



PRAHEALTHSCIENCES

# **PRA INSIGHTS REPORT**

## **2018 ISPOR-North America Survey Results**

Real World Solutions

June 2018



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## INTRODUCTION

The International Society for Pharmacoeconomics and Outcomes Research (ISPOR) is the leading global scientific and educational organization for health economics and outcomes research (HEOR.) ISPOR's mission is to promote HEOR excellence to improve decision-making for health globally.

As our industry landscape for Real World Research has changed exponentially, our Real World Solutions team performed a short, primarily multiple-choice questionnaire, run across all three exhibition days of ISPOR's Annual North America meeting. Our aim was to gather insights on important developments in the real world research space, including the impact of the 21<sup>st</sup> Century Cures Act on our industry.

## METHODOLOGY

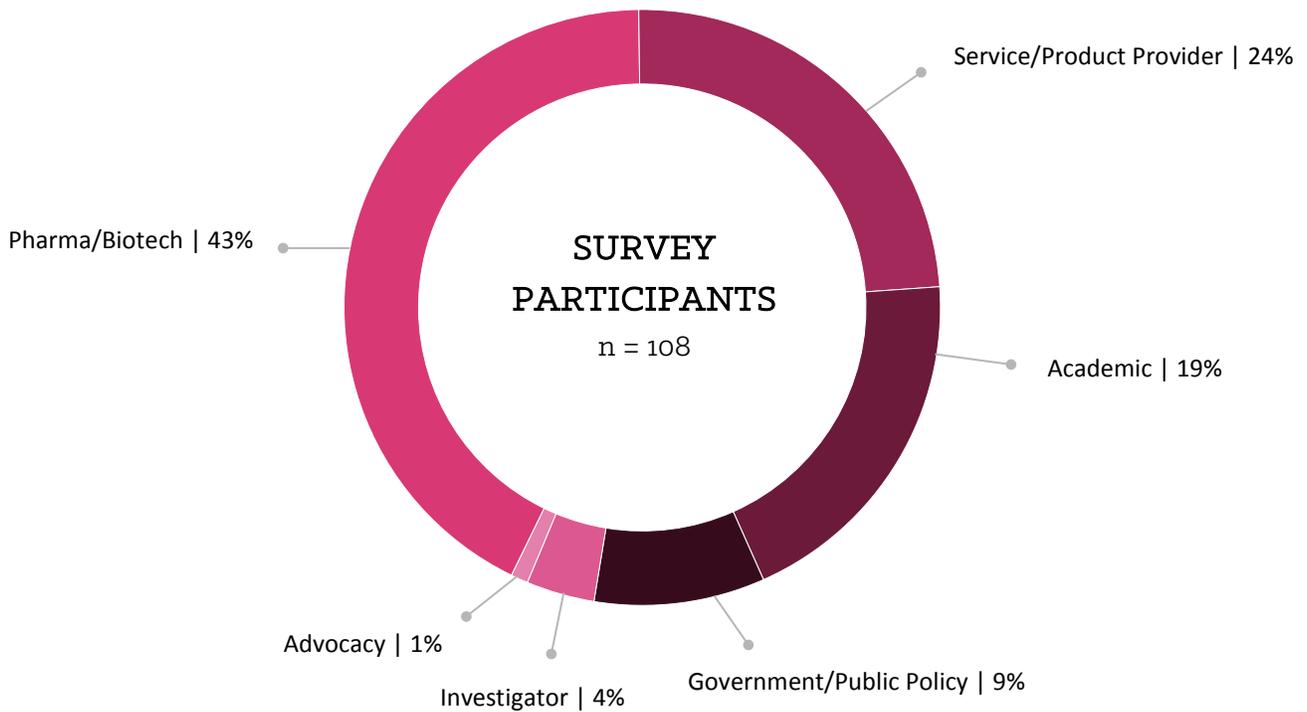
Data for this report were gathered during exhibit hours at the ISPOR Annual NA Meeting over the 21<sup>st</sup>-23<sup>rd</sup> of May 2018, in Baltimore, MD. PRA ran a five-question survey over the three exhibition days, obtaining a total of 108 responses.



## RESULTS

Participants self-selected their company affiliation from six choices.

Of the 108 responses, the highest category of response (43%) identified as coming from an “Pharmaceutical/Biotech” background, followed by 24% from “Service/Product Provider,” 19% for “Academic,” 9% for “Government/Public Policy,” 4% for “Investigator,” and just 1% for “Advocacy.” This largely reflected the attendance of the conference itself.



n = 108	
Pharmaceutical/Biotech company	46
Service/Product Provider to the Industry	26
Academic	21
Government/Public Policy	10
Investigator/Site	4
Advocacy	1



1. How familiar are you with the 21st Century Cures Act (21CCA)? [choose one]

n = 108	
Very familiar	18
Somewhat familiar	53
Not at all familiar	32
The 21 <sup>st</sup> Century...what?	5

**Observations and Conclusions:**

Although two-thirds of our survey respondents had some familiarity with 21CCA, only 17% of respondents consider themselves “very familiar” with it. About 34% of the responders had no familiarity with it.

2. The 21st Century Cures Act (21CCA) includes many provisions which relate to the use of real-world evidence (RWE) in drug development. Select ALL the statements below that are true about the 21CCA and RWE: [choose all that are true]

n = 108	
RWE means data from sources other than randomized trials <b>(TRUE)</b>	62
RWE can support approval of a new drug. <b>(FALSE)</b>	58
RWE can support approval of a new indication for an already-approved drug. <b>(TRUE)</b>	63
RWE includes registries, claims, and patient-centered outcomes research. <b>(TRUE)</b>	62
I haven't a clue!	16

**Observations and Conclusions:**

Although 15% admitted they were unsure of the provisions of 21CCA, the other results reveal an uncertainty not only regarding how RWE can be used (or not used) in product development, but even an uncertainty about just what is RWE. For example, more than half of the respondents believed – incorrectly – that RWE can support approval of a new drug.



- 3. How much of an impact will 21CCA have on the organization for which you work? (choose one)

n = 107 (1 respondent did not answer)	
A large impact	48
Some impact	43
I don't know/I'm not sure	12
Not much of an impact	4
Blank	1

**Observations and Conclusions:**

Despite the lack of understanding of 21CCA, almost 85% of the respondents believe it will have an impact on their organization.

*The 21st Century Cures Act, enacted in 2016, provides many potential opportunities for biopharmaceutical companies to advance their development pipelines more quickly and more efficiently in the U.S.*

Read more on this concept: [21st Century Cures Act and Real-World Evidence](#)



4. How much of an impact will 21CCA have on you personally [choose one]

n = 106; (2 respondents did not answer)	
Some impact	46
A large impact	29
I don't know/I'm not sure	18
Not much of an impact	13
Blank	2

**Observations and Conclusions:**

Again, even without knowledge of all the details, 71% of respondents believed that 21CCA will impact them personally.

5. Of the many provisions in 21CCA, select those you or your company are most interested in/would like more information about: [choose all that apply]

n = 106 (2 respondents did not answer)	
Incorporating the patient experience into the drug development process	48
Leveraging RWE to reduce drug development timelines and expense	47
Collecting RWE to support label-expansion for an approved product	47
I don't know/I'm unsure	18
Meeting interoperability of health information requirements and impact to EHR utilization	12
Blank	2

**Observations and Conclusions:**

The responses to this question show three areas of keen interest for the survey respondents: the patient experience and a desire to incorporate it into the drug development process; leveraging RWE to reduce both timelines and expenses; and employing RWE to support label expansion.



## CONCLUSION

As shown in this brief survey, there is still much uncertainty surrounding 21CCA. However, some key findings are evident. First, those who work in biopharmaceutical research feel that whether they understand 21CCA or not, it will have a direct effect on their work. Second, these researchers are keenly aware that RWE is a critical element of the product development process going forward. An understanding of and appreciation for real world evidence as well as the 21CCA has become a must-have rather than a nice-to-have in our industry.

## RESOURCES

For more information about 21CCA, Real World Evidence or Real World Studies, please contact:

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