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

Answered: 18 Skipped: 1

ANSWER CHOICES	RESPONSES	
Name:	0.00%	0
Code Number	100.00%	18
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	5601	6/17/2016 12:02 AM
2	6145	6/2/2016 10:15 AM
3	4356	5/31/2016 11:50 PM
4	8259	5/31/2016 9:46 PM
5	9876	5/31/2016 6:45 PM
6	2281	5/31/2016 5:44 PM
7	8624	5/31/2016 12:41 PM
8	4818	5/27/2016 6:01 PM
9	2703	5/26/2016 7:14 PM
10	3816	5/26/2016 7:01 PM
11	2658	5/26/2016 2:49 PM
12	1963	5/25/2016 9:46 AM
13	3555	5/23/2016 5:12 PM
14	9901	5/20/2016 4:04 PM
15	8074	5/20/2016 1:47 PM
16	3968	5/17/2016 5:08 PM
17	3263	5/17/2016 4:59 PM
18	9502	5/17/2016 4:55 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.	

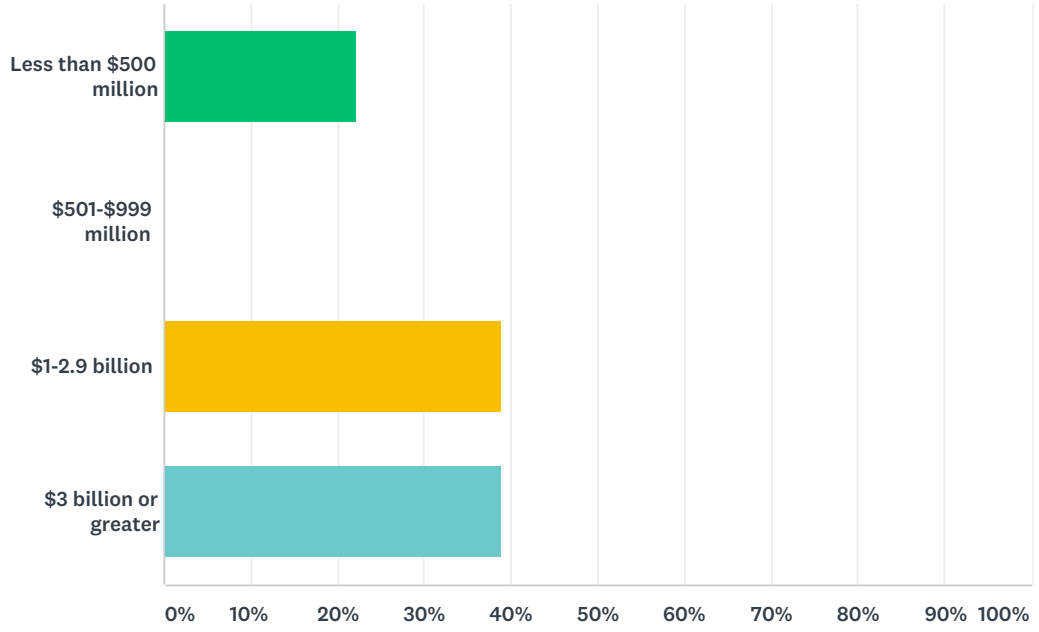
#	COUNTRY:	DATE
	There are no responses.	

#	EMAIL ADDRESS:	DATE
	There are no responses.	

#	PHONE NUMBER:	DATE
	There are no responses.	

Q2 We would like to understand the size of your company. What is your company's annual total R&D spend?

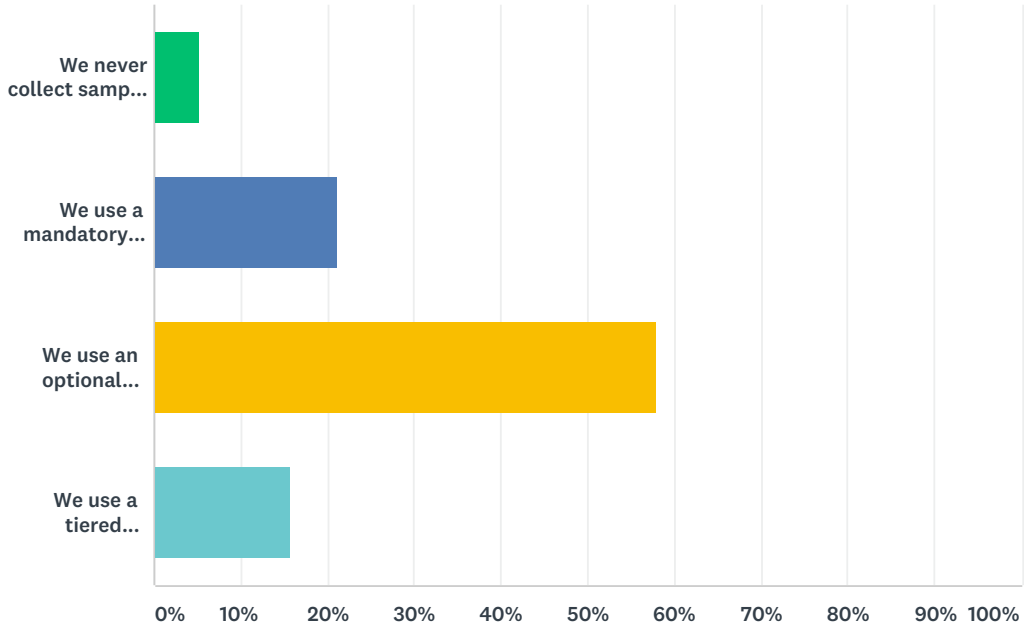
Answered: 18 Skipped: 1



ANSWER CHOICES	RESPONSES	
Less than $500 million	22.22%	4
$501-$999 million	0.00%	0
$1-2.9 billion	38.89%	7
$3 billion or greater	38.89%	7
TOTAL		18

Q3 When you collect DNA, what is your company's current strategy for collection of DNA samples for unspecified future research? (one response per company)

Answered: 19 Skipped: 0



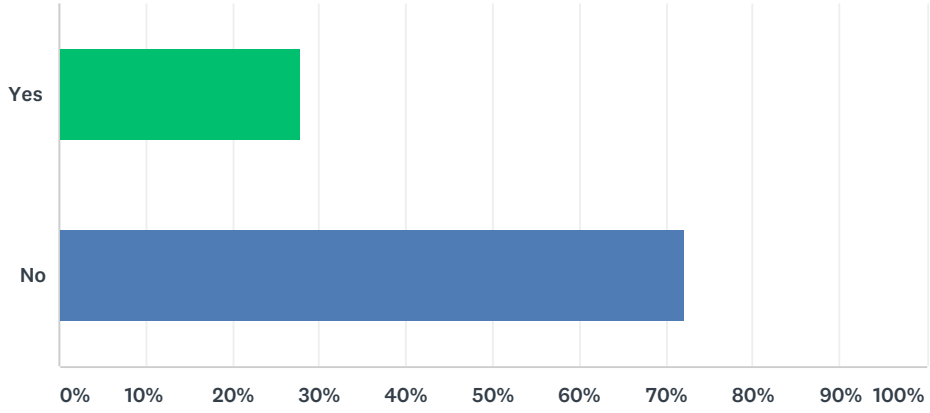
ANSWER CHOICES	RESPONSES	
We never collect samples for unspecified future research. We only collect a DNA samples when we have a pre-specified test.	5.26%	1
We use a mandatory collection approach. Where permitted by law/institution policy we require that subjects give a sample for unspecified future research as part of participating in the clinical trial. If you select this option please indicate below what your approach is if not permitted.	21.05%	4
We use an optional collection approach. Subjects who participate in the main clinical study can choose to give a DNA sample for optional unspecified future use.	57.89%	11
We use a tiered collection approach within the same study. We use mandatory collection unspecified future research related to drug response with optional participation for additional future use (whether limited or unlimited in scope but not limited to drug response). Please indicate what is included in mandatory, optional scope.	15.79%	3
TOTAL		19

#	IF YOU SELECTED OPTION 2 ABOVE PLEASE INDICATE YOUR APPROACH WITH COUNTRIES/INSTITUTIONS THAT DO NOT SUPPORT MANDATORY COLLECTION OF SAMPLES FOR UNSPECIFIED FUTURE USE (E.G. DO NOT ALLOW THE SITE TO PARTICIPATE IN THE STUDY, REVERT TO OPTIONAL COLLECTION APPROACH, ...)NOTE THIS BOX MAY ALSO BE USED TO DESCRIBE STRATEGIES NOT INDICATED IN THE LIST.	DATE
1	Tiered approach: mandatory= drug response; optional= subject's disease, related conditions, use as controls, studying natural variation, and technology development.	5/31/2016 6:45 PM
2	Our tiered collection allows for drug response and disease and we still have a broad unspecified Consent which is useful in countries that dont allow mandatory collection	5/31/2016 5:44 PM
3	US sites only require mandatory collections	5/26/2016 10:59 PM
4	optional sample collection	5/26/2016 7:01 PM
5	US mandatory other countries may be optional depending on the country itself	5/26/2016 2:49 PM

6	Mandatory sampling is sometimes implemented to look at specific genes or pathways associated to the disease of interest or the drug, but we are also implementing mandatory sampling for Whole Genome Sequencing, to look at disease and response to drug. Most of our clinical trials also include optional collection of samples for future research, to facilitate the development of personalized medicine and diagnostic development: this includes collection of a DNA sample.	5/25/2016 9:46 AM
7	We don't consider this unspecified future use since our research scope is quite limited and clearly presentedin the consent and protocol. Countries that don't allow this are Argentina (only some ECs), Canada (some ECs), Hungary, India, Italy, Spain, Turkey, US (the VA and state of Oregon), the following also have EC variability (Japan, Germany, Romania)	5/23/2016 5:12 PM

Q4 Are you planning to change this strategy in the next 1-2 years?

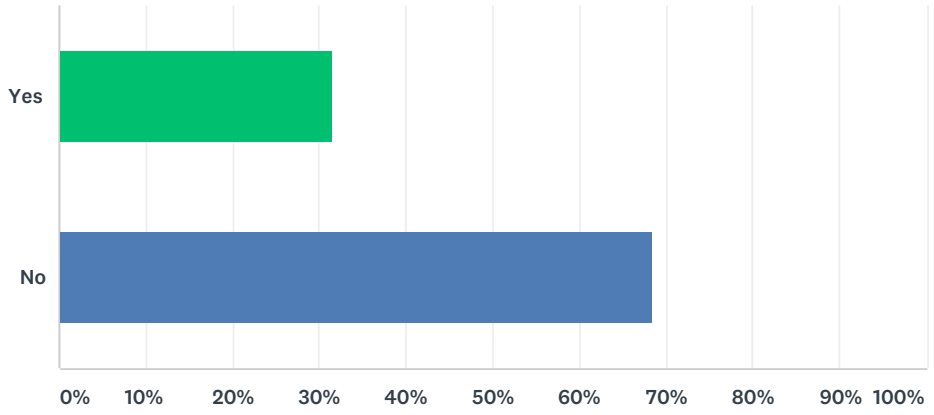
Answered: 18 Skipped: 1



ANSWER CHOICES	RESPONSES	
Yes	27.78%	5
No	72.22%	13
TOTAL		18

Q5 Do you proactively track your collection rates?

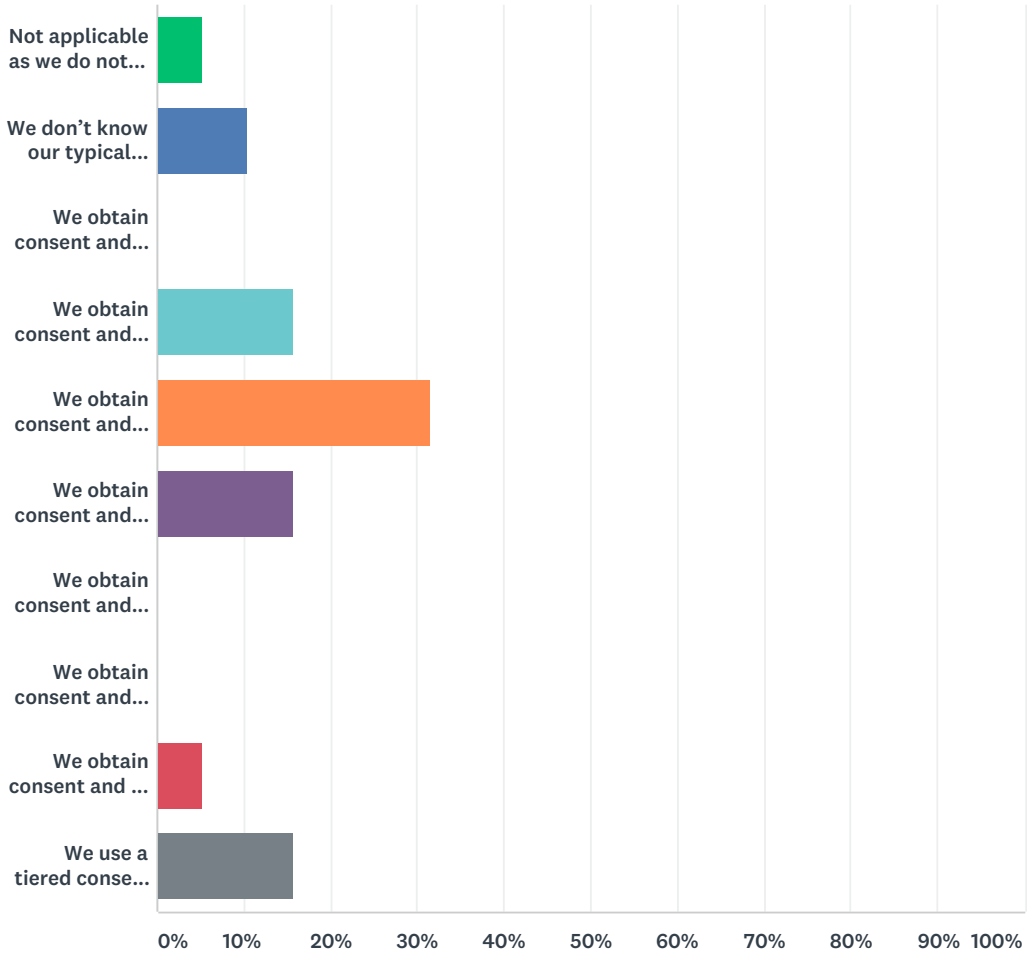
Answered: 19 Skipped: 0



ANSWER CHOICES	RESPONSES	
Yes	31.58%	6
No	68.42%	13
TOTAL		19

Q6 Considering your approach in the previous question, which range below best describes your typical experience with collecting DNA samples for unspecified future research?

Answered: 19 Skipped: 0



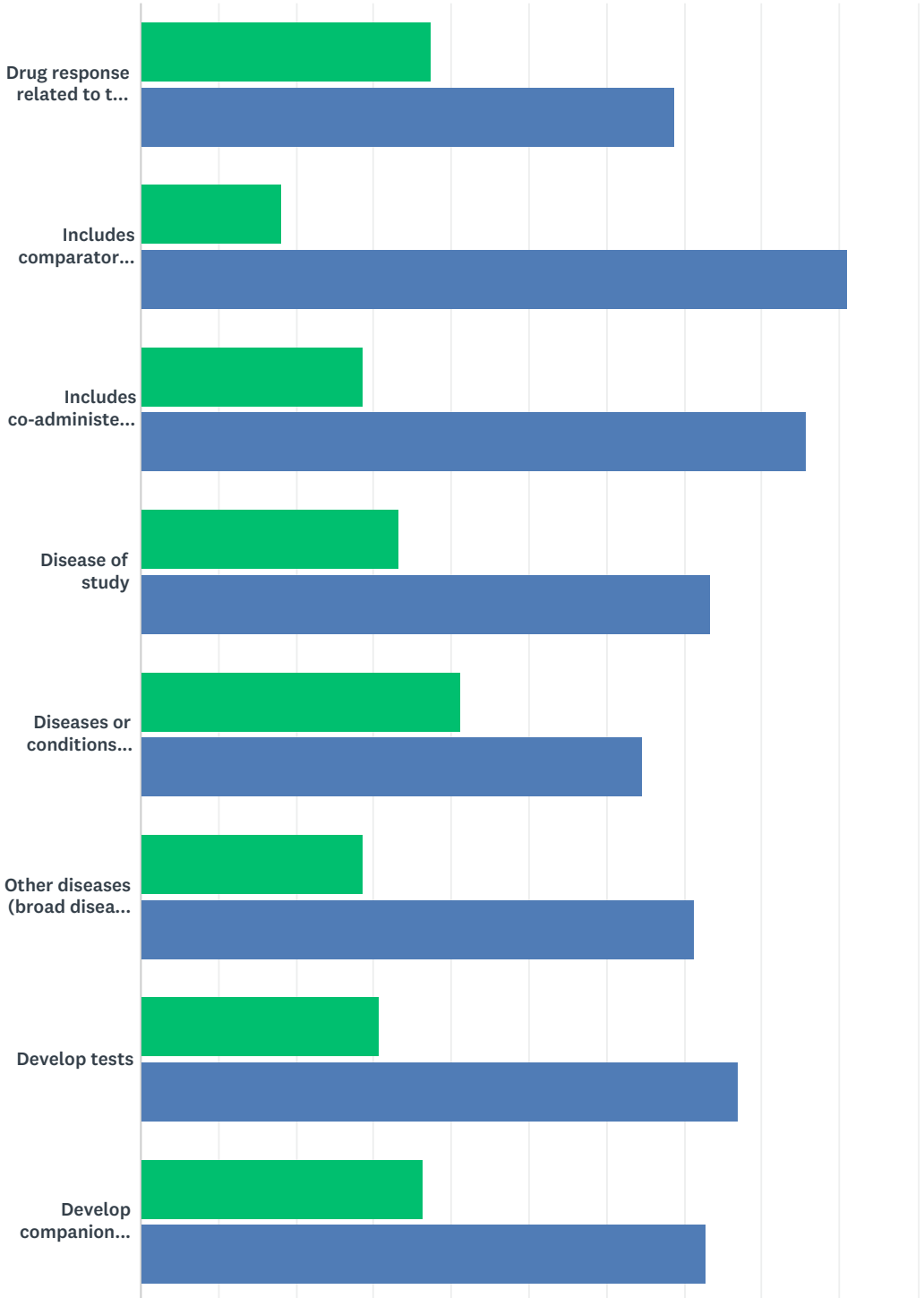
ANSWER CHOICES	RESPONSES	
Not applicable as we do not collect samples for unspecified future research.	5.26%	1
We don't know our typical collection rates.	10.53%	2
We obtain consent and sample from 50% of subjects or less	0.00%	0
We obtain consent and sample from 50-70% of subjects	15.79%	3
We obtain consent and sample from 70-80% of subjects	31.58%	6
We obtain consent and sample from 80-90% of subjects	15.79%	3
We obtain consent and sample from 90% or more of subjects	0.00%	0
We obtain consent and sample from 100% of subjects	0.00%	0
We obtain consent and DNA sample from all subjects who participate in the clinical trial.	5.26%	1

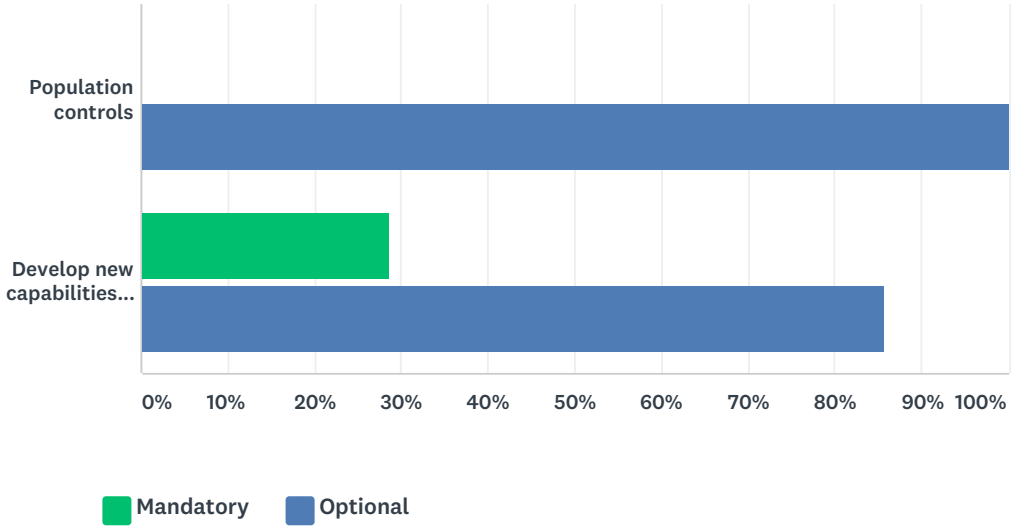
We use a tiered consent and obtain -----% for mandatory and ----% for optional tiered consent. (Please indicate percentages in the box below)	15.79%	3
TOTAL		19

#	IF YOU UTILIZED A TIERED APPROACH THEN PLEASE INDICATE COLLECTION RATES FOR ALL TIERS.	DATE
1	we have 100% collection for our mandatory Phase 1 collection and around 60% for our Phase 2-4 optional collection	6/17/2016 12:02 AM
2	We are getting about 80 - 90 % in both but we have very limited data for mandatory at this point. we also dont know if the mandatory has improved our optional collection rate at this point	5/31/2016 5:44 PM
3	we don't assess these metrics at this time, but hope to in the future. But if the sample is mandatory, we rarely fails to collect it.	5/26/2016 7:01 PM
4	around 90% for mandatory and around 70% for optional	5/25/2016 9:46 AM

Q7 What is the scope of research for your DNA samples for unspecified future research? What research do you ask subjects to grant permission to do?(If you utilize a tiered consent strategy then you may select one option for each tier. If you do not utilize a tiered consent option then please select one answer based on whether your primary strategy for unspecified future use sampling is mandatory or optional consent.)

Answered: 18 Skipped: 1





	MANDATORY	OPTIONAL	TOTAL RESPONDENTS
Drug response related to the investigational product	37.50% 6	68.75% 11	16
Includes comparator drugs	18.18% 2	90.91% 10	11
Includes co-administered drugs	28.57% 4	85.71% 12	14
Disease of study	33.33% 5	73.33% 11	15
Diseases or conditions related to the disease of study	41.18% 7	64.71% 11	17
Other diseases (broad disease understanding)	28.57% 2	71.43% 5	7
Develop tests	30.77% 4	76.92% 10	13
Develop companion diagnostics	36.36% 4	72.73% 8	11
Population controls	0.00% 0	100.00% 5	5
Develop new capabilities or methods	28.57% 2	85.71% 6	7

#	OTHER (PLEASE SPECIFY)	DATE
1	Related to drug's MOA	6/17/2016 12:02 AM
2	For "Disease or conditions related to the disease of study" and "co-administered drugs" there is less consistency on whether or not these are included.	5/23/2016 5:12 PM

Q8 What factors do you feel have the greatest influence on collection rates?

Answered: 18 Skipped: 1

#	RESPONSES	DATE
1	Site Coordinator influence to subjects	6/17/2016 12:02 AM
2	Regulatory, IRB/EC restrictions	6/2/2016 10:15 AM
3	Country-specific issues that limit what and how samples can be collected. Also, education and motivation of medical staff at clinical trial sites; when high, collection rates are higher.	5/31/2016 11:50 PM
4	having a prespecified reason to ask for a sample	5/31/2016 9:46 PM
5	1) IRB /EC decisions; 2) local regulations	5/31/2016 6:45 PM
6	LAws and regulations as well as IRBS and their understanding of what we are trying to do and the limitations of the research	5/31/2016 5:44 PM
7	cultural attitude, investigator opinion	5/31/2016 12:41 PM
8	Country regulations; site-specific interest in PGx research	5/27/2016 6:01 PM
9	Patient consent forms (ICF), study design	5/26/2016 10:59 PM
10	Site's active engagement in understanding the importance of research.	5/26/2016 7:14 PM
11	If the PI has a good understanding and interest in research goals then rate of collection is nearly 100%	5/26/2016 7:01 PM
12	patient understanding, country laws	5/26/2016 2:49 PM
13	ECs/IRBs understanding what we want to do, Investigators' willingness to support the research we want to do	5/25/2016 9:46 AM
14	Education (investigators, site staff and patients)	5/23/2016 5:12 PM
15	buy-in from site investigators, IRB/ECs	5/20/2016 4:04 PM
16	proper explanation by site staff	5/20/2016 1:47 PM
17	Well crafted ICF and protocol with clear and informative language that is supplemented with other training, FAQ, manuals, or work instruction for sites/Clin Ops to use	5/17/2016 5:08 PM
18	Local law; negative opinion of EC/IRB;	5/17/2016 4:59 PM

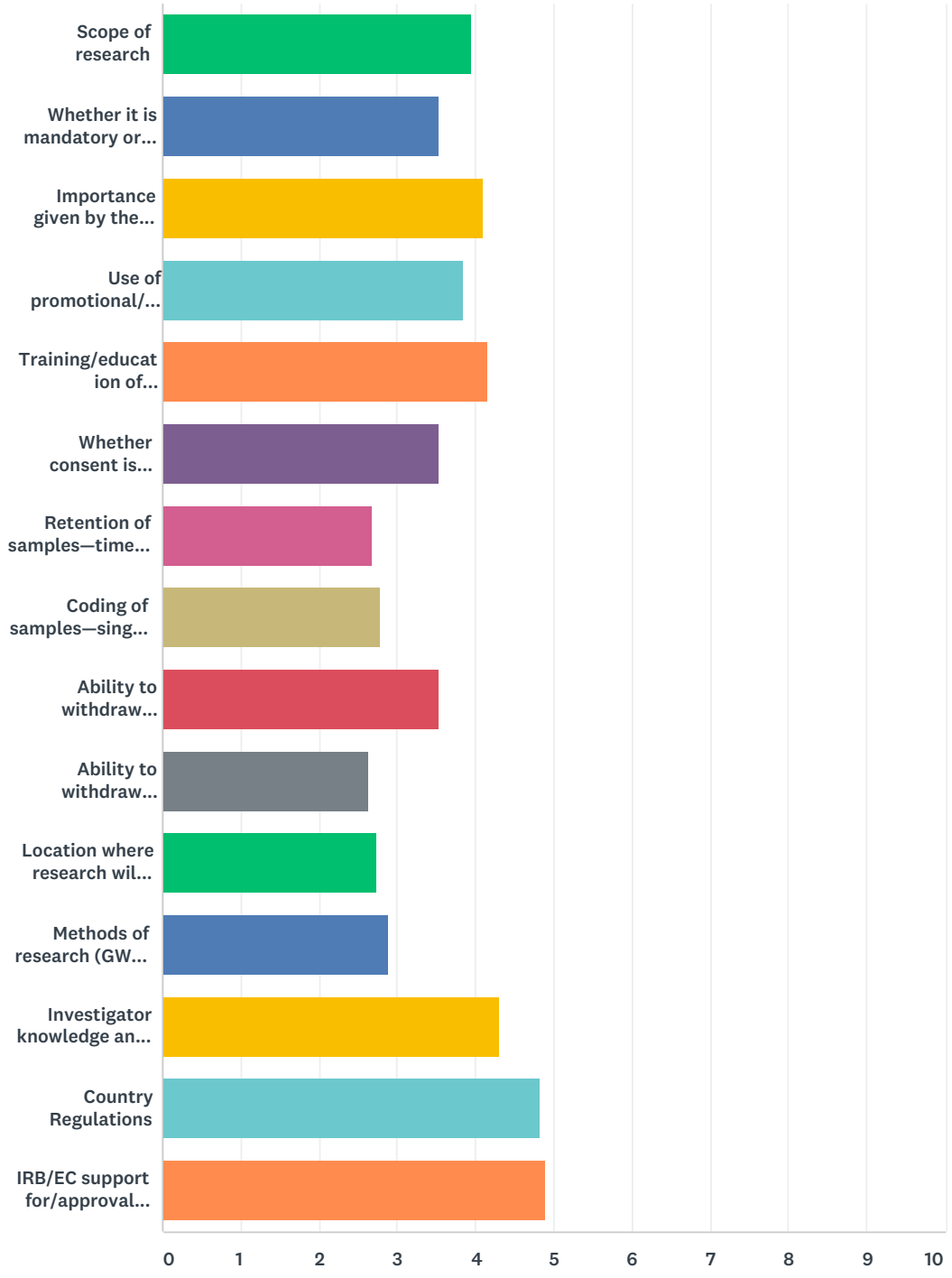
Q9 What do you feel are the greatest challenges to overcome to improve collection rates?

Answered: 18 Skipped: 1

#	RESPONSES	DATE
1	Internal study team acceptance and EC country approval (ease of approval)	6/17/2016 12:02 AM
2	Education to enable change in position of institutions that implement restrictions	6/2/2016 10:15 AM
3	Education can generally be addressed relatively easy (as the I-PWG has discussed and is acting). Regulatory/Health authorities/IRBs are more difficult challenges.	5/31/2016 11:50 PM
4	Different country regulations and how the regulations are "interpreted" by IRBs and ECs	5/31/2016 9:46 PM
5	1) Global harmonization to allow mandatory collection; 2) internal clinical team agreement	5/31/2016 6:45 PM
6	Eductaion on tthe scope and limitations of performing genetic research in clinical trials	5/31/2016 5:44 PM
7	distrust towards pharma companies, cultural attitude, doubtfulness of patients/subjects	5/31/2016 12:41 PM
8	IRBs/EC and country regulations	5/27/2016 6:01 PM
9	IRBs and institutional policies	5/26/2016 10:59 PM
10	Internal challenge to convince clinical teams importance of research samples.	5/26/2016 7:14 PM
11	finding ideal study sites to meet the needs of the clinical trial. Improving the understanding of the countries whose regulations negatively impact the ability to carry out needed research for improving treatment strategies.	5/26/2016 7:01 PM
12	education	5/26/2016 2:49 PM
13	Understanding and addressing concerns from ECs/IRBs, gaining buy in from investigators at Investigator's meeting	5/25/2016 9:46 AM
14	Variability in laws/regulations (and the fact that these are ever changing) and inconsistency between ethics committees within the same country and across the globe (this can result in constant education and re-education to enable your collection strategy to be approved)	5/23/2016 5:12 PM
15	IRB/ECs	5/20/2016 4:04 PM
16	site resources to understand and explain the PGx portion of the study	5/20/2016 1:47 PM
17	Educating IRBs on the value/benefit of this work and limited risk to patients. Influencing regional and country-level revisions to laws.	5/17/2016 5:08 PM
18	Harmonization of laws;	5/17/2016 4:59 PM

Q10 Which do you feel have the most influence with regard to obtaining high collection rates?

Answered: 19 Skipped: 0



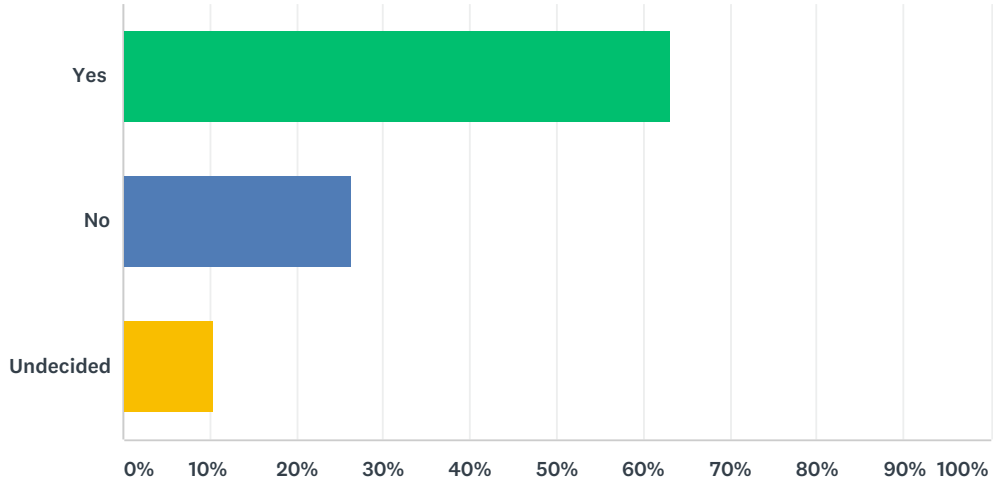
	VERY IMPORTANT	IMPORTANT	SOMEWHAT IMPORTANT	NOT VERY IMPORTANT	NOT SURE	N/A	TOTAL	WEIGHTED AVERAGE
Scope of research	31.58% 6	36.84% 7	26.32% 5	5.26% 1	0.00% 0	0.00% 0	19	3.95

Whether it is mandatory or not	22.22% 4	33.33% 6	22.22% 4	11.11% 2	5.56% 1	5.56% 1	18	3.53
Importance given by the clinical team	36.84% 7	42.11% 8	15.79% 3	5.26% 1	0.00% 0	0.00% 0	19	4.11
Use of promotional/education materials (e.g. brochures)	21.05% 4	47.37% 9	26.32% 5	5.26% 1	0.00% 0	0.00% 0	19	3.84
Training/education of investigators and site/staff	36.84% 7	42.11% 8	21.05% 4	0.00% 0	0.00% 0	0.00% 0	19	4.16
Whether consent is presented combined with the main study consent (regardless of whether optional or mandatory collection) (i.e. consent is presented on same day/time as main study consent)	26.32% 5	31.58% 6	21.05% 4	15.79% 3	5.26% 1	0.00% 0	19	3.53
Retention of samples—time described in informed consent	5.26% 1	15.79% 3	21.05% 4	57.89% 11	0.00% 0	0.00% 0	19	2.68
Coding of samples—single coding, double-coding, anonymization	15.79% 3	10.53% 2	21.05% 4	47.37% 9	5.26% 1	0.00% 0	19	2.79
Ability to withdraw consent and or request destruction of samples	26.32% 5	21.05% 4	31.58% 6	21.05% 4	0.00% 0	0.00% 0	19	3.53
Ability to withdraw consent and or request destruction of data	11.11% 2	5.56% 1	22.22% 4	44.44% 8	5.56% 1	11.11% 2	18	2.63
Location where research will occur	0.00% 0	26.32% 5	31.58% 6	36.84% 7	5.26% 1	0.00% 0	19	2.74
Methods of research (GWAS, Whole-genome sequencing, candidate genes)	10.53% 2	21.05% 4	26.32% 5	36.84% 7	5.26% 1	0.00% 0	19	2.89
Investigator knowledge and or support of DNA research	57.89% 11	21.05% 4	15.79% 3	5.26% 1	0.00% 0	0.00% 0	19	4.32
Country Regulations	84.21% 16	15.79% 3	0.00% 0	0.00% 0	0.00% 0	0.00% 0	19	4.84
IRB/EC support for/approval of DNA research	89.47% 17	10.53% 2	0.00% 0	0.00% 0	0.00% 0	0.00% 0	19	4.89

#	PLEASE INDICATE ANY OTHER FACTORS WHICH YOU CONSIDER TO BE IMPORTANT.	DATE
1	specified vs un-specified gene targets	5/26/2016 10:59 PM
2	Being explicit about method of research would definitely have an impact on number of questions and concerns from ECs/IRBs, so requires more education	5/25/2016 9:46 AM

Q11 Based on the discussion today do you perceive that mandatory collection results in higher collection rates than optional collection?

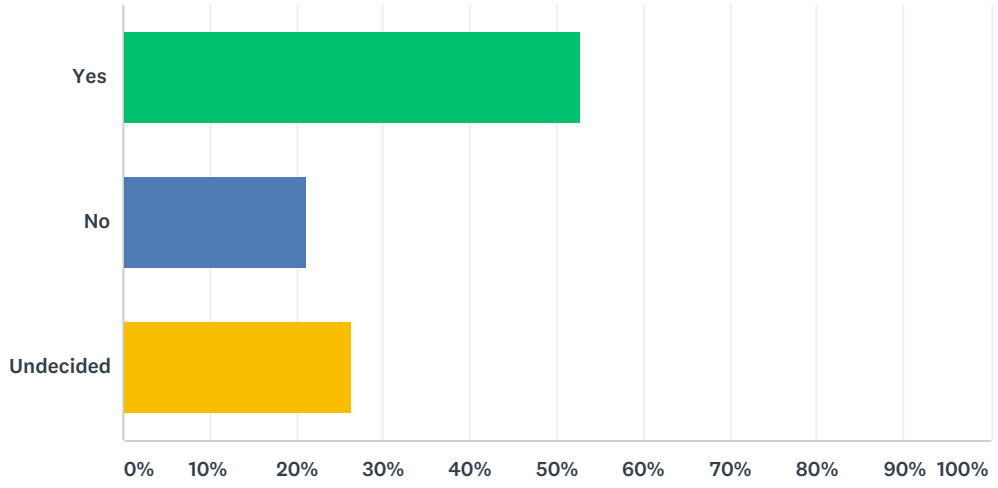
Answered: 19 Skipped: 0



ANSWER CHOICES	RESPONSES	
Yes	63.16%	12
No	26.32%	5
Undecided	10.53%	2
TOTAL		19

Q12 Based on the discussion today do you perceive that mandatory collection results in less risk of collection bias (PGx population compared to main trial population) than optional collection?

Answered: 19 Skipped: 0



ANSWER CHOICES	RESPONSES	
Yes	52.63%	10
No	21.05%	4
Undecided	26.32%	5
TOTAL		19