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Concentrics Research LLC

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SUMMARY REPORT

Project “Aristotle” Comprehension Study

January 23-24, 2014

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Project “Aristotle” Comprehension Study

Background:

Based on learnings from POTIGA REMS Year 1, GSK is interested in assessing a potential question alternative in the POTIGA REMS survey for use in Year 2 assessment. This comprehension study evaluated physician assessment on the ease of understanding of the new alternative compared to the previous question wording. This research was conducted over a span of two (2) days via an online survey.

Original Wording (Option A)

Which of the following urinary symptoms, if any, should you specifically advise patients taking POTIGA to watch out for? (Please select all that apply)

- Pain when urinating
- Difficulty starting urination
- Renal colic
- Inability to urinate
- None of the above
- I don't know

New Alternate Wording (Option B)

The label for POTIGA recommends that you should advise patients taking POTIGA to watch out for which of the following urinary symptoms, if any? (Yes, No or Don't Know options for each)

- Pain when urinating
- Difficulty starting urination
- Renal colic
- Inability to urinate
- Urinary incontinence

The goal of the study was to assess the clarity of a revised survey question related to symptoms compared to the previous survey question in a group of physicians.

Methods:

Physicians were recruited via internet panel group (geographically diverse, representation from all 50 states). The survey was conducted online, with approximate interview time of 10 minutes. An honorarium was provided at \$25 per physician, which correlated to the lowest average salary (family medicine), which earns \$125 per hour on average.

In order to participate, physicians must have been currently in active practice, and able to read, speak and understand English. They could not be currently employed by or be a representative of a pharmaceutical company or manufacturer of medicines or healthcare products, be a contributor/editor to

Project “Aristotle” Comprehension Study

published guideline committees for epilepsy or UR, or be an employee of GSK or Concentrics Research. They also could not have a visual impairment that would prevent their ability to read independently or have participated in a previous REMS study for POTIGA.

Physicians were first asked to review both question options and asked to rate each option independently on the ease of understanding the question and answer choices, without any additional context. They were then asked to select the option they thought contained question text and answer choices that were easier to understand, based on a comparison of the two options.

Next, physicians were provided with a link to the Dear Healthcare Provider letter for POTIGA and asked to review the letter. Following their review, they were again asked to select the option they thought contained question text and answer choices that were easier to understand, based on a comparison of the two options, now that they had the context of the Dear HCP letter. Finally, physicians were asked to respond to each question option based on what they read in the letter. Open-ended questions were included for physicians to provide rationale for their ease of understanding preference selections, as well as the rationale for their response to each question option.

Dates:

This pre-test was conducted January 23rd and 24th, 2014.

Reporting Method:

This report summary will detail the findings and recommendations in order to inform the next stage of testing.

Analysis Method:

A statistical analysis was not completed due to the small sample sizes. Data was assessed to determine physician stated ease of understanding (%), along with coded verbatim comments related to question wording to help inform the next REMS assessment.

Results (n=101):

Online surveys were conducted with 101 physicians, recruited via Internet panel, over the course of two days (January 23 and 24). Physician respondents primarily classified themselves as Family Medicine/General Practice (37%, n=37) or Internal Medicine (32%, n=32), with the remainder specializing in Pediatrics (23%, n=23) or Neurology (9%, n=9).

As shown in [Table 1](#) and [Table 2](#), both question options were rated similarly when independently assessed. Option A (75%) was rated directionally higher than Option B (71%) when assessing the top-2 box score (“Extremely easy”/“Very easy to understand”), and had fewer physician respondents rate it as “Not very easy to understand” (2%) as compared to Option B (8%).

Project “Aristotle” Comprehension Study

Table 1: Physician Ease of Understanding – No Context – Independent Assessment

		Total	
Total Responding:		101	
Q#	Objective	n	%
Q1	How would you rate the ease of understanding the question and answer choices for Option A (Top 2 Box – Extremely Easy or Very Easy to Understand)	76	75.2
Q2	How would you rate the ease of understanding the question and answer choices for Option B (Top 2 Box – Extremely Easy or Very Easy to Understand)	72	71.3

Table 2: Physician Ease of Understanding – No Context – Independent Assessment – All Response Options (Q1 & Q2)

		Total	
Total Responding:		101	
Q#	Objective	n	%
Q1	How would you rate the ease of understanding the question and answer choices for Option A?		
	Extremely easy to understand	43	42.6
	Very easy to understand	33	32.7
	Somewhat easy to understand	23	22.8
	Not very easy to understand	2	2.0
	Not at all easy to understand	--	--
Q2	How would you rate the ease of understanding the question and answer choices for Option B?		
	Extremely easy to understand	36	35.6
	Very easy to understand	36	35.6
	Somewhat easy to understand	21	20.8
	Not very easy to understand	8	7.9
	Not at all easy to understand	--	--

Project “Aristotle” Comprehension Study

When asked to select the one option that they felt contained question text and answer choices that were easier to understand, physicians were more likely to choose Option A (62%) over Option B (38%). The top reasons why Option A was selected are listed in [Table 4](#), including that it was viewed as more straightforward (n=29), easier to respond to (n=15), with fewer choices (n=9) and easier to read (n=9). Physicians who preferred Option B liked that it was a better/more direct measure for each specific item (n=14), and thought it was easier to read (n=5) and easier to navigate (n=5).

Table 3: Physician Ease of Understanding – No Context – Comparative Assessment

		Total	
Total Responding:		101	
Q#	Objective	n	%
Q3	Based on your opinion, after reviewing both options, which option do you think contains question text and answer choices that are easier to understand?		
	<i>Selected Option A</i>	63	62.4
	<i>Selected Option B</i>	38	37.6

Table 4: Reasons for Physician Ease of Understanding – No Context – Comparative Assessment

		Total	
Total Responding:		101	
Q3B – Which option do you think contains question text and answer choices that are easier to understand? Why do you say that?		n	%
<i>Preferred Option A – Top Mentions</i>			
	Straightforward/simpler/more clear	29	28.7%
	Easier to respond to	15	14.9%
	Fewer choices	9	8.9%
	Easier to read	9	8.9%
	Familiarity/more comfortable/prefer multiple choice	6	5.9%
	B is confusing/hard to follow/too busy	5	5.0%
<i>Preferred Option B – Top Mentions</i>			
	Better/more direct measure for each specific item/address individually instead of all at once	14	13.9%
	Easier to read/better visual	5	5.0%
	Easy to navigate/respond to	5	5.0%
	Easier to understand	4	4.0%
	Displays choices better	4	4.0%
	More comprehensive/thorough	3	3.0%
	Grid/chart/graphics	3	3.0%
	Don't like 'Don't Know' in A – not selective for individual symptoms like B	3	3.0%

Project “Aristotle” Comprehension Study

After physicians reviewed the Dear HCP letter to provide context to the question and response options, they were again asked to provide their preference on which option was easier to understand. The outcome was very similar, with Option A (60%) again being the clear choice over option B (40%). Rationale provided was again very similar as well (as shown in [Table 6](#)).

Table 5: Physician Ease of Understanding – With Context – Comparative Assessment

		Total	
Total Responding:		101	
Q#	Objective	n	%
Q4	Based on your opinion, after reviewing the Dear HCP letter and both options, which option do you think contains question text and answer choices that are easier to understand?		
	<i>Selected Option A</i>	61	60.4
	<i>Selected Option B</i>	40	39.6

Table 6: Reasons for Physician Ease of Understanding – With Context – Comparative Assessment

		Total	
Total Responding:		101	
Q4B – After reviewing the Dear HCP letter and both options, which option do you think contains question text and answer choices that are easier to understand? Why do you say that?		n	%
<i>Preferred Option A – Top Mentions</i>			
	Straightforward/simpler/more clear	33	32.7%
	Easier to respond to	13	12.9%
	Easier to read	7	6.9%
	Easier to understand	6	5.9%
	Familiarity/more comfortable/prefer multiple choice	3	3.0%
	Addresses symptoms	3	3.0%
<i>Preferred Option B – Top Mentions</i>			
	Better/more direct measure for each specific item/address individually instead of all at once	12	11.9%
	Easier to read/better visual	7	6.9%
	Easy to navigate/respond to	5	5.0%
	Easier to understand	5	5.0%
	More appropriate question/pertinent/clearer writing	4	4.0%
	Prefer chart/table form/layout	4	4.0%
	More options	3	3.0%
	Don't like 'Don't Know' in A – not selective for individual symptoms like B	3	3.0%

Project “Aristotle” Comprehension Study

Following the review of the Dear HCP letter and subsequent assessments, physicians were asked to respond to each question option based on what they had read. Just fewer than half of physicians were able to provide a correct response to Option A (49%), while only 13% were able to respond correctly to Option B. Full details of the responses are provided in [Table 8](#).

Table 7: Physician ‘Comprehension’ (based on review of Dear HCP letter)

		Total	
Total Responding:		101	
Q#	Objective	n	%
Q5	Based on what you read in the Dear HCP letter, how would you answer the question shown as Option A? (% Correct*)	49	48.5
Q6	Based on what you read in the Dear HCP letter, how would you answer the question shown as Option B? (% Correct**)	13	12.9

*Selected all 3 correct responses - ‘Pain when urinating’, ‘Difficulty starting urination’ and ‘Inability to Urinate’ – and no incorrect responses

**Selected ‘Yes’ for all 3 correct items - ‘Pain when urinating’, ‘Difficulty starting urination’ and ‘Inability to Urinate’ - and selected ‘No’ for both ‘Renal colic’ and ‘Urinary incontinence’.

Table 8: Physician ‘Comprehension’ – All Responses

		Total		Yr 1 REMS (Physician Only)	
Total Responding:		101		168	
Q#	Objective	n	%	n	%
Q5	Based on what you read in the Dear HCP letter, how would you answer the question shown as Option A: Which of the following urinary symptoms, if any, should you specifically advise patients taking POTIGA to watch out for? (Please select all that apply) (% Correct*)				
	Pain when urinating	50	49.5	38	22.6
	Difficulty starting urination	83	82.2	98	58.3
	Renal colic	16	15.8	17	10.1
	Inability to urinate	95	94.1	129	76.8
	None of the above	1	1.0	1	0.6
	I don’t know	2	2.0	12	7.1
Q6	Based on what you read in the Dear HCP letter, how would you answer the question shown as Option B: The label for POTIGA recommends that you should advise patients taking POTIGA to watch out for which of the following urinary symptoms, if any? (% Correct*)				
	Pain when urinating (% Yes)	55	54.5		
	Difficulty starting urination (% Yes)	90	89.1		
	Renal colic (% No)	59	58.4		
	Inability to urinate (% Yes)	94	93.1		
	Urinary incontinence (% No)	55	54.5		

Project “Aristotle” Comprehension Study

Conclusion:

This comprehension assessment provided insights into physician ease of understanding of the revised and original question wording and answer choice options for one key objective relating to urinary symptom advisements for the POTIGA REMS study. Physicians identified the original wording and answer choices (Option A) as easier to understand, both before and after they were provided with the context of the Dear HCP letter. Overall, physicians did not score well in terms of understanding the correct answers on either version of the question, as fewer than 50% provided a fully correct response to either option. The original wording (Option A) scored directionally higher (49% correct) as opposed to the revised wording (13% correct), but neither wording option should be considered optimal for this objective.

Recommendations:

Concentrics Research recommends the following based on this study:

1. Assess FDA feedback upon receipt to determine next steps for the program as a whole.
2. If Year 2 will move forward, assess the response choice ‘Pain when urinating’ and consider changing to ‘Dysuria’ or ‘Dysuria (pain when urinating)’, since that is the terminology used in the PI and Dear HCP letter. This was the primary area of confusion, regardless of question option.
3. If Year 2 will move forward, assess whether additional testing is needed or viability of moving forward with one of these two options.