

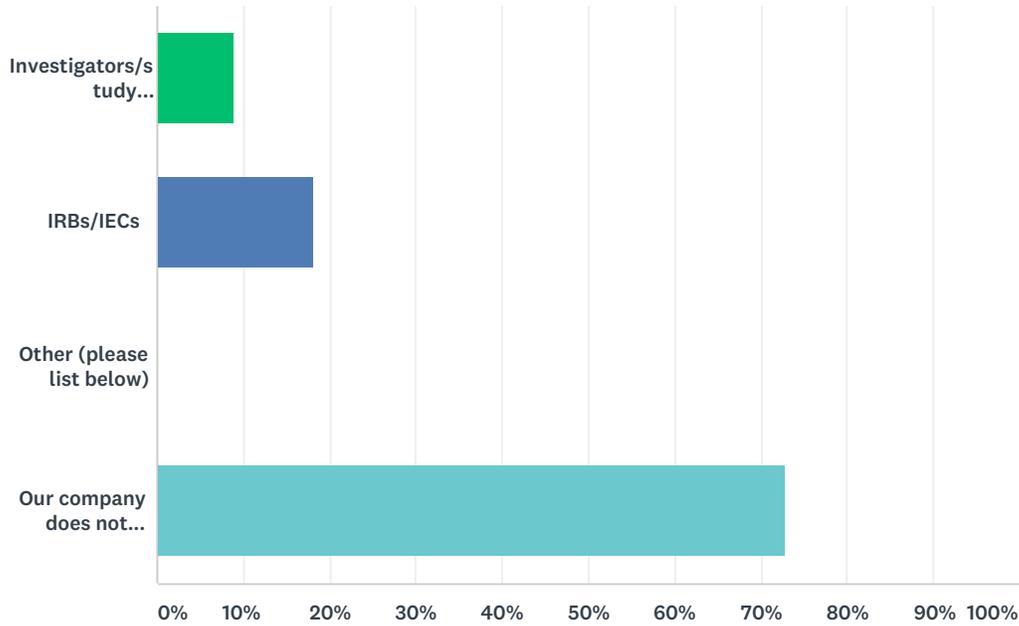
Q1 Please enter the ID number that was assigned to your company

Answered: 11 Skipped: 0

#	RESPONSES	DATE
1	6523	7/29/2014 1:36 PM
2	5342	7/18/2014 9:58 PM
3	2656	7/18/2014 2:37 PM
4	9513	7/15/2014 4:03 PM
5	6297	7/15/2014 3:42 PM
6	6529	7/15/2014 6:44 AM
7	5735	7/8/2014 4:51 PM
8	9164	7/8/2014 2:42 PM
9	5735	7/7/2014 5:31 PM
10	7634	7/7/2014 2:58 PM
11	6920	7/3/2014 12:07 PM

Q2 Who do you distribute these brochures to most often (please select only one option below)

Answered: 11 Skipped: 0



ANSWER CHOICES	RESPONSES	
Investigators/study coordinators	9.09%	1
IRBs/IECs	18.18%	2
Other (please list below)	0.00%	0
Our company does not distribute these brochures	72.73%	8
TOTAL		11

Q3 Please explain why your company has not distributed either of these brochures

Answered: 8 Skipped: 3

#	RESPONSES	DATE
1	In many cases in country study teams were not aware of the brochures	7/29/2014 1:37 PM
2	Provide company prepared materials	7/18/2014 9:58 PM
3	New to the I-PWG and unaware of brochure	7/15/2014 4:04 PM
4	not sure how the best way is to distribute (?)	7/15/2014 3:44 PM
5	For a long time, this was a lack of awareness that these brochures existed. Also, our company has their own documentation that we were distributing	7/15/2014 6:46 AM
6	Not approved by Legal for distribution	7/8/2014 4:51 PM
7	We try to reduce the amount of material provided regarding the sampling. For example, we have greatly reduced the text in the protocol and ICD about this as well. Having another piece of material to submit to IRB/ECs and investigators is one more thing on top of all the other materials/activities for clinical teams.	7/8/2014 2:44 PM
8	HAs not been brought up as a limiting factor and clinical development generally believes that they can communicate their own rationale quite well.	7/7/2014 3:00 PM

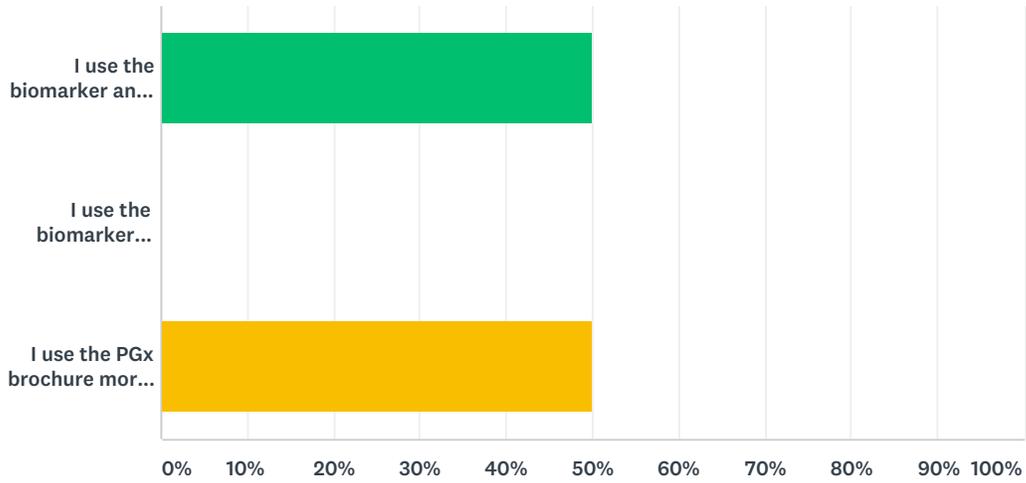
Q4 Please list who you distribute these brochures to most often

Answered: 1 Skipped: 10

#	RESPONSES	DATE
1	CROs, Investigators/coordinators	7/3/2014 12:08 PM

Q5 Do you distribute both brochures equally or do you find you provide one of these two brochures more often than the other?

Answered: 2 Skipped: 9



ANSWER CHOICES	RESPONSES	
I use the biomarker and PGx brochures equally	50.00%	1
I use the biomarker brochure more often than the PGx brochure	0.00%	0
I use the PGx brochure more often than the biomarker brochure	50.00%	1
TOTAL		2

Q6 If you find you use one brochure more often than the other please explain why:

Answered: 1 Skipped: 10

#	RESPONSES	DATE
1	We receive more questions from IRBs/IECs regarding PGx collection and have found the brochure a helpful resource at explaining the usefulness of this type of genetic research.	7/18/2014 2:39 PM

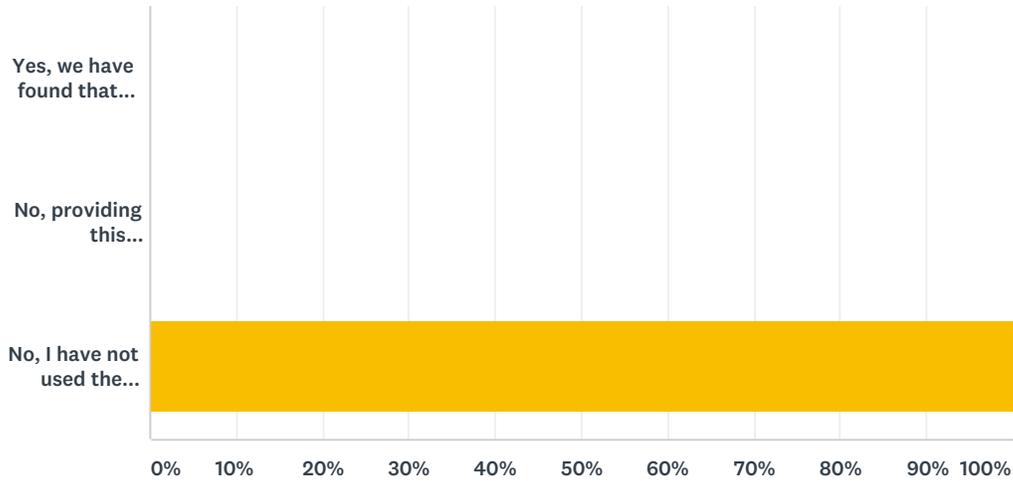
Q7 How often do you use these brochures and in what context (e.g. only around 50% of the time when we have trials with a relevant research component)?

Answered: 2 Skipped: 9

#	RESPONSES	DATE
1	I would say we periodically use these brochure, maybe around 10% of the time. One of the reasons is that they are quite lengthy and therefore I am uncertain if IRBs are reading through all of the information provided.	7/18/2014 2:39 PM
2	For every study with a PGx component	7/3/2014 12:09 PM

Q8 Did providing this brochure(s) proactively help to decrease the number of inquiries from IRBs/IECs with protocol submissions?

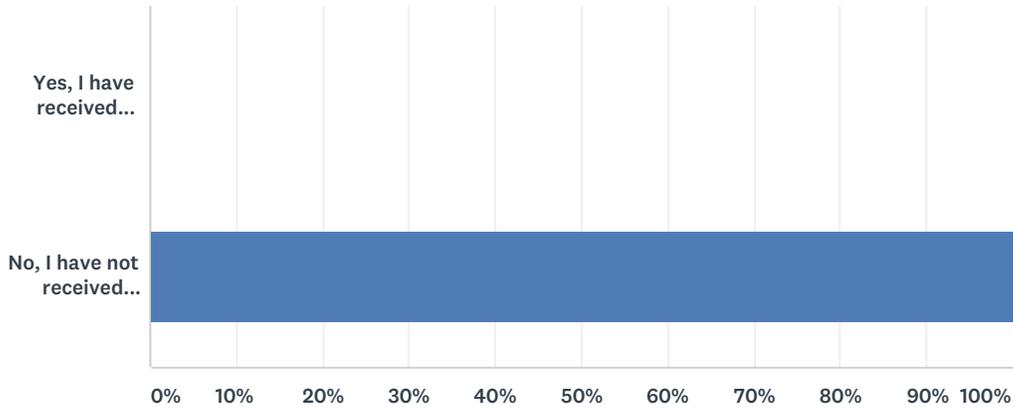
Answered: 2 Skipped: 9



ANSWER CHOICES	RESPONSES	
Yes, we have found that providing this brochure(s) decreased the number of questions raised by IRBs/IECs	0.00%	0
No, providing this brochure(s) proactively has NOT decreased the number of questions raised by IRBs/IECs	0.00%	0
No, I have not used the brochure(s) for this purpose	100.00%	2
TOTAL		2

Q9 Have you ever received feedback that the brochure(s) provide a biased perspective of biomarker and PGx sample collection?

Answered: 2 Skipped: 9



ANSWER CHOICES	RESPONSES	
Yes, I have received feedback that the biomarker and PGx brochures provide a biased perspective	0.00%	0
No, I have not received feedback that the biomarker and PGx brochures provide a biased perspective	100.00%	2
TOTAL		2

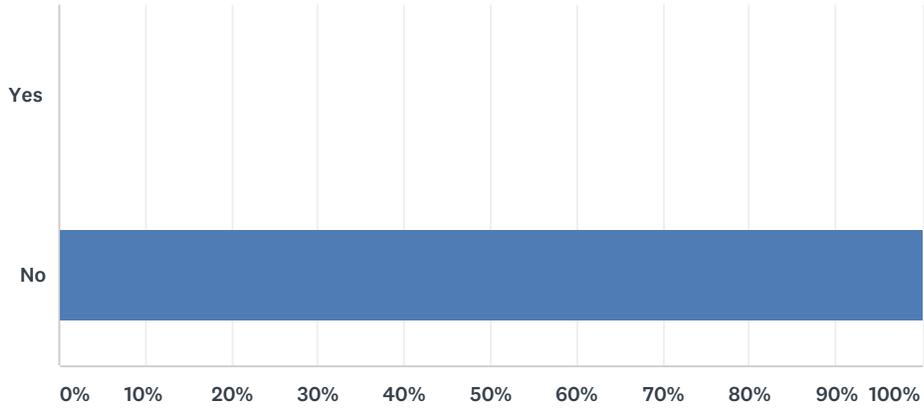
Q10 Please elaborate on who provided this feedback and why the recipient of the brochure felt it was biased

Answered: 1 Skipped: 10

#	RESPONSES	DATE
1	Has not been raised as a concern	7/3/2014 12:09 PM

Q11 Have you had these brochures translated?

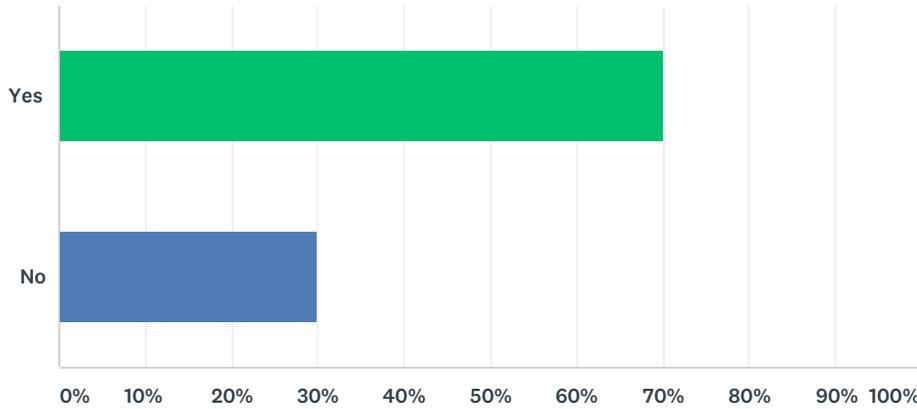
Answered: 2 Skipped: 9



ANSWER CHOICES	RESPONSES	
Yes	0.00%	0
No	100.00%	2
TOTAL		2

Q12 Do you feel there is a need for the I-PWG to provide brochures in more than one language on the website?

Answered: 10 Skipped: 1



ANSWER CHOICES	RESPONSES	
Yes	70.00%	7
No	30.00%	3
TOTAL		10

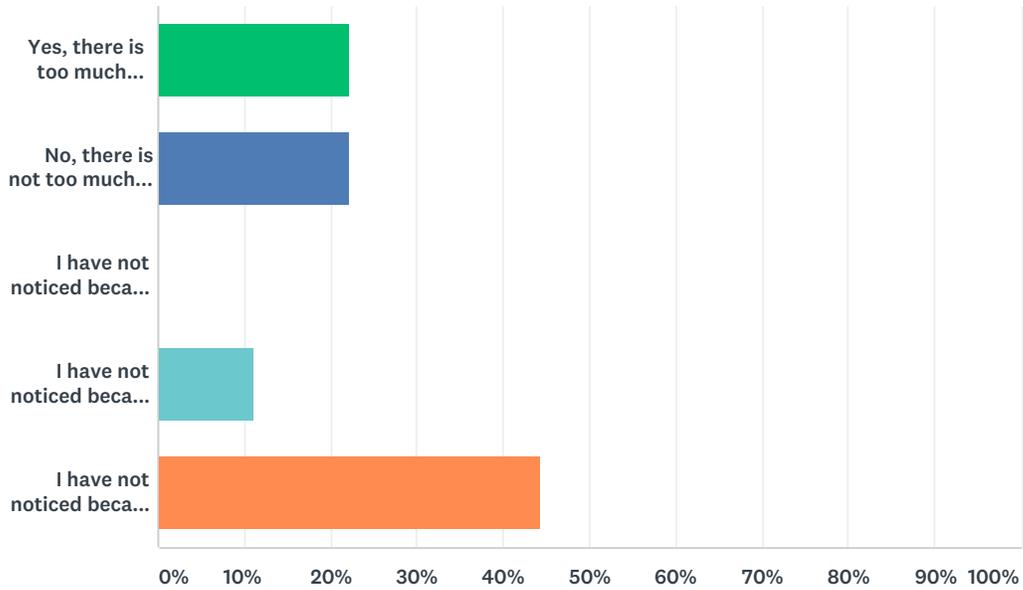
Q13 What languages do you think would be most useful?

Answered: 8 Skipped: 3

#	RESPONSES	DATE
1	Simple Chinese, Spanish	7/29/2014 1:41 PM
2	Spanish, German, French, Japanese	7/18/2014 9:59 PM
3	Spanish, Chinese, French	7/18/2014 2:41 PM
4	German, French, Spanish, Chinese, Japanese, Portugese	7/15/2014 4:05 PM
5	japanese, spanish, chinese, Portuguese	7/15/2014 3:47 PM
6	Spanish, French, Chinese	7/8/2014 4:53 PM
7	(Answered "no" to previous question)	7/8/2014 2:44 PM
8	German, French, Italian,	7/7/2014 3:01 PM

Q14 Do you feel there is too much overlap between the biomarker and PGx brochures?

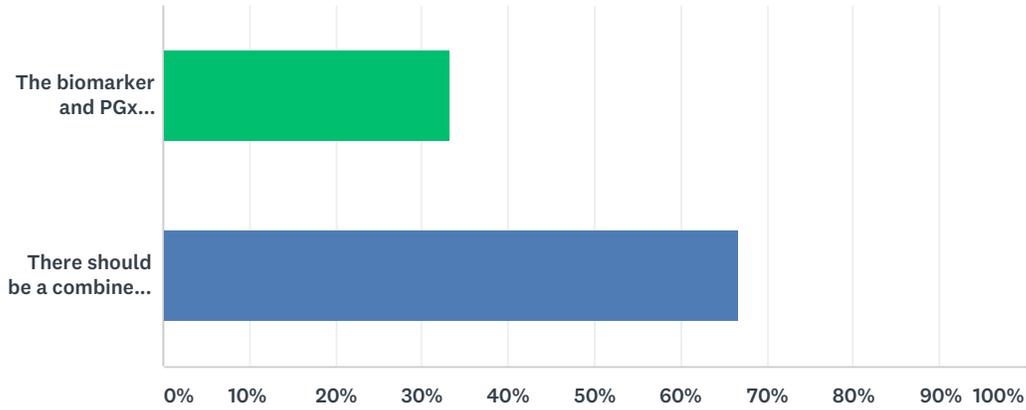
Answered: 9 Skipped: 2



ANSWER CHOICES	RESPONSES	
Yes, there is too much overlap	22.22%	2
No, there is not too much overlap. I feel it is useful to have a separate brochure covering each of these topics	22.22%	2
I have not noticed because I have only used the biomarker brochure	0.00%	0
I have not noticed because I have only used the PGx brochure	11.11%	1
I have not noticed because I do not use either brochure and don't recall their content	44.44%	4
TOTAL		9

Q15 Do you find the current brochures helpful, or do you think the content should be combined into a single brochure that covers both biomarker and PGx research?

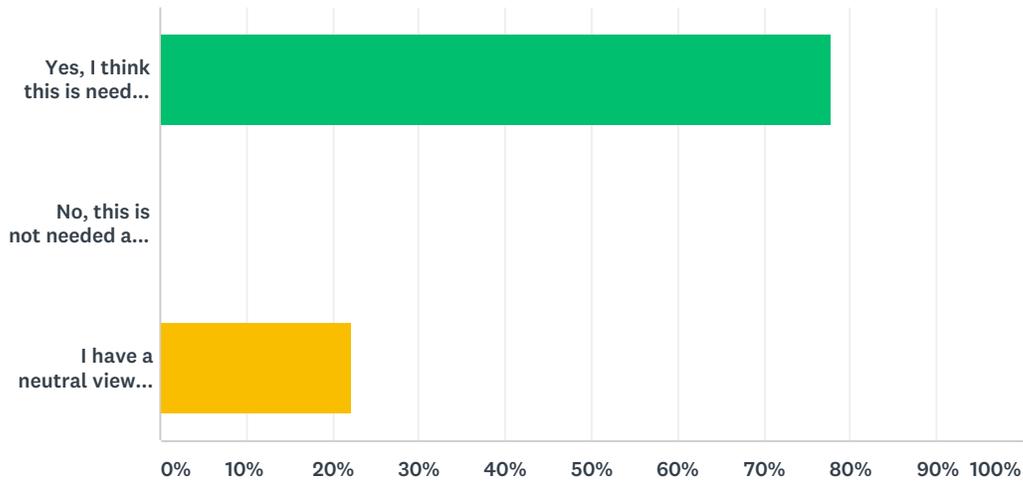
Answered: 9 Skipped: 2



ANSWER CHOICES	RESPONSES	
The biomarker and PGx brochures should be kept separate	33.33%	3
There should be a combined brochure, there is no need for us to have both a biomarker brochure and a PGx brochure	66.67%	6
TOTAL		9

Q16 Do you think it would be helpful for us to create a one page document that summarizes key points from both the biomarker and PGx brochures?

Answered: 9 Skipped: 2



ANSWER CHOICES	RESPONSES	
Yes, I think this is needed because the current brochures may be too lengthy for some audiences	77.78%	7
No, this is not needed and the current format of the brochures has worked well for us	0.00%	0
I have a neutral view, it would be nice to have this available but I don't currently view this as a "must have"	22.22%	2
TOTAL		9

Q17 What sections do you think are most helpful from the biomarker brochure and why?

Answered: 4 Skipped: 7

#	RESPONSES	DATE
1	The flow diagram of biomarker research is nice (this would be a good starting point for the one page summary document referenced above)	7/18/2014 10:04 PM
2	Defining what a biomarker is and why biomarker research is important is are essential elements of the brochure. I really like the exmaples that are given and the way they are divided up into predictive biomarkers for safety and efficacy, and surrogate and prognostic biomarkers...examples are always very helpful.	7/18/2014 6:08 PM
3	pictures and visuals	7/15/2014 3:55 PM
4	Do not use brochure	7/8/2014 2:46 PM

Q18 What sections do you think are least helpful from the biomarker brochure and why?

Answered: 4 Skipped: 7

#	RESPONSES	DATE
1	The "Biomarkers are already a reality in healthcare" section could be condensed and included as a subpoint in the "Why biomarker research is important" section	7/18/2014 10:04 PM
2	I think the section on "Importance to Drug Development" and "How are Biomarkers Being Used in Drug/Vaccine Development" have some redundancies, this information could all be combined into a single section. If the audience for the brochures are IRB/IEC members and investigators I feel a lot can be taking out of section 7 on Informed Consent since much of the information there should be common knowledge for those individuals (e.g. consent is needed but policies/regulations vary, consent can be either optional or required, etc) From this section it may be most helpful to explain why it can be a challenge to specify the details of research that will be conducted in the future.	7/18/2014 6:08 PM
3	too lengthy and needs a one page summary	7/15/2014 3:55 PM
4	Do not use brochure	7/8/2014 2:46 PM

Q19 Are there topics not covered in the biomarker brochure that you would like to see covered?

Answered: 5 Skipped: 6

#	RESPONSES	DATE
1	what to do with critical value biomarker that may indicate serious risk to subject	7/18/2014 10:04 PM
2	The section on return of results may need updating based on the paper that was written by the I-PWG recently.	7/18/2014 6:08 PM
3	no	7/15/2014 3:55 PM
4	No	7/8/2014 2:46 PM
5	Why these studies are done	7/3/2014 12:12 PM

Q20 What sections do you think are most helpful from the PGx brochure and why?

Answered: 6 Skipped: 5

#	RESPONSES	DATE
1	Why is PGx important>How is it used in Drug development>Definitions>What is DNA?, What is pharmacogenomics, Privacy & Confidentiality, Samples for DNA Analysis>Sample coding category table: The general order in the response reflected feedback from stakeholders. Basic understanding of why PGx is important and how it is being used was deemed most useful	7/29/2014 2:48 PM
2	The explanations of how PG information is collected, labeled, and used (especially country-specific) is very helpful and useful.	7/18/2014 10:04 PM
3	Again here, I think defining PGx (especially showing the picture) is very helpful.	7/18/2014 6:08 PM
4	pictures/visuals; more bullet points can be utilized	7/15/2014 3:55 PM
5	Do not use brochure	7/8/2014 2:46 PM
6	Explanation of what thesebiomarkers and pharmacogenomics are	7/3/2014 12:12 PM

Q21 What sections do you think are least helpful from the PGx brochure and why?

Answered: 5 Skipped: 6

#	RESPONSES	DATE
1	References section overload the brochure, country specific laws section is not as useful in non-specified countries	7/29/2014 2:48 PM
2	Sample labeling section can be shortened	7/18/2014 10:04 PM
3	There is more that could be done to combine some of the information from "How is PGx Being used in Drug Development?" with the section "PGx Already a Reality in Drug Labels" to shorten up this brochure. The section on Informed consent isn't very robust here and considering the audience I don't think we are saying anything novel that others wouldn't be aware of. Again here, the Return of Results section may need some updating based on the recent publication from the group. While I think Table 1 may be helpful it seems the current concerns by IRBs/ERBs has shifted from a need to provide this level of detail around privacy to discussing more transparency in the informed consent. However, our brochure is heavily focused on privacy and informed consent has only a paragraph - more may need to be done to explore the focus and be sure we are speaking to more current concerns of ethics boards and investigators.	7/18/2014 6:08 PM
4	more pictures, charts, visuals would be useful	7/15/2014 3:55 PM
5	Do not use brochure	7/8/2014 2:46 PM

Q22 Are there topics not covered in the PGx brochure that you would like to see covered?

Answered: 4 Skipped: 7

#	RESPONSES	DATE
1	update reference to new FDA/OHRG guidance	7/18/2014 10:04 PM
2	See comments above relating to sections of the PGx brochure that are least helpful.	7/18/2014 6:08 PM
3	no	7/15/2014 3:55 PM
4	No	7/8/2014 2:46 PM