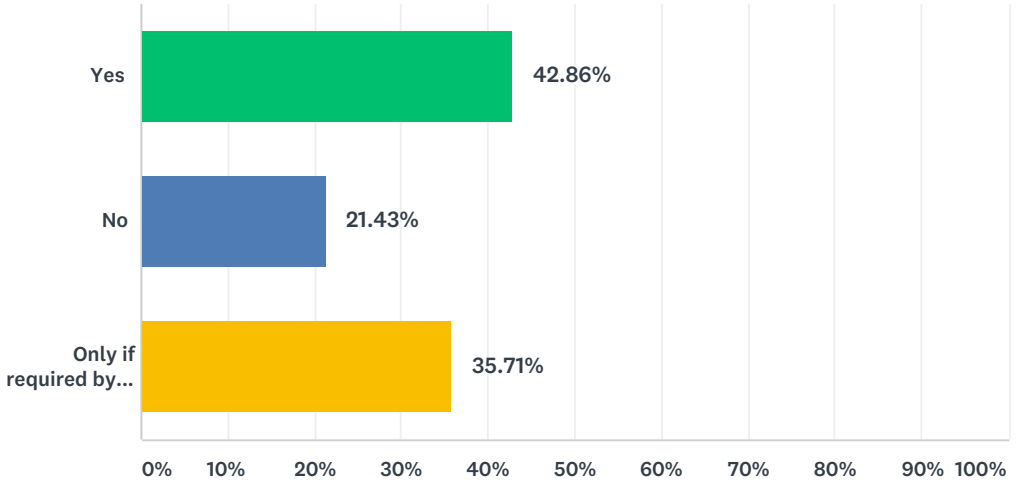
Answered: 14 Skipped: 0



ANSWER CHOICES	RESPONSES	
Yes	42.86%	6
No	57.14%	8
Only if required by country regulation or institution policy	0.00%	0
TOTAL		14

Q32 In the informed consent , do you describe where the samples collected for DNA analysis will be stored?

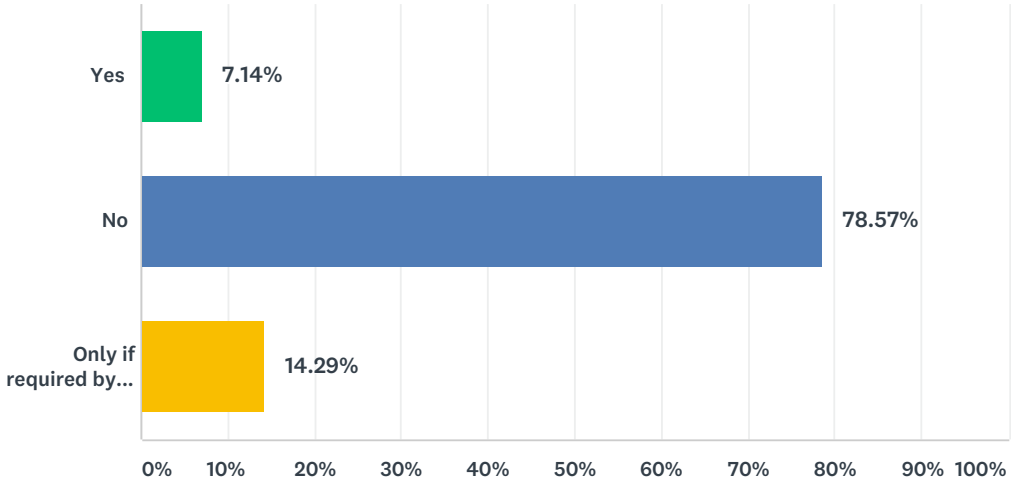
Answered: 14 Skipped: 0



ANSWER CHOICES	RESPONSES	
Yes	42.86%	6
No	21.43%	3
Only if required by country regulation or institution policy	35.71%	5
Total Respondents: 14		

Q33 In your informed consent do you describe where the genetic data will be stored?

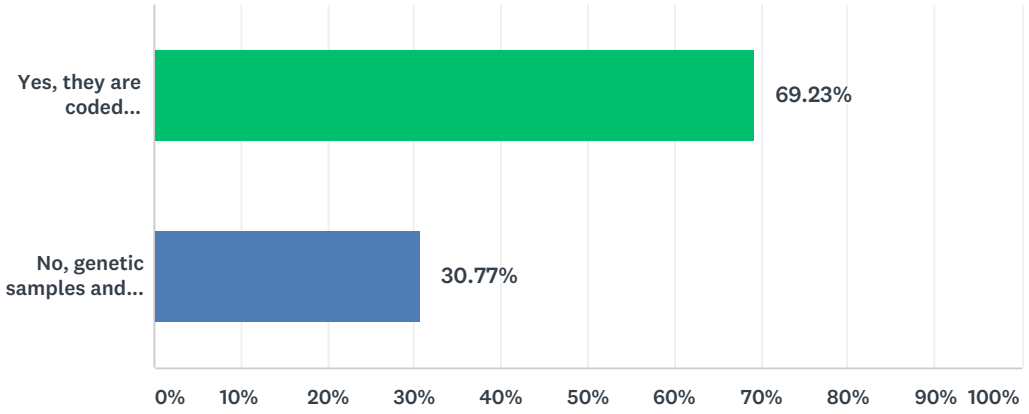
Answered: 14 Skipped: 0



ANSWER CHOICES	RESPONSES	
Yes	7.14%	1
No	78.57%	11
Only if required by country regulation or institution policy	14.29%	2
TOTAL		14

Q34 In this section we would like to understand coding procedures used for DNA samples and the resulting data.Does your company apply a more stringent level of coding for genetic samples?

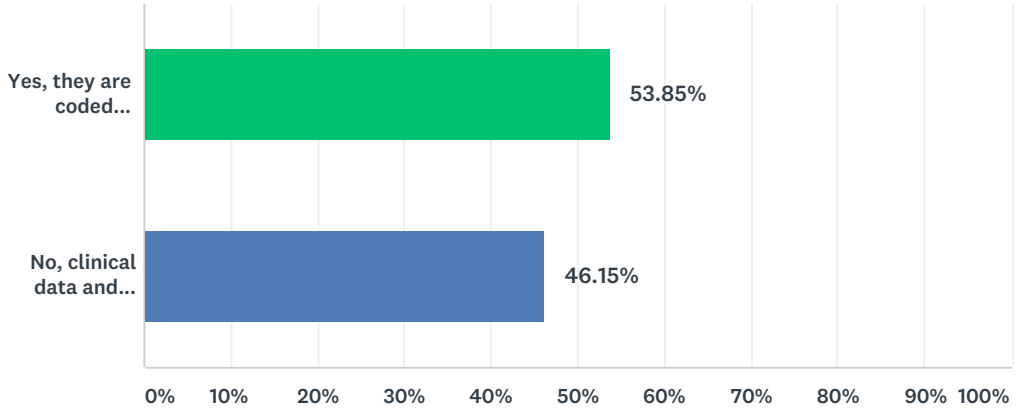
Answered: 13 Skipped: 1



ANSWER CHOICES	RESPONSES	
Yes, they are coded differently	69.23%	9
No, genetic samples and clinical samples are coded the same	30.77%	4
TOTAL		13

Q35 Does your company apply a more stringent level of coding to genetic data?

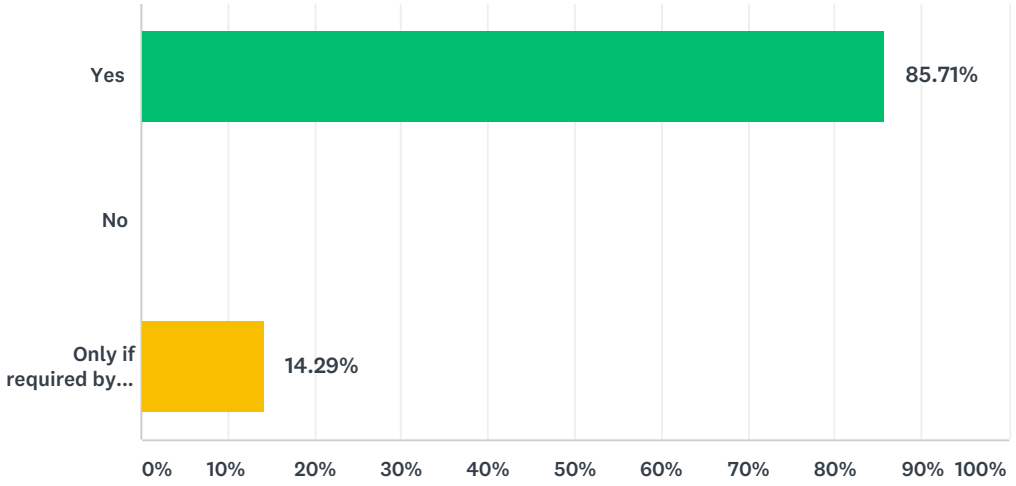
Answered: 13 Skipped: 1



ANSWER CHOICES	RESPONSES	
Yes, they are coded differently	53.85%	7
No, clinical data and genetic data are coded the same	46.15%	6
TOTAL		13

Q36 In the informed consent template, do you describe how genetic samples and data are coded?

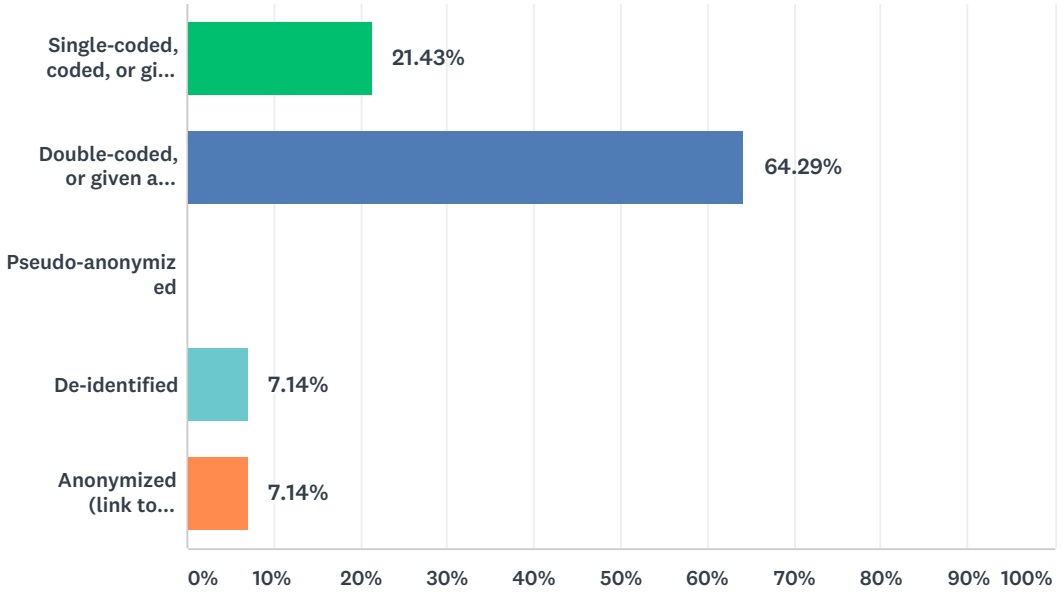
Answered: 14 Skipped: 0



ANSWER CHOICES	RESPONSES	
Yes	85.71%	12
No	0.00%	0
Only if required by country regulation or institution policy	14.29%	2
TOTAL		14

Q37 In your informed consent, what words do you use to describe how the DNA sample will be coded?

Answered: 14 Skipped: 0

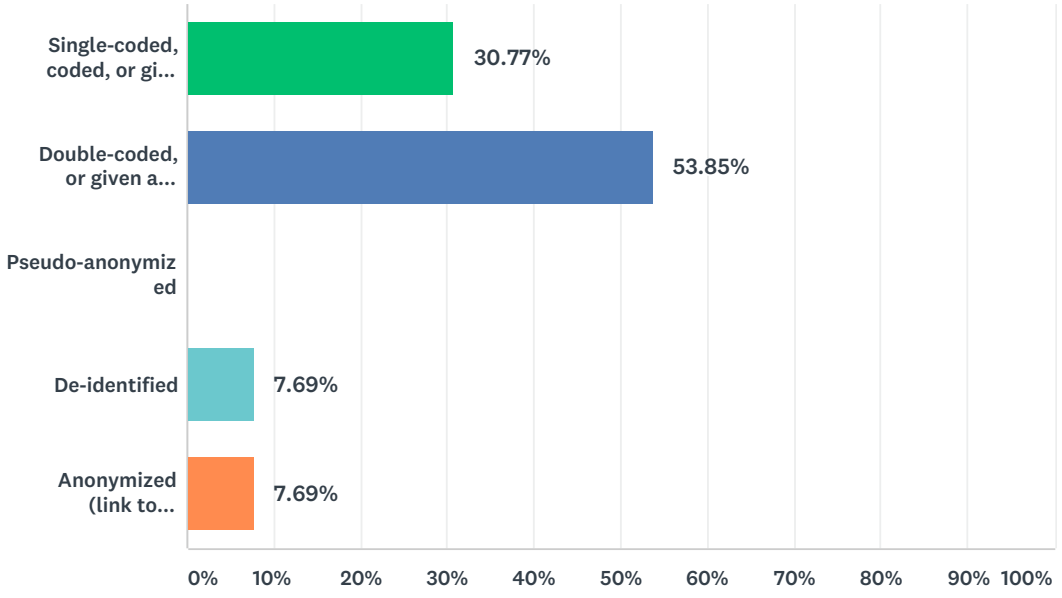


ANSWER CHOICES	RESPONSES	
Single-coded, coded, or given the same code as other clinical trial samples	21.43%	3
Double-coded, or given a separate or additional code from other clinical trial samples	64.29%	9
Pseudo-anonymized	0.00%	0
De-identified	7.14%	1
Anonymized (link to personal information or clinical study code is irreversibly broken)	7.14%	1
TOTAL		14

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

Q38 In your informed consent, what words do you use to describe how the genetic data will be coded?

Answered: 13 Skipped: 1



ANSWER CHOICES	RESPONSES	
Single-coded, coded, or given the same code as other clinical trial information	30.77%	4
Double-coded, or given a separate or additional code from other clinical trial information	53.85%	7
Pseudo-anonymized	0.00%	0
De-identified	7.69%	1
Anonymized (link to personal information or clinical study code is irreversibly broken)	7.69%	1
TOTAL		13

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

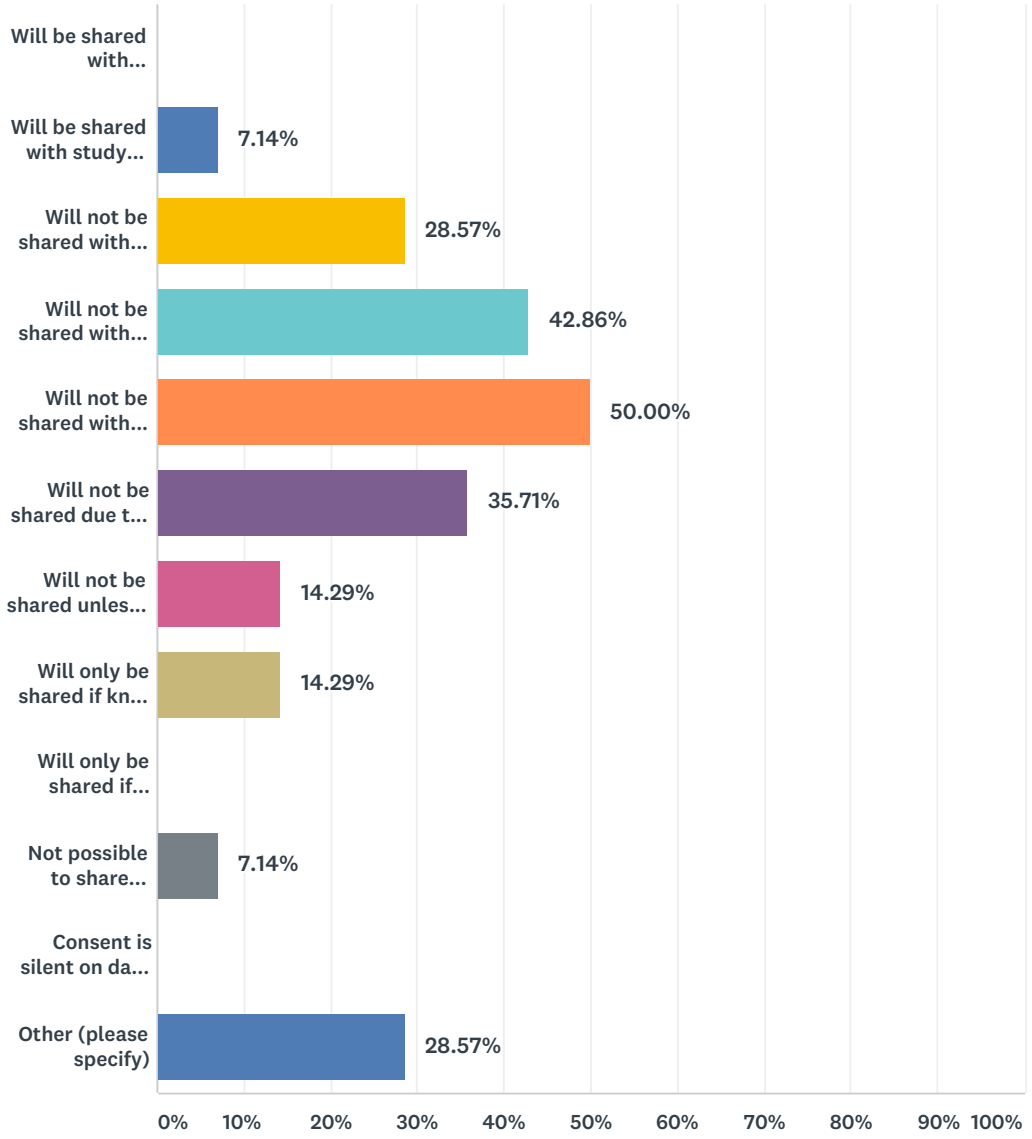
Q39 If you use a coding procedure other than single coding then please describe how and when you apply the procedure to the sample and or genetic data (e.g. double coding, anonymisation).

Answered: 12 Skipped: 2

#	RESPONSES	DATE
1	Samples are relabelled prior to DNA extractions. Complete anonymization is performed prior to any analysis done.	3/20/2015 2:58 PM
2	We ship special barcoded samples to the site. The link to the original patient ID is kept in special secured folder in the secured data area. Only designated individuals have access to the link table that are not part of the main study.	11/13/2014 11:00 AM
3	N/A	10/29/2014 3:24 AM
4	when sample arrives at our company, in our repository, it is assigned a new random number: second code generated by a double coding software. The link between patient ID and second code is safely stored in the software with very limited number of people able to access the link. Access to link is restricted and documented. Double coding of sample takes place before DNA is analyzed so genetic data generated from DNA sample is also double coded	10/22/2014 6:32 AM
5	NA	10/21/2014 12:07 PM
6	NA	10/20/2014 7:57 PM
7	It is applied at DNA extraction at the biorepository	10/20/2014 3:29 PM
8	Samples are double coded upon DNA extraction. When released for testing, they are released with the double code. All resulting genetic data is double coded and requires a linking back to the clinical data/original subject ID.	10/17/2014 7:57 PM
9	2nd code is displayed on sample label. Genetic data is stored with 2nd code.	10/16/2014 10:16 PM
10	this step usually occurs at our central lab	10/15/2014 1:46 PM
11	the sample is given another code in addition to the accession number and we are provided with a key at the end of the study	10/10/2014 6:57 PM
12	as per standard procedure for double coding, after DNA isolation.	10/2/2014 8:29 PM

Q40 This series of questions relates to sample and data sharing as described in the informed consent.How does your informed consent langauge address the return of individual participants genetic results (check all that apply)

Answered: 14 Skipped: 0



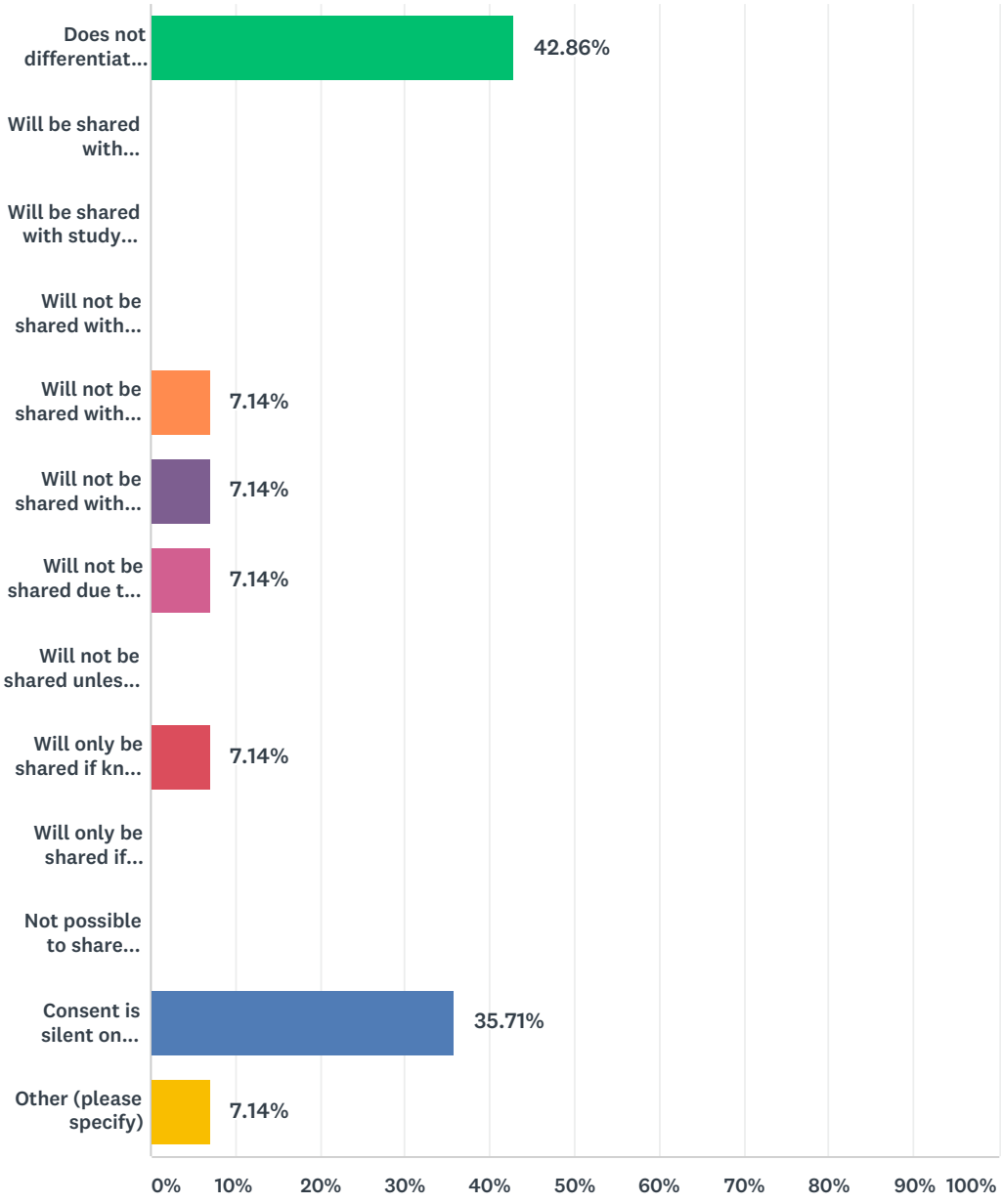
ANSWER CHOICES	RESPONSES	
Will be shared with participant	0.00%	0
Will be shared with study doctor	7.14%	1
Will not be shared with anyone	28.57%	4
Will not be shared with study doctor	42.86%	6
Will not be shared with participant	50.00%	7

Will not be shared due to "research" nature of the results	35.71%	5
Will not be shared unless required by law	14.29%	2
Will only be shared if known to be medically relevant	14.29%	2
Will only be shared if requested by the participant	0.00%	0
Not possible to share results as they are anonymized	7.14%	1
Consent is silent on data sharing	0.00%	0
Other (please specify)	28.57%	4
Total Respondents: 14		

#	OTHER (PLEASE SPECIFY)	DATE
1	For Spain, need to state that subjects have the right to request their genetic research results.	10/29/2014 3:24 AM
2	If required by law we add a sentence to consent to express this. We had a sentence that said that Sponsor would pay for Dx testing in teh event there was a result which we deemed to be clininically significant.	10/20/2014 3:29 PM
3	If required by law to return results, we will modify the consent to state that we will return due to XX Law.	10/17/2014 7:57 PM
4	if requested by law data will be shared with the participant	10/2/2014 8:29 PM

Q41 How does your informed consent language address individual participant level "incidental findings"? (check all that apply)

Answered: 14 Skipped: 0



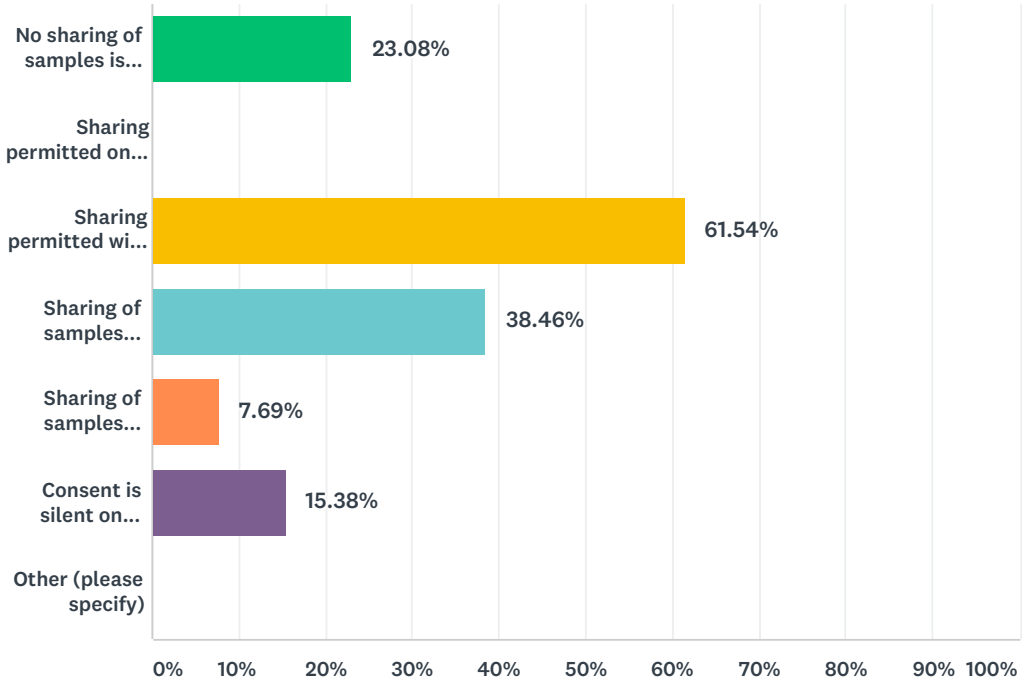
ANSWER CHOICES	RESPONSES	
Does not differentiate between research results and incidental findings	42.86%	6
Will be shared with participant	0.00%	0
Will be shared with study doctor	0.00%	0
Will not be shared with anyone	0.00%	0
Will not be shared with study doctor	7.14%	1

Will not be shared with participant	7.14%	1
Will not be shared due to "research" nature of the results	7.14%	1
Will not be shared unless required by law	0.00%	0
Will only be shared if known to be medically relevant	7.14%	1
Will only be shared if requested by the participant	0.00%	0
Not possible to share results as they are anonymized	0.00%	0
Consent is silent on individual participant level "incidental findings"	35.71%	5
Other (please specify)	7.14%	1
Total Respondents: 14		

#	OTHER (PLEASE SPECIFY)	DATE
1	Under certain conditions IF data maybe shared with study doctor/participant	10/16/2014 10:16 PM

Q42 Does your informed consent form allow sharing of samples? (check all that apply)

Answered: 13 Skipped: 1

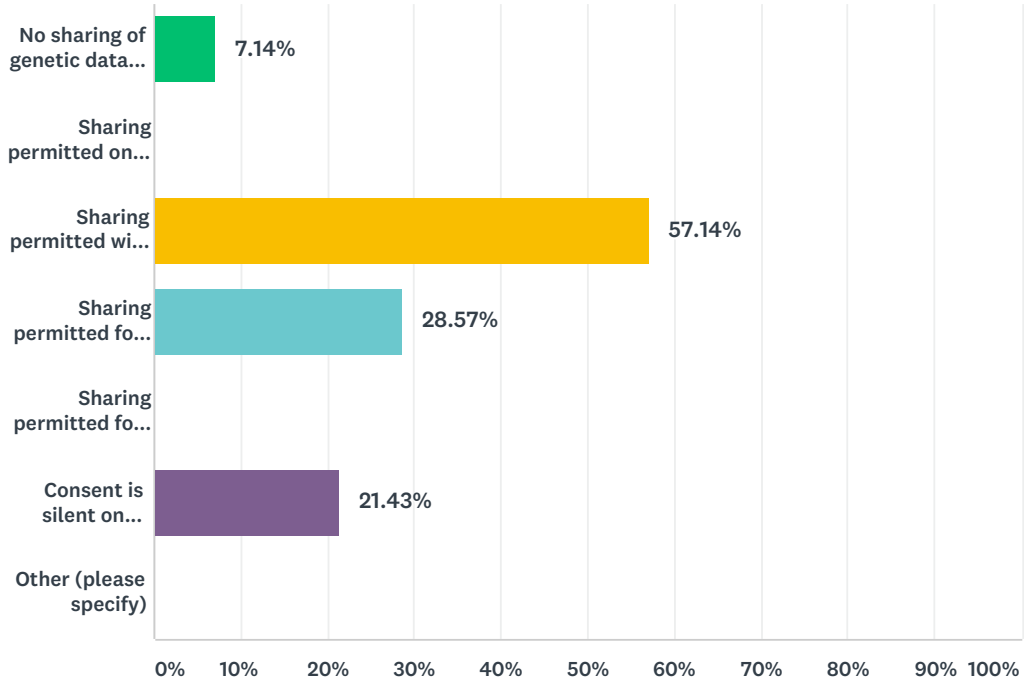


ANSWER CHOICES	RESPONSES	
No sharing of samples is permitted	23.08%	3
Sharing permitted only with additional ethics approvals	0.00%	0
Sharing permitted with companies or universities working with my company (3rd party and affiliates)	61.54%	8
Sharing of samples permitted for uses aligned with the informed consent	38.46%	5
Sharing of samples permitted for secondary use	7.69%	1
Consent is silent on sharing of samples	15.38%	2
Other (please specify)	0.00%	0
Total Respondents: 13		

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

Q43 Does your informed consent allow sharing of genetic data with other scientists? (check all that apply)

Answered: 14 Skipped: 0

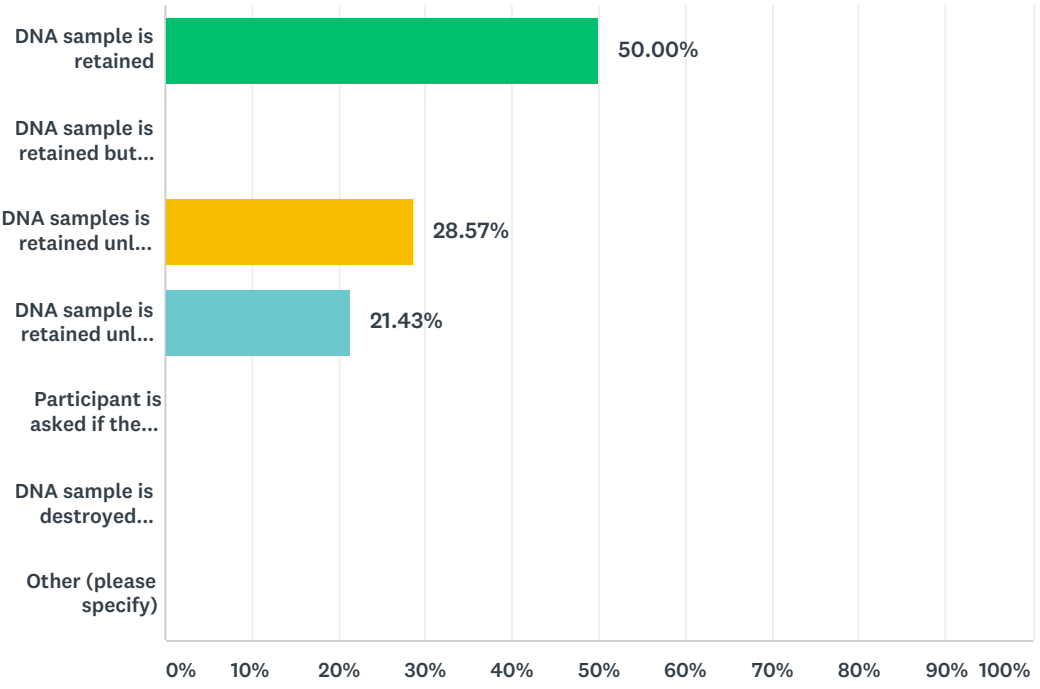


ANSWER CHOICES	RESPONSES	
No sharing of genetic data is permitted	7.14%	1
Sharing permitted only with additional ethics approvals	0.00%	0
Sharing permitted with companies or universities working with my company (3rd party and affiliates)	57.14%	8
Sharing permitted for uses aligned with the informed consent	28.57%	4
Sharing permitted for secondary use	0.00%	0
Consent is silent on sharing of genetic data	21.43%	3
Other (please specify)	0.00%	0
Total Respondents: 14		

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

Q44 This series of questions relates to how the informed consent describes what happens when a participant leaves the study and or withdraws their consent to participate in either the main clinical study or the DNA substudy if a separate sub-study is conducted.If a subject discontinues the main clinical study but does not withdraw their consent for the study which of the following best describes what happens to their DNA sample?

Answered: 14 Skipped: 0

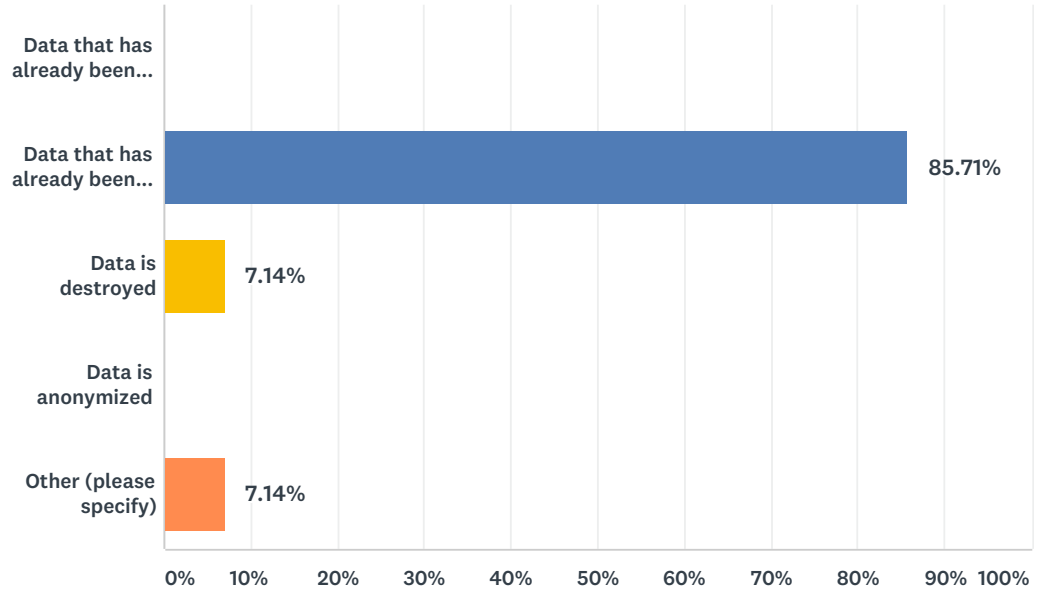


ANSWER CHOICES	RESPONSES	
DNA sample is retained	50.00%	7
DNA sample is retained but no further testing or analysis is conducted	0.00%	0
DNA samples is retained unless participant withdraws consent for the DNA research also	28.57%	4
DNA sample is retained unless the participant requests destruction of the sample	21.43%	3
Participant is asked if they want to continue participation in the DNA research	0.00%	0
DNA sample is destroyed (along with all derivatives)	0.00%	0
Other (please specify)	0.00%	0
TOTAL		14

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

Q45 If a subject discontinues the study but does not withdraw their consent which of the following best describes what happens to their genetic data?

Answered: 14 Skipped: 0

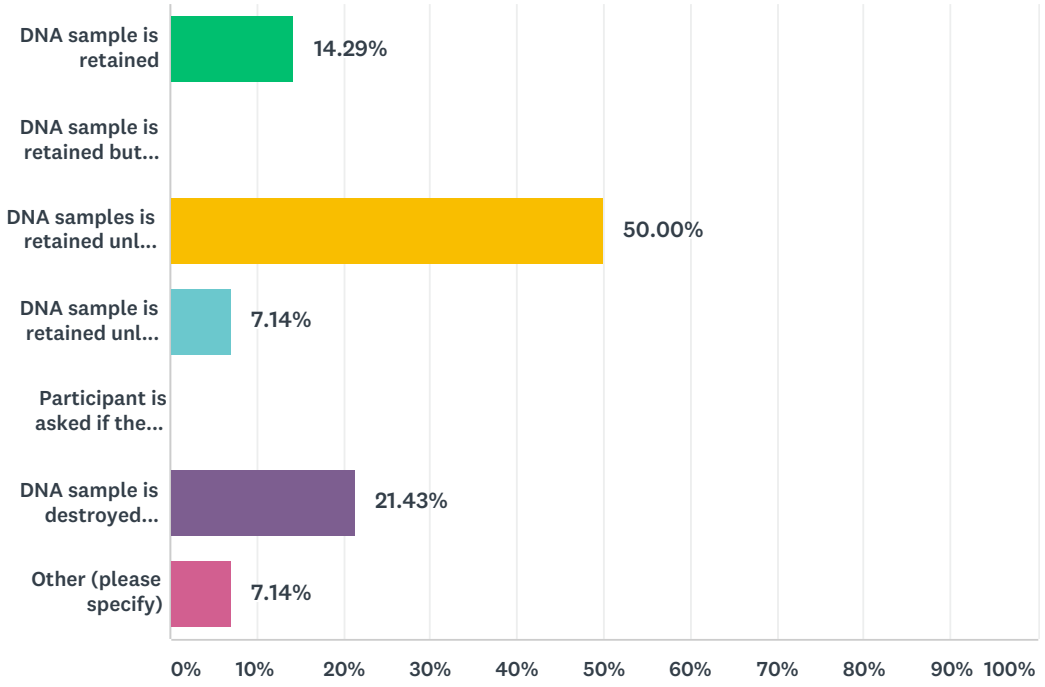


ANSWER CHOICES	RESPONSES	
Data that has already been generated is retained but is not used for analysis	0.00%	0
Data that has already been generated is retained and is continued to be used for analysis	85.71%	12
Data is destroyed	7.14%	1
Data is anonymized	0.00%	0
Other (please specify)	7.14%	1
TOTAL		14

#	OTHER (PLEASE SPECIFY)	DATE
1	Genetic data can only be generated after anonymization, therefore, any data that has already been generated is retained and is continued to be used for analysis	3/20/2015 2:58 PM

Q46 If a participant withdraws consent from the main clinical study which of the following best describes what happens to their DNA sample?

Answered: 14 Skipped: 0

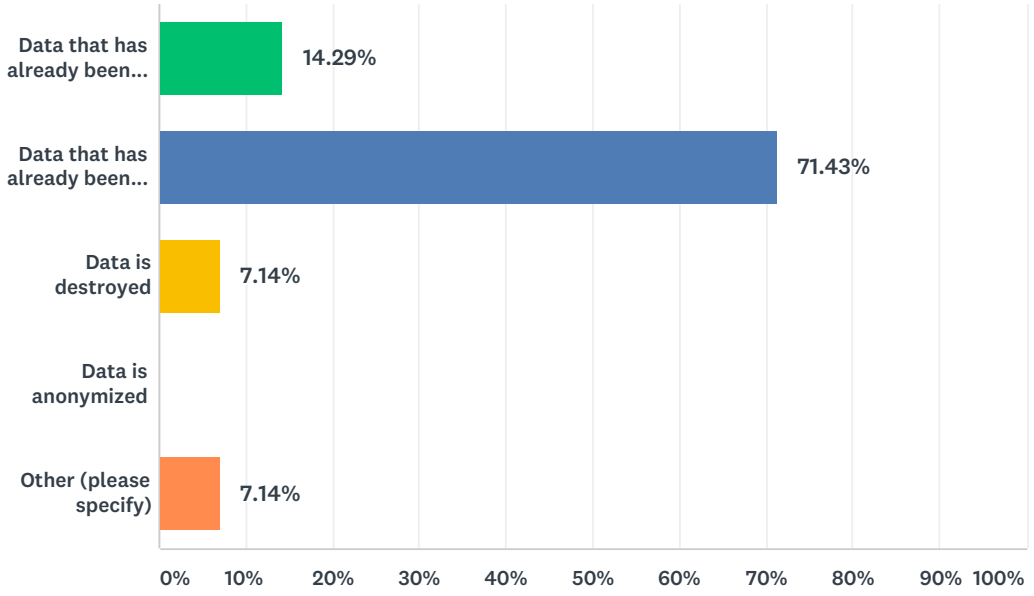


ANSWER CHOICES	RESPONSES	
DNA sample is retained	14.29%	2
DNA sample is retained but no further testing or analysis is conducted	0.00%	0
DNA samples is retained unless participant withdraws consent for the DNA research also	50.00%	7
DNA sample is retained unless the participant requests destruction of the sample	7.14%	1
Participant is asked if they want to continue participation in the DNA research	0.00%	0
DNA sample is destroyed (along with all derivatives)	21.43%	3
Other (please specify)	7.14%	1
TOTAL		14

#	OTHER (PLEASE SPECIFY)	DATE
1	DNA sample is destroyed (along with all derivatives), if the patient withdraws before anonymization	3/20/2015 2:58 PM

Q47 If a participant withdraws consent from the main clinical study which of the following best describes what happens to their genetic data?

Answered: 14 Skipped: 0

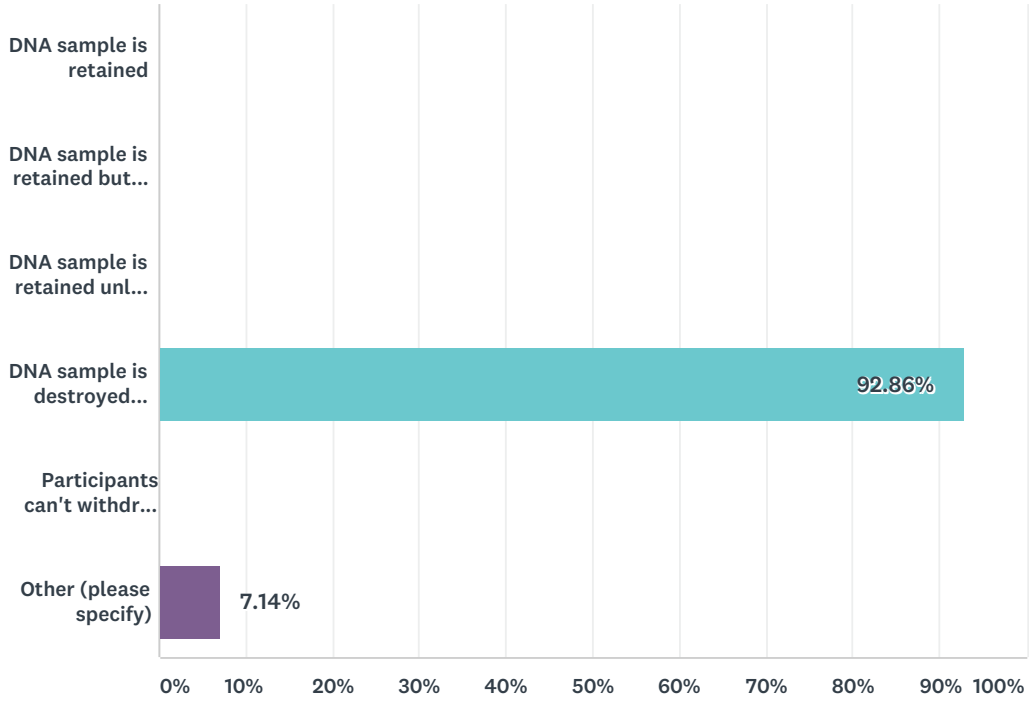


ANSWER CHOICES	RESPONSES	
Data that has already been generated is retained but is not used for analysis	14.29%	2
Data that has already been generated is retained and is continued to be used for analysis	71.43%	10
Data is destroyed	7.14%	1
Data is anonymized	0.00%	0
Other (please specify)	7.14%	1
TOTAL		14

#	OTHER (PLEASE SPECIFY)	DATE
1	Genetic data can only be generated after anonymization, therefore, any data that has already been generated is retained and is continued to be used for analysis	3/20/2015 2:58 PM

Q48 If the participant withdraws consent for the DNA research which of the following best describes what happens to their DNA sample?

Answered: 14 Skipped: 0

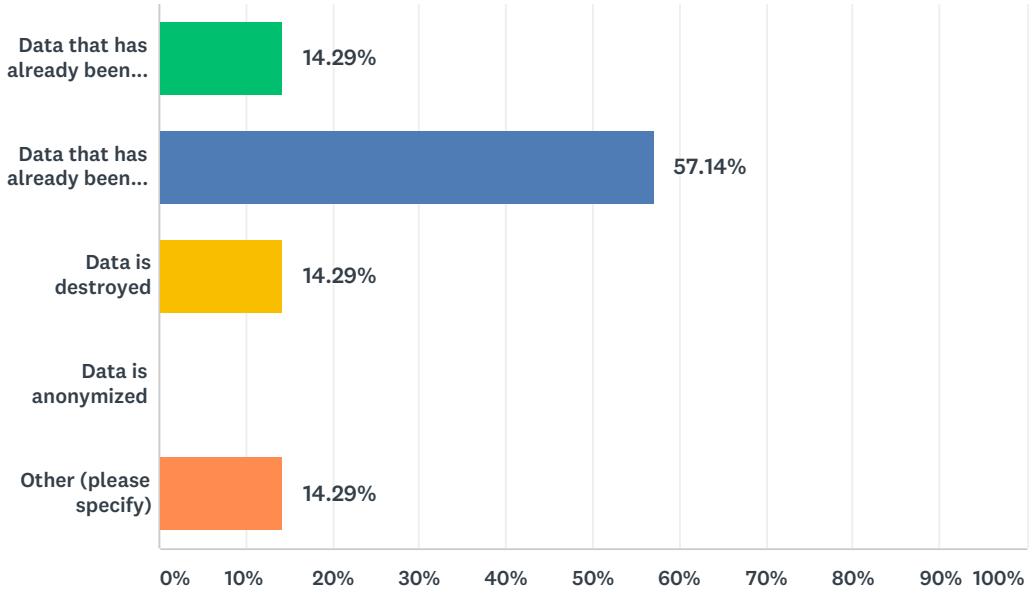


ANSWER CHOICES	RESPONSES	
DNA sample is retained	0.00%	0
DNA sample is retained but no further testing or analysis is conducted	0.00%	0
DNA sample is retained unless the participant requests destruction of the sample	0.00%	0
DNA sample is destroyed (along with all derivatives)	92.86%	13
Participants can't withdraw from the DNA research without withdrawing consent from the main study	0.00%	0
Other (please specify)	7.14%	1
TOTAL		14

#	OTHER (PLEASE SPECIFY)	DATE
1	DNA sample is destroyed (along with all derivatives), if the patient withdraws before anonymization; otherwise it is retained.	3/20/2015 2:58 PM

Q49 If the participant withdraws consent for the DNA research which of the following best describes what happens to their genetic data?

Answered: 14 Skipped: 0

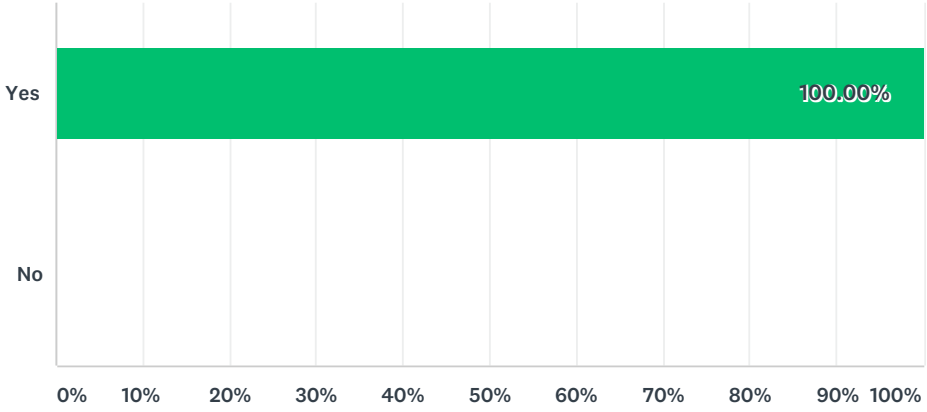


ANSWER CHOICES	RESPONSES	
Data that has already been generated is retained but is not used for analysis	14.29%	2
Data that has already been generated is retained and is continued to be used for analysis	57.14%	8
Data is destroyed	14.29%	2
Data is anonymized	0.00%	0
Other (please specify)	14.29%	2
TOTAL		14

#	OTHER (PLEASE SPECIFY)	DATE
1	Data is destroyed, if the patient withdraws before anonymization; otherwise it is retained.	3/20/2015 2:58 PM
2	Do not have experience or a policy with respect to this. Current thinking is that data that have already been generated are retained to protect the integrity of analyses which have already been performed but are not used for further analyses.	10/29/2014 3:24 AM

Q50 Does your company permit changes to the model or template informed consent form to accomodate local requirements such as country regulations, institution policies and or ethics committee requests?

Answered: 14 Skipped: 0

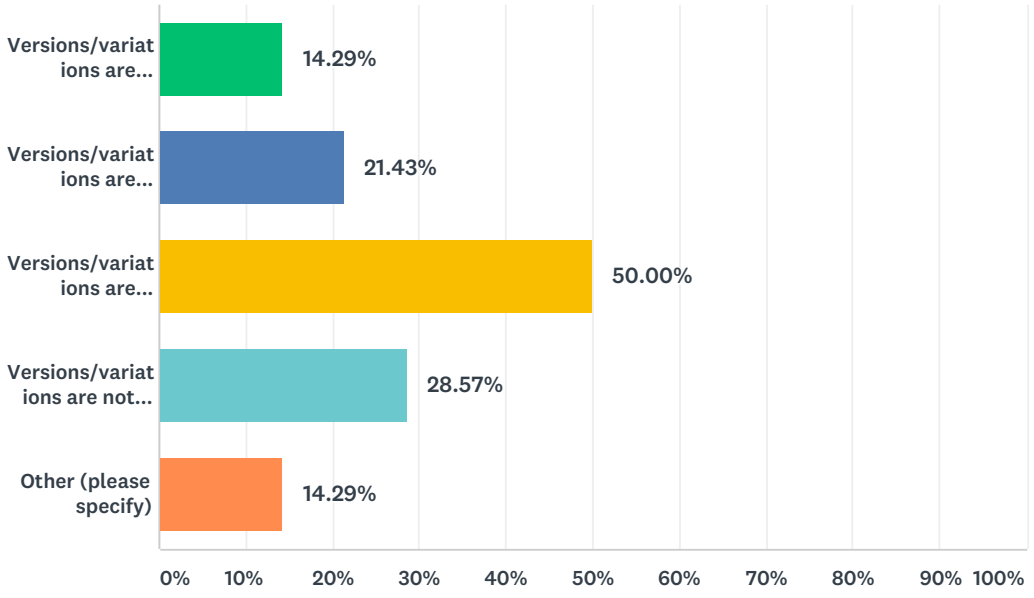


ANSWER CHOICES	RESPONSES	
Yes	100.00%	14
No	0.00%	0
TOTAL		14

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

Q51 How does your company track the versions/variations that are permitted in the Informed consent per the previous question? (choose all that apply)

Answered: 14 Skipped: 0

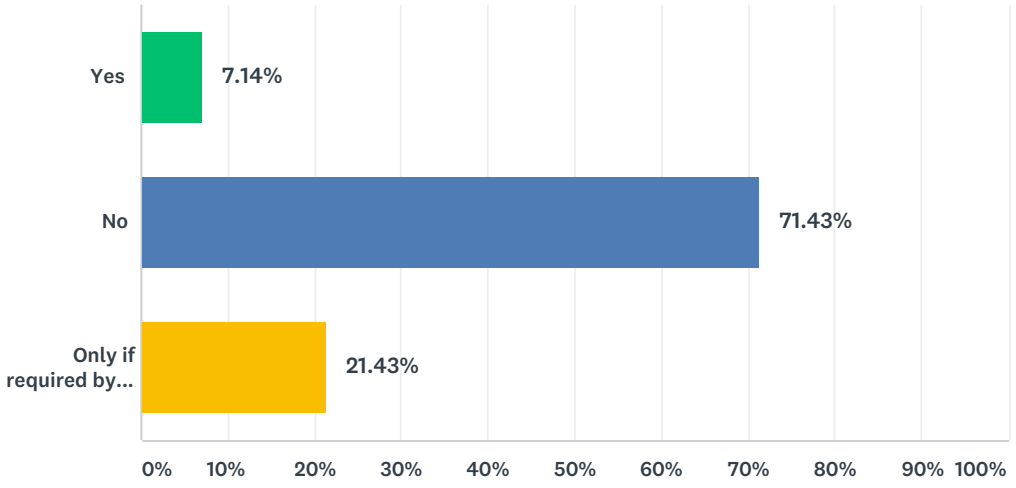


ANSWER CHOICES	RESPONSES	
Versions/variations are recorded in the Case Report Form	14.29%	2
Versions/variations are recorded in a log (e.g. a spreadsheet or similar)	21.43%	3
Versions/variations are recorded in a sample tracking system	50.00%	7
Versions/variations are not recorded separately from the IC template	28.57%	4
Other (please specify)	14.29%	2
Total Respondents: 14		

#	OTHER (PLEASE SPECIFY)	DATE
1	Only variants that place restrictions on the use of the samples or their storage duration are captured. These are recorded on a separate form in the study documentation folder.	10/29/2014 3:24 AM
2	EC/IRB approved ICFs stored in TMF	10/16/2014 10:17 PM

Q52 In your informed consent do you include options for participants (for example, to choose how long their sample will be stored, what research it will be used for or who has access to their sample or data)?

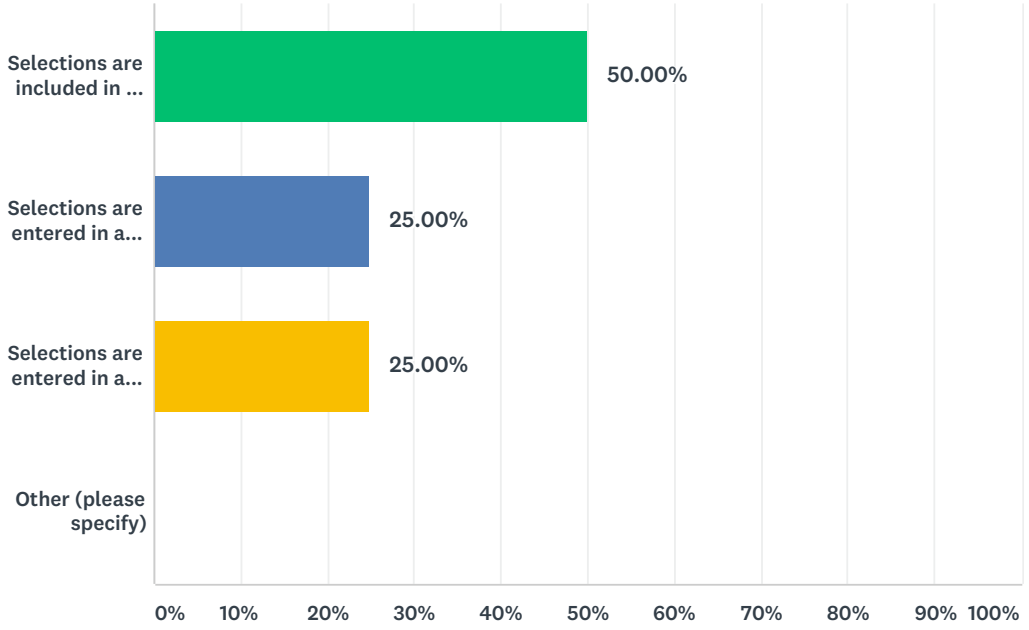
Answered: 14 Skipped: 0



ANSWER CHOICES	RESPONSES	
Yes	7.14%	1
No	71.43%	10
Only if required by country regulation or institution policy	21.43%	3
TOTAL		14

Q53 How are participant level choices tracked?

Answered: 4 Skipped: 10

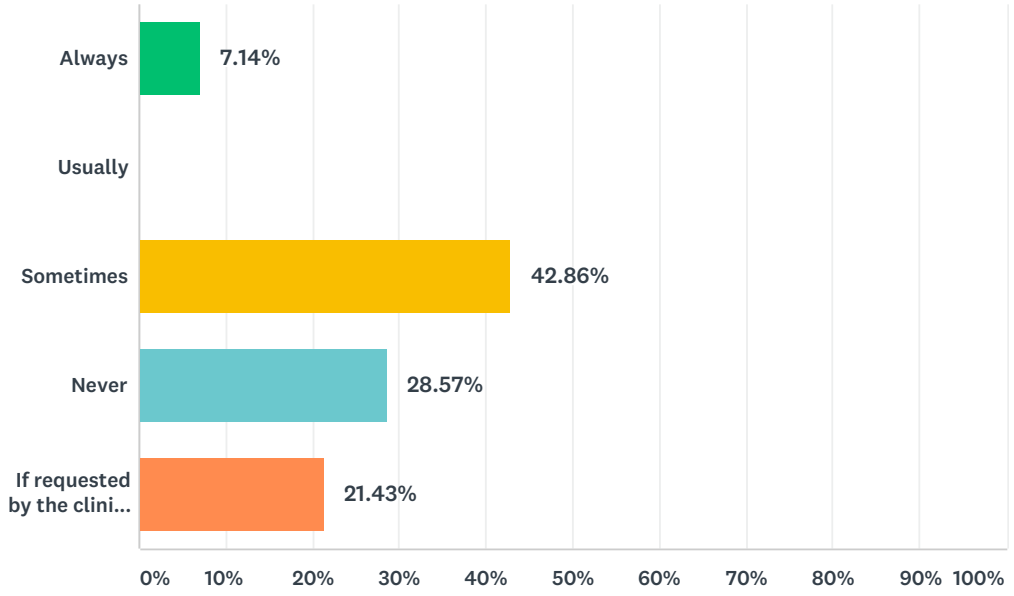


ANSWER CHOICES	RESPONSES	
Selections are included in the Case Report Form	50.00%	2
Selections are entered in a tracking log	25.00%	1
Selections are entered in a sample tracking system (e.g. LIMS)	25.00%	1
Other (please specify)	0.00%	0
TOTAL		4

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

Q54 This final series of questions relates to education and training either within your company, to ethics committees or to clinical site staff.Do you provide training on DNA research including pharmacogenetics and or genetic research to clinical teams within your company?

Answered: 14 Skipped: 0



ANSWER CHOICES	RESPONSES	
Always	7.14%	1
Usually	0.00%	0
Sometimes	42.86%	6
Never	28.57%	4
If requested by the clinical team	21.43%	3
TOTAL		14

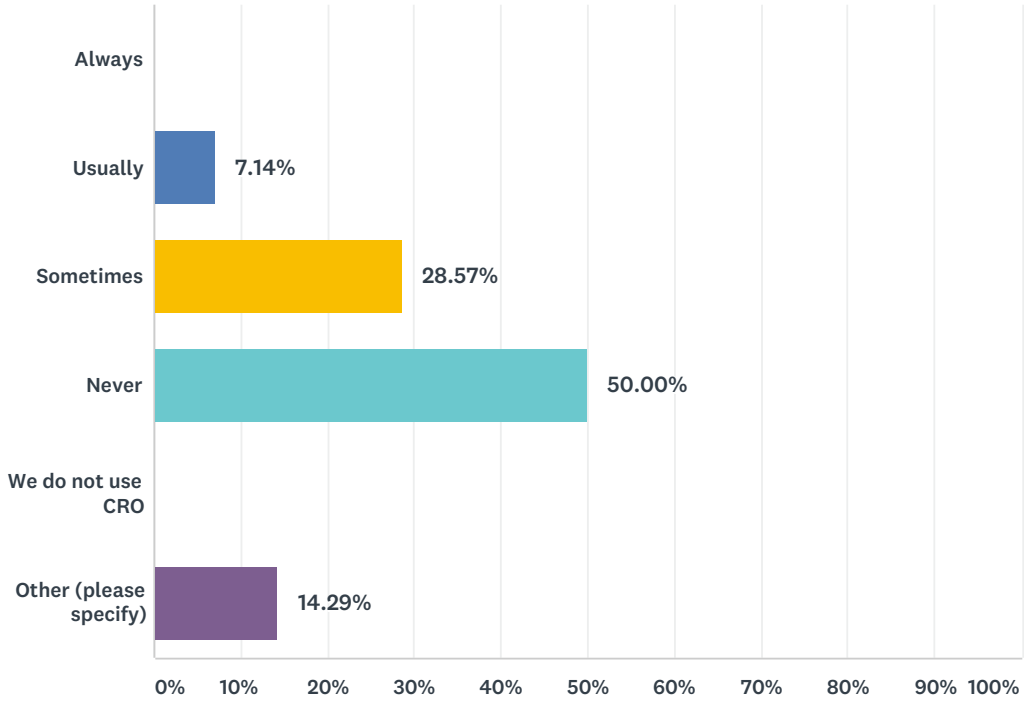
Q55 Please describe which study team members are trained? (check all that apply)

Answered: 7 Skipped: 7

#	RESPONSES	DATE
1	CRA Clinical Trial Monitors	11/13/2014 11:04 AM
2	Physicians (project(clinical ops clinical scientists	10/22/2014 7:33 PM
3	Study Managers, CRA, Data Managers	10/21/2014 12:11 PM
4	All Development Operations Personnel. Site exploration personnel.	10/20/2014 7:58 PM
5	Study physicians, clinical scientists and operations personnel	10/17/2014 7:58 PM
6	Clinical Trial Lead	10/16/2014 10:17 PM
7	clinical scientists, protocol managers, biomarker leads	10/15/2014 1:49 PM

Q56 Do you provide training on DNA research, pharmacogenetics and or genetic research, to Contract Research Organizations who run or partially run studies on your companies behalf?

Answered: 14 Skipped: 0

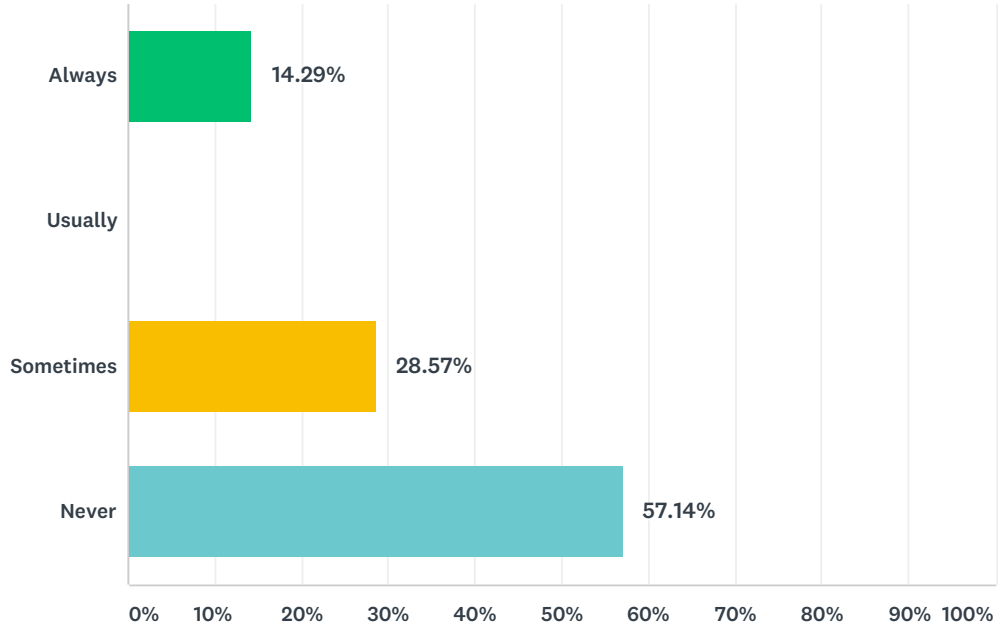


ANSWER CHOICES	RESPONSES	
Always	0.00%	0
Usually	7.14%	1
Sometimes	28.57%	4
Never	50.00%	7
We do not use CRO	0.00%	0
Other (please specify)	14.29%	2
TOTAL		14

#	OTHER (PLEASE SPECIFY)	DATE
1	Sometimes but it is very rare	10/22/2014 7:33 PM
2	We would never contract with a CRO that did not understand pharmacogenetics.	10/20/2014 7:58 PM

Q57 Do you provide educational materials to the ethics committee or IRB as part of the submission?

Answered: 14 Skipped: 0

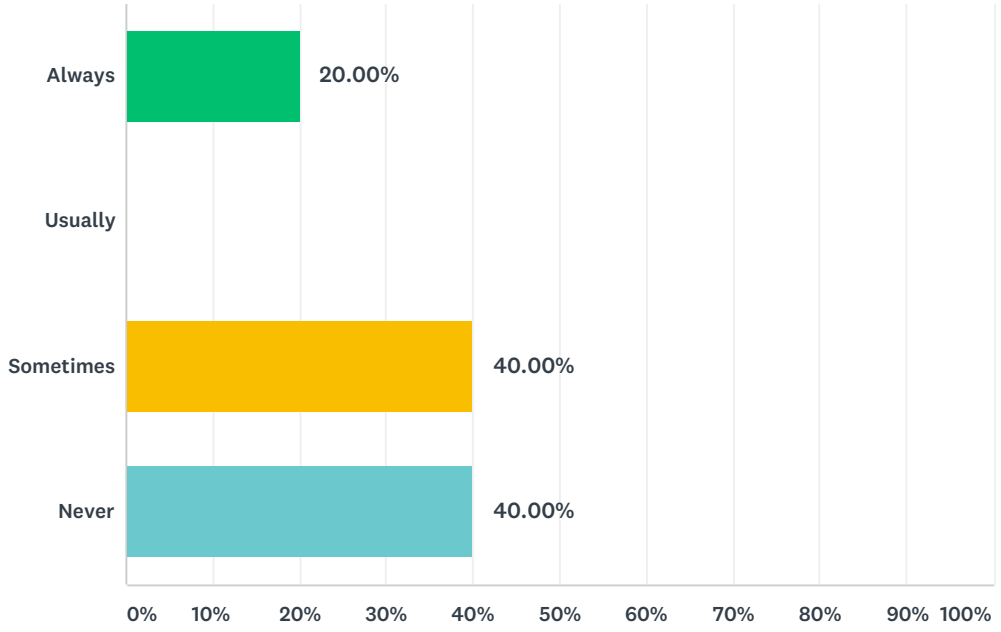


ANSWER CHOICES	RESPONSES	
Always	14.29%	2
Usually	0.00%	0
Sometimes	28.57%	4
Never	57.14%	8
TOTAL		14

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

Q58 Do you provide the I-PWG educational brochure(s) to Ethic Committee or IRB with the submission?

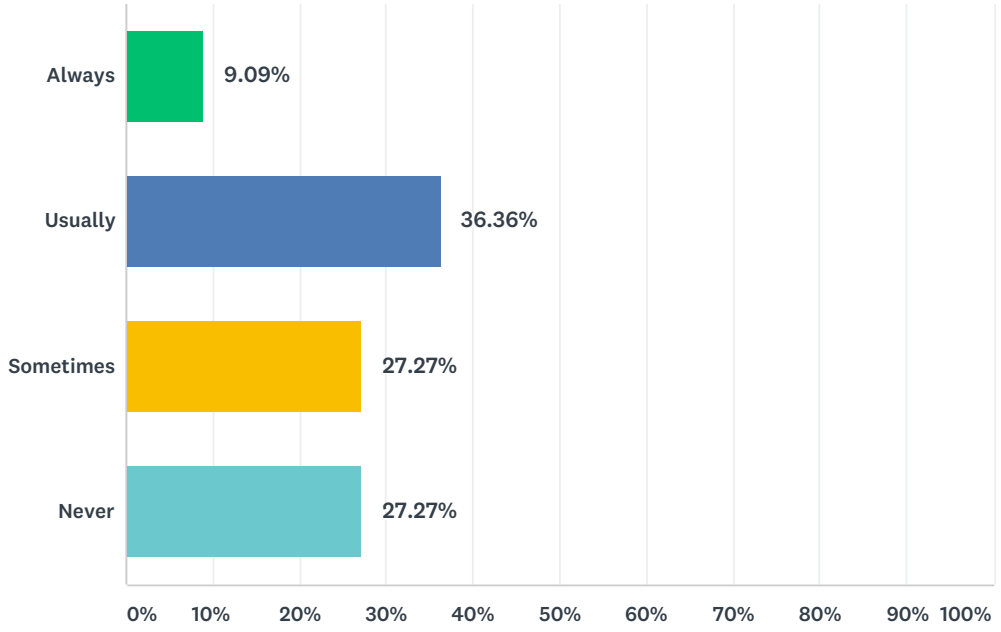
Answered: 5 Skipped: 9



ANSWER CHOICES	RESPONSES	
Always	20.00%	1
Usually	0.00%	0
Sometimes	40.00%	2
Never	40.00%	2
TOTAL		5

Q59 Do you provide educational materials and or training to the Investigator/ Site Staff on DNA research and collection?

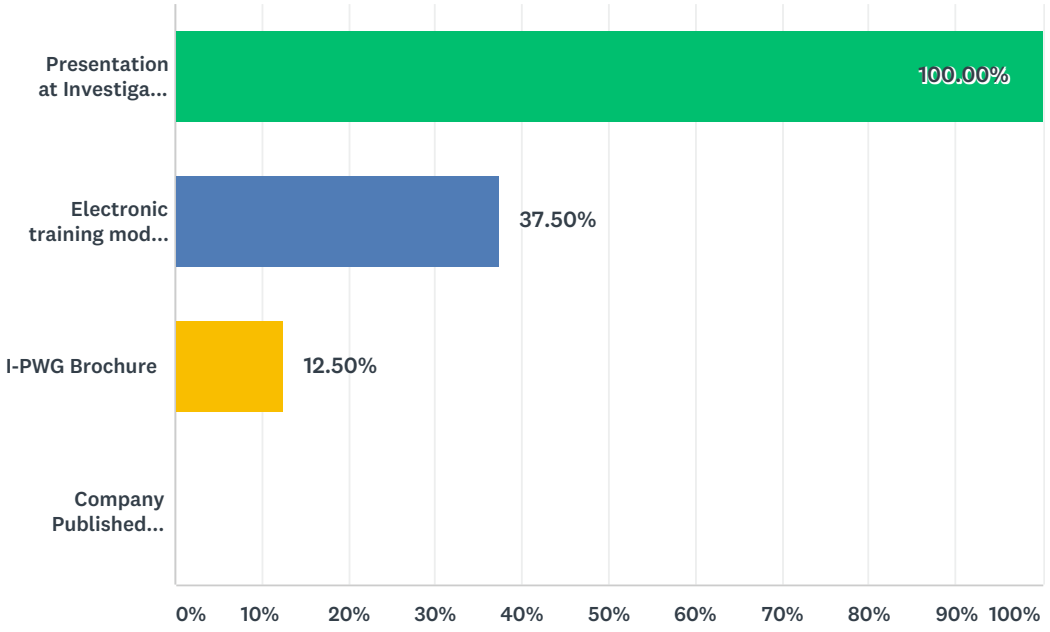
Answered: 11 Skipped: 3



ANSWER CHOICES	RESPONSES	
Always	9.09%	1
Usually	36.36%	4
Sometimes	27.27%	3
Never	27.27%	3
TOTAL		11

Q60 Which of the following educational tools do you provide to the Investigator/Site Staff? (check all that apply)

Answered: 8 Skipped: 6

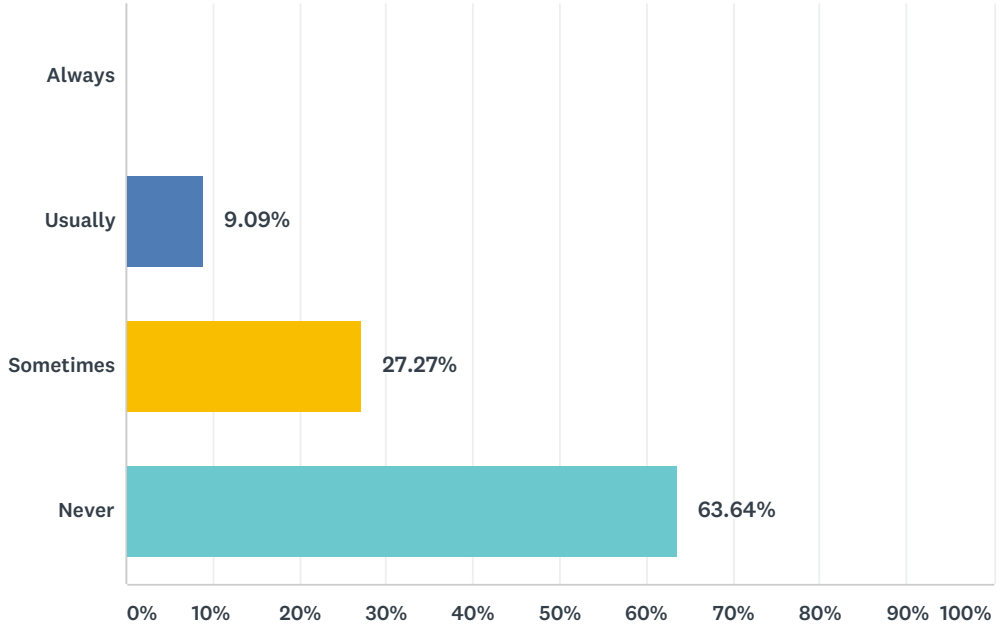


ANSWER CHOICES	RESPONSES	
Presentation at Investigator Meeting	100.00%	8
Electronic training module (e-learning)	37.50%	3
I-PWG Brochure	12.50%	1
Company Published Brochure	0.00%	0
Total Respondents: 8		

#	OTHER (PLEASE SPECIFY)	DATE
1	Training materials provided to study sites are lmited to the specifics of collection details, not about PGx/genetics research. This information is presented in the lab manual and often at the Investigator Meeting.	10/29/2014 3:24 AM

Q61 Do you provide educational materials for study participants?

Answered: 11 Skipped: 3



ANSWER CHOICES	RESPONSES	
Always	0.00%	0
Usually	9.09%	1
Sometimes	27.27%	3
Never	63.64%	7
TOTAL		11

#	PLEASE DESCRIBE WHAT TYPE OF MATERIALS YOU PROVIDE TO PARTICIPANTS.	DATE
1	Biomarker brochure for patients (optional for team to include)	10/22/2014 7:35 PM
2	Patient Brochure	10/21/2014 12:18 PM
3	not sure if we do or do not	10/15/2014 1:50 PM

Q62 If you have approval to do so, please insert your protocol language which describes DNA research. Please ensure that company/institution name is redacted and replaced with generic terms such as "company" or "sponsor"

Answered: 3 Skipped: 11

#	RESPONSES	DATE
1	DNA samples from subjects who separately consent for additional pharmacogenetic analysis may be analyzed for genetic factors contributing to the subject's response to study treatment, in terms of pharmacokinetics, pharmacodynamics, efficacy, tolerability and safety. Such genetic factors may include genes for drug metabolizing enzymes, drug transport proteins, genes within the target pathway, or other genes believed to be related to drug response. Some genes currently insufficiently characterized or unknown may be understood to be important at the time of analysis. Pharmacogenetic analyses will be limited to studying response to the disease therapy; no other analyses will be performed. The samples may be analyzed as part of a multi-study assessment of genetic factors involved in the response to this drug, or drugs of these classes. The samples may also be used for the development of diagnostic tests related to this drug, (or drugs of these classes). The results of additional pharmacogenetic analyses may not be reported with the clinical study report.	11/26/2014 12:46 AM

2	7.3 Banked Biospecimens 7.3.1. Markers of Drug Response Studying the variation in genetic markers and other biomarkers may help to explain some of the variability in response seen with some drugs among different individuals. This is referred to as pharmacogenomic/biomarker research. Comparing the deoxyribonucleic acid (DNA), ribonucleic acid (RNA), protein, and metabolite variation patterns of subjects who respond well and those who respond poorly to treatment may help to better define the most appropriate group of patients in which to target a given treatment. Collecting biospecimens for exploratory pharmacogenomic/biomarker analyses and retaining them in the sponsor's bank makes it possible to better understand the drug's mechanism of action and to seek explanations for differences in, for example, exposure, efficacy, tolerability, or safety not anticipated prior to the beginning of the study. Providing these biospecimens is a required study activity for study sites and subjects, unless prohibited as such by local regulations or ethics committee decision. [Instructional text: Do not list names of specific genes or biomarkers to be studied. Banked biospecimens are collected under a broad consent with no restrictions on which particular genes or biomarkers can be studied; nor is there a commitment to analyze the biospecimens. If a biospecimen is needed for planned genomic or biomarker analysis, that biospecimen should be listed in another section of the protocol appropriate for those specified collections.] To protect subjects' confidentiality, the banked biospecimens and data generated from them will be coded with the subject's study identification (ID) number. Samples will be kept in a facility accessible only by badge swipe. Data will be stored on password-protected computer systems. The key between the code and the subject's personal identifiers will be held at the study site; the researchers using the biospecimens and data generated from them will not have access to the key nor any personally identifying information. Biospecimens will only be used for the purposes described here and in the informed consent document/patient information sheet; any other uses require additional ethical approval. Unless a time limitation is required by local regulations or ethical requirements, biospecimens will be stored indefinitely to allow for future research on the topics described here, including research conducted during the lengthy drug development process and also postmarketing research. Subjects can withdraw their consent for the use of their biospecimens at any time by making a request to the investigator, in which event any remaining biospecimen will be destroyed; data already generated from the biospecimens will continue to be stored to protect the integrity of existing analyses. It is very unlikely that results generated from the biospecimens will have any clinical, diagnostic, or therapeutic implications for the individual study participants. Subjects are notified in the informed consent document/patient information sheet that their results will not be given to them, unless required by local laws or regulations, in which case results will be returned via the investigator. Results will not be provided to family members or other physicians, nor will they be recorded in the subject's medical record. There is no intention to contact subjects after completion of the clinical study. A 4-mL blood biospecimen Prep D1 (K2 edetic acid (ethylenediaminetetraacetic acid) (EDTA) whole blood collection optimized for DNA analysis) will be collected at the baseline visit to be retained for potential pharmacogenomic/biomarker analyses related to drug response, unless prohibited by local regulations or ethics committee decision. [Instructional text: When a reduced blood draw volume is needed, eg, in pediatric studies, change Prep D1 to Prep D1.5 and change 4-mL to 2-mL.] For example, putative safety biomarkers, drug-metabolizing enzyme genes, drug-transport protein genes, or genes thought to be related to the mechanism of drug action may be examined. The banked biospecimens will be collected from all subjects unless prohibited by local regulations or ethics committee decision. Detailed collection, processing, storage, and shipment instructions are provided in <the central laboratory manual/a separate document>. It is possible that the use of these biospecimens may result in commercially viable products. Subjects will be advised in the informed consent document/patient information sheet that they will not be compensated in this event. 7.3.2. Additional Research Unless prohibited by local regulations or ethics committee decision, subjects will be asked to indicate on the consent form whether they will allow the banked biospecimens to also be used for the following research: [Instructional text: delete this bullet point for studies of healthy volunteers] Investigations of the disease under study in the clinical study, and related conditions; Biospecimens may be used as controls. This includes use in case-control studies of diseases for which sponsor is researching drug therapies; use in characterizing the natural variation among people in genes, RNA, proteins, and metabolites; and use in developing new technologies related to pharmacogenomics/biomarkers. Subjects need not provide additional biospecimens for the uses described in this section; the biospecimen specified in the Markers of Drug Response section will be used. Subjects may still participate in the clinical study if they elect not to allow their banked biospecimens to be used for the additional purposes described in this section.	10/29/2014 3:24 AM

3	The PGx research that may be conducted in the future with acquired buccal swab samples is exploratory. The objective of this research will be to analyze or determine genes of relevance to clinical response, pharmacokinetics, and toxicity/safety issues. By analyzing genetic variations, it may be possible to predict an individual subject's response to treatment in terms of efficacy and/or toxicity.	10/20/2014 7:59 PM

Q63 If you have approval to do so, please insert your template consent language which describes DNA research. Please ensure that company/institution name is redacted and replaced with "company" or "sponsor".

Answered: 3 Skipped: 11

#	RESPONSES	DATE
1	The sponsor of the sub-studies wants to use some of your blood to study your genetic information. Your genetic information is what makes you different from anyone else. Some genetic information controls things like the color of your hair or eyes. Other genetic information might make you more likely to get certain diseases or affect whether a drug helps you and/or gives you side effects. You might have heard of chemical structures like DNA, RNA, chromosomes, genes, proteins, and metabolites, all of which make up a part of your genetic information, and they and other genetic information may be studied by the sponsor as described in this form. Although genetic tests might be used to sequence your DNA, RNA, chromosomes, and genes, the analysis of any genetic tests will be limited only to results that might relate to the investigational drug being tested in the main study, the study indication and other diseases or medical conditions. The purpose of this study is to determine if your genetic information has any relation to or impact on our drug, indication or disease state or affect how the disease state or medical conditions develop and progress, how they can be diagnosed or treated, and their causes and symptoms. Your genetic information may also help explain the way drugs act on such diseases or the way drugs are broken down in the body. If you participate in the sub-studies, your samples and genetic information may also be used for development of diagnostic tests in the future. Your samples and genetic information will not be used for any other purpose without your permission, and will be tested only by the sponsor and/or people or companies working with the sponsor. Your blood will not be sold to other people or companies.	11/26/2014 12:46 AM
2	A 4 mL blood sample will be taken. The sample(s) may be used to study your genes (also called DNA), RNA, proteins and metabolites in order to understand subjects' responses to the study drugs in this study (such as safety findings or drug level patterns). This is called "pharmacogenomics" or "biomarker" research. The results of future studies could trigger the need to test the samples; therefore, the samples will be held by the study sponsor for many years (no time limit). Data generated from the samples will be kept by the study sponsor to preserve the integrity of analyses which have been performed. Samples and data generated from them may be shared with other researchers, provided confidentiality is upheld and they are used only for research on the topics described in this document. Research results will not be returned to you or your study doctor. Additional use of your sample(s) -- OPTIONAL: In addition to the research on drug response described above, you can also choose to allow your pharmacogenomic/biomarker sample(s) to be used in research on the following topics: o to study [insert disease/condition which subjects in the clinical trial have] and related conditions. [Instructional text: This bullet point is only for studies in patient populations. Do not include this bullet point for studies of healthy volunteers.] o in comparisons with information from the samples of other people, including subjects with other conditions or diseases. This is called using the sample as a "control". This also includes using the samples to study natural variation in DNA, RNA, proteins, or metabolites, or to develop new pharmacogenomic or biomarker technologies. If you do not want your sample(s) to be used in this additional research, you can still take part in the drug study. Please make your choice and initial one of the statements below: _____ Initials I AGREE TO ALLOW MY PHARMACOGENOMIC/BIOMARKER SAMPLE(S) TO BE USED [FOR ADDITIONAL RESEARCH RELATED TO MY DISEASE/CONDITION, AND FOR USE] AS A CONTROL SAMPLE. [Instructional text: Include bracketed text in studies of patient populations, not in studies of healthy volunteers.] OR _____ Initials I DO NOT AGREE TO ALLOW MY PHARMACOGENOMIC/BIOMARKER SAMPLE(S) TO BE USED [FOR ADDITIONAL RESEARCH RELATED TO MY DISEASE/CONDITION, AND FOR USE] AS A CONTROL SAMPLE. [Instructional text: Include bracketed text in studies of patient populations, not in studies of healthy volunteers.]	10/29/2014 3:24 AM
3	We do not have this specifically, it is included in the clinical protocol.	10/20/2014 7:59 PM