



Real World Evidence

Healthcare Professional Feedback on Proposed Standards for Presentation of RWE in Drug Advertising Directed to Health Professionals



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Executive Summary

In May 2023, the Pharmaceutical Advertising Advisory Board (PAAB) initiated research with Healthcare Professionals, looking to solicit expert opinion regarding the proposed incorporation of Real-World Evidence (RWE) into drug advertising.

Those who successfully passed screening were invited to complete a 29 question online survey made up of quantitative and qualitative questions.



Key findings

- A total of 60 healthcare professionals successfully completed the survey.
- While the initial objective was to gather responses from 100 doctors, the research was concluded upon reaching 60 participants. This decision was informed by the consistent responses received, indicating a saturation of opinions and diminishing the necessity to pursue the remaining 40 participants.
- The majority of respondents exhibited a consistent agreement in both the value and proposed presentation of Real World Evidence in Canadian drug advertising.

Methodology

In May 2023, the Pharmaceutical Advertising Advisory Board (PAAB) initiated a systematic recruitment and screening process aimed at healthcare professionals within Canada. The objective was to solicit their expert opinions regarding the proposed incorporation of Real-World Evidence (RWE) into pharmaceutical advertising.

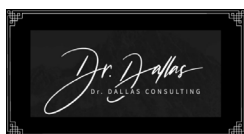
Eligible participants, having successfully undergone the screening process, were provided with the draft guidance document elucidating the rationale behind the introduction of RWE. Subsequent to their review of this material, these professionals were prompted to participate in a structured online survey. This survey encompassed both quantitative and qualitative research questions to ensure a holistic understanding of their perspectives.

Those who successfully completed the online survey were provided with \$100 CAD digital gift card honoraria for their services.

Demographics

The research survey engaged 60 healthcare professionals, reflecting diversity in hospitals, practices, and specialties. Participants hail from across Canada, including British Columbia, Alberta, Ontario and Quebec. Moreover, the participant pool covers a spectrum of medical specialties, with the notable majority (20%) in Oncology.

Institutions*



*full list of institutions in Appendix 1

Demographics

Specialty



Oncology
19.64%



**General
Medicine**
8.93%



Ophthalmology
8.93%



Pharmacy
8.93%



**Family Medicine
/Medicine**
7.14%

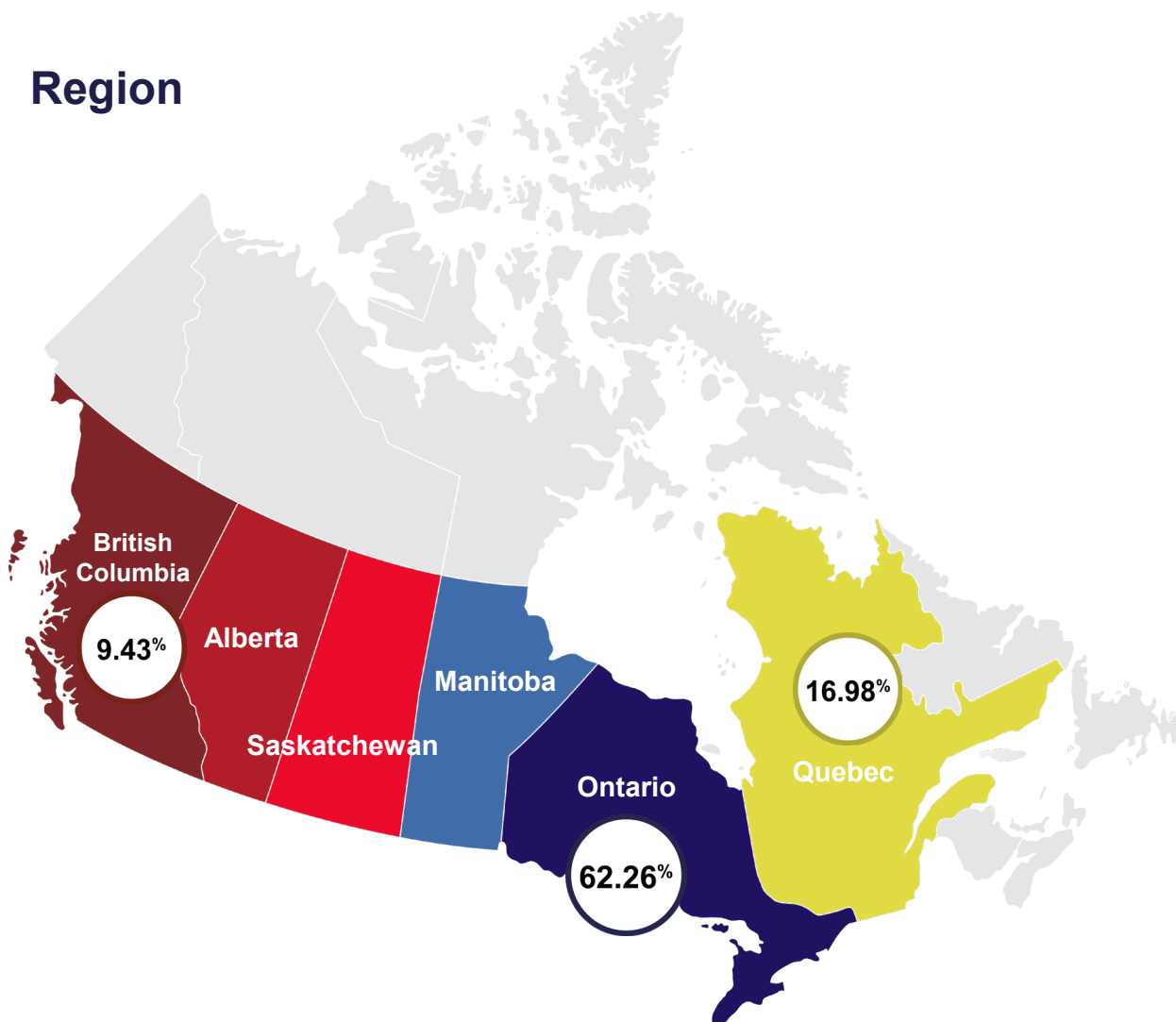


**Emergency
Medicine**
5.36%

Specialty	% of Total
Cardiology	3.57%
Clinical Research	3.57%
Family Physician	3.57%
Mental Health	3.57%
Paediatrics	3.57%
Public Health	3.57%
Geriatrics	1.79%
Hematopathology	1.79%
Immunology	1.79%
Lifestyle Medicine & Aesthetic Medicine	1.79%
Neurogastroenterology	1.79%
Neurology/Neurosciences/Cardiovascular	1.79%
Neurophysiology	1.79%
Neuropsychology	1.79%
Obstetrics & Gynecologist	1.79%
Physical Medicine and Rehabilitation	1.79%
Rheumatology	1.79%

Demographics

Region



Region	% of Total
Ontario	62.26%
Quebec	16.98%
British Columbia	9.43%
Alberta	3.77%
Manitoba	3.77%
Saskatchewan	3.77%

1

RWE Visual Presentation

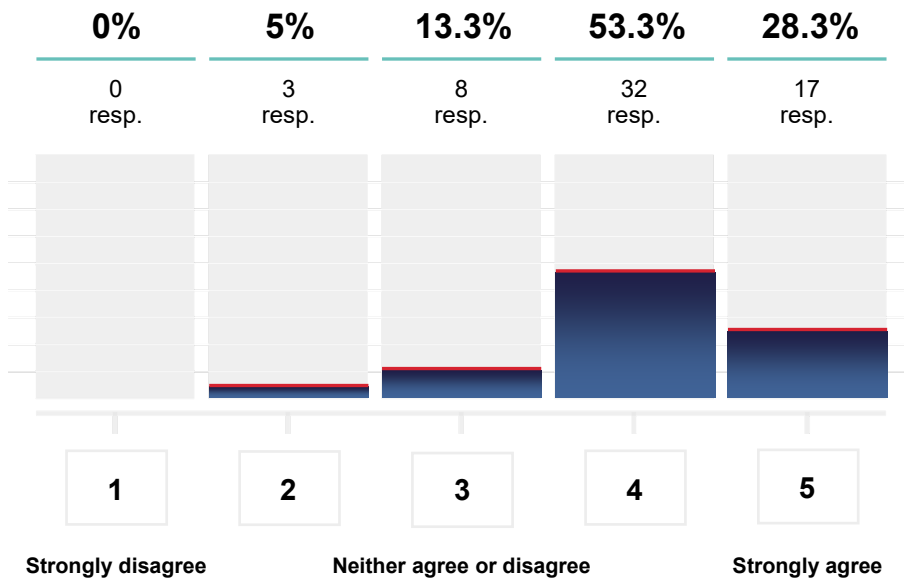
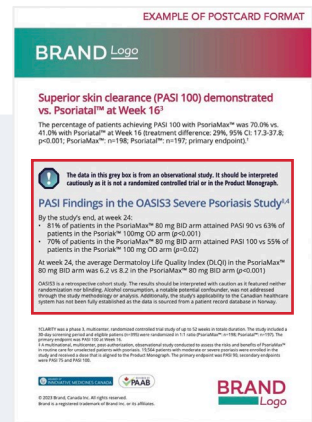


RWE Visual Presentation

Based on the draft guidance document you just viewed, please let us know if:

The visual cues (icon, grey call out box, limitation copy) will help you easily differentiate between gold-standard evidence and RWE presentations.

(60 out of 60 people answered this question)



Respondents were asked to expand on their answer. Thematic analysis identified 3 themes noted below. Overall, respondents felt that the presentation of RWE could be easily differentiated from RCTs in this format.

Theme 1: There Is Effective Visual Differentiation. N = 12

Many doctors appreciated the use of visual elements like colours and boxes which helped them differentiate and focus on key areas of the content, making it visually engaging and easy to separate.

"The three elements used to identify the level of evidence are well easily recognizable."

Theme 2: Clarity of Content Presentation. N = 10

The presentation of the content was found to be clear and concise by several respondents. They felt that the layout, item order, and overall content structure were pertinent and effective in conveying the intended message.

"The presentation and language of this information make it very easy to find and dissect current study data on a product."

Theme 3: Effective Attention Draw and Highlights. N = 8

Several doctors felt that specific design elements, such as the use of a box or certain icons effectively drew their attention to key areas, ensuring that crucial data wouldn't be missed even in a quick scan.

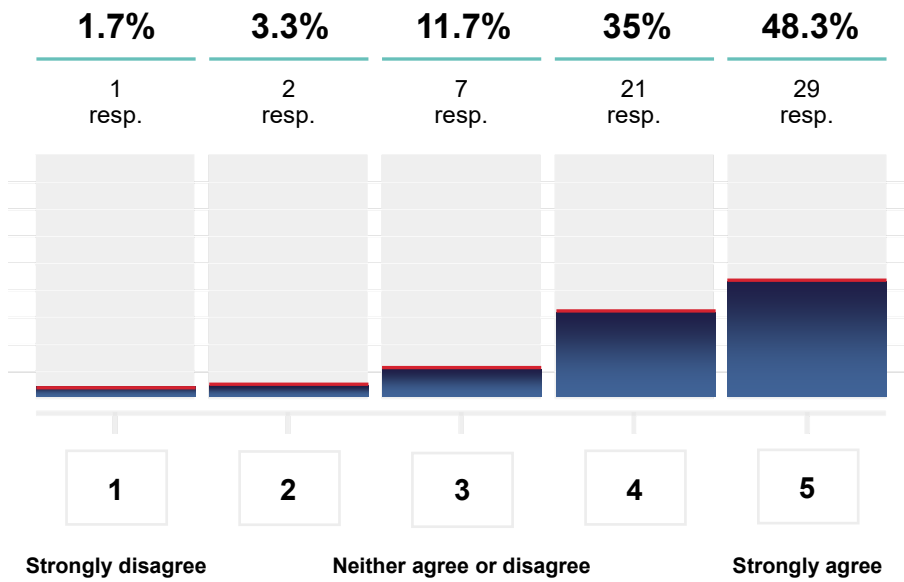
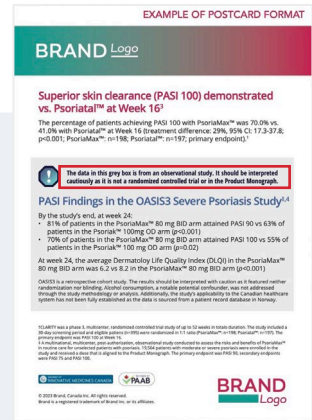
"The grey box draws your eye in - the ! alerts you to the type of study used and the text at the bottom of the results extrapolate the 'caveat' to reviewing the findings, all while not crowding the grey box and overwhelming the eye."

RWE Visual Presentation

The following explanatory statement will accompany the RWE presentation:
"The data in this grey box is from an observational study. It should be interpreted cautiously as it is not a randomised controlled trial or in the Product Monograph."

The inclusion of this explanatory statement will be a useful consideration when looking at data provided in advertising material.

(60 out of 60 people answered this question)



The statement in the grey box adds a layer of clarity and transparency by differentiating real-world data from randomized controlled trials and the Product Monograph, allowing clinicians to make more informed judgments.

Theme 1: Educational & Reminder Value. N = 7

The statement not only informs but also educates and reminds clinicians about the levels and quality of evidence. The verbatim indicates that the statement has an educational value, serving as a reminder of evidence quality, especially beneficial for medical professionals.

"For the non-experienced clinician, ie nurse or PA, there needs to be a bit more explanation because I don't believe they understand the nuance between different types of studies."

Theme 2: Design & Visualization Improvements. N = 6

Doctors suggest that while the statement is valuable, enhancing visual elements like the font size, colours, or inclusion of a graphical representation could offer a quicker and more effective comprehension of the evidence levels. While doctors appreciate the transparency of the statement, there are suggestions for improvements in design and visualization, such as clearer lettering, colour coding, and graphical representation to enhance understanding.

"Considering the level of evidence should have some kind of colour identifier to differentiate between RCTs and observational studies for example."

Theme 3: Clarity & Transparency. N = 5

The verbatim consistently indicates that doctors value clear labelling and transparency about the quality and type of evidence provided, as it helps them interpret the data correctly.

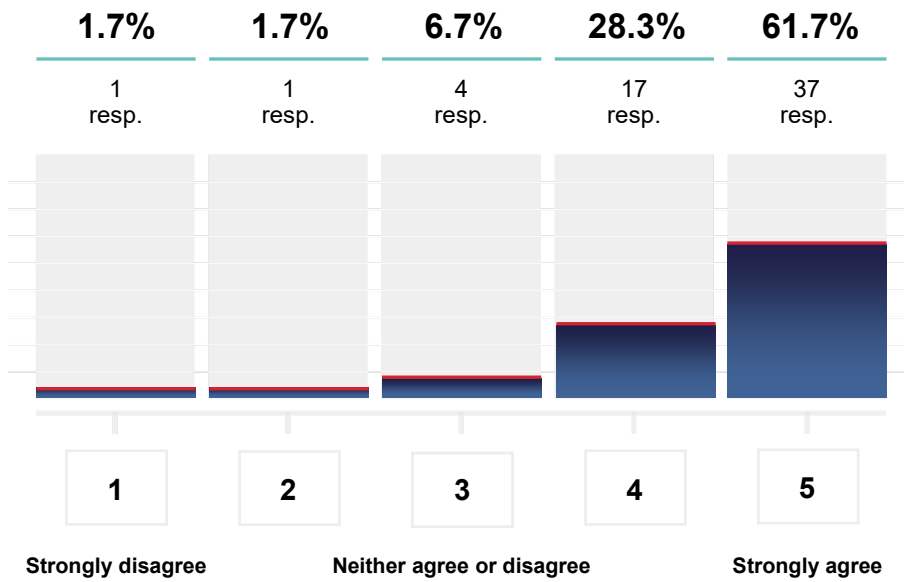
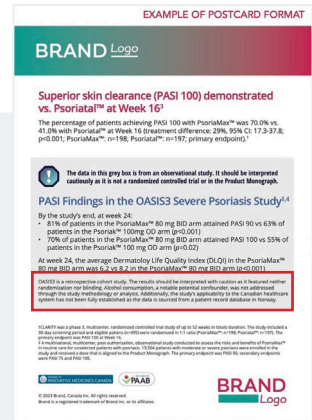
"Yes, I think this helps quickly to identify the way in which the evidence should be interpreted."

RWE Visual Presentation

The image is highlighting the key limitations of the RWE study.

It is important to me that the key limitations of the RWE studies are presented prominently.

(60 out of 60 people answered this question)



Participants perceived the image as effectively underscoring the constraints of RWE. While they expressed favourable opinions towards the present proposal, they also offered additional suggestions for enhanced support.

Theme 1: Presentation & Accessibility. N = 18

Respondents highlighted the need for the information to be presented in a manner that's easily accessible and understandable, even for those with varying degrees of healthcare knowledge. This includes suggestions on font size, formatting, and the use of clear language.

"It is important to have ready access to study limitation, however, make sure the language is readily understood by those with varying degrees of healthcare/study knowledge."

Theme 2: Clinical Relevance & Decision-Making. N = 8

Respondents consistently mentioned that having a clear summary of the limitations aids in their decision-making, especially in time-constrained clinical scenarios. Presenting the limitations directly influences clinicians' decision-making process by allowing them to quickly discern the study's relevance and applicability to their specific patient population.

"In clinical practice, you often do not have sufficient time to read through the entire study. The summary highlighted at the top is essential to gathering the key points in decision making."

Theme 3: Transparency & Trustworthiness N = 6

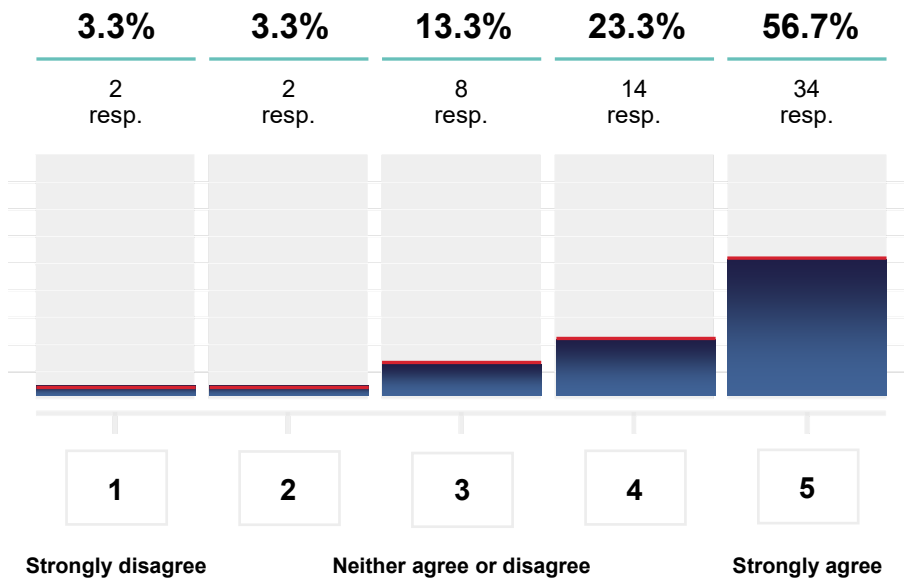
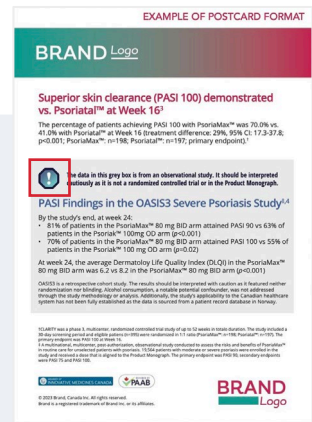
Respondents emphasized the importance of making readers aware of study limitations to ensure that they can trust the data, understand its applicability, and assess its relevance to clinical practice. Outlining the limitations of a study will provide the necessary transparency to clinicians and ensure trustworthiness of the presented data.

"It is important to report these limitations because it provides transparency and allows readers to understand the potential constraints and weaknesses of the study's findings."

RWE Visual Presentation

The prominent positioning of the icon within the grey box will be a helpful reminder that the associated content should be interpreted with **care and caution**.

(60 out of 60 people answered this question)



Participants felt that the icon effectively grabs attention due to its design and therefore would be an effective symbol for this purpose. Further feedback suggests improvements in colour differentiation and questions the universal interpretation of its symbol in a medical context.

Theme 1: Visual Attractiveness & Attention-Grabbing Capability N = 9

The icon effectively captures attention due to its prominence and its nature as a visual cue. A majority of the respondents feel that the icon, whether due to its size, placement, or nature, stands out and successfully draws the reader's attention.

"The icon always catches people's attention more."

Theme 2: Feedback on Colour & Differentiation N = 8

While the icon attracts attention, there is room for improvement in terms of colour contrast and differentiation from surrounding content. Many respondents suggest enhancing the colour or positioning of the icon to make it more discernible, especially if its intention is to draw the HCPs attention to the study limitations.

"The colour of the icon matches that of the top of the page, so isn't that differentiated. If it's truly cautionary (which it is), I recommended a colour that reflects that more – e.g. red."

Theme 3: Universality & Interpretation of the Symbol N = 6

The exclamation mark as a symbol is largely seen as universal, but there are varying opinions on its clarity for conveying the intended message.

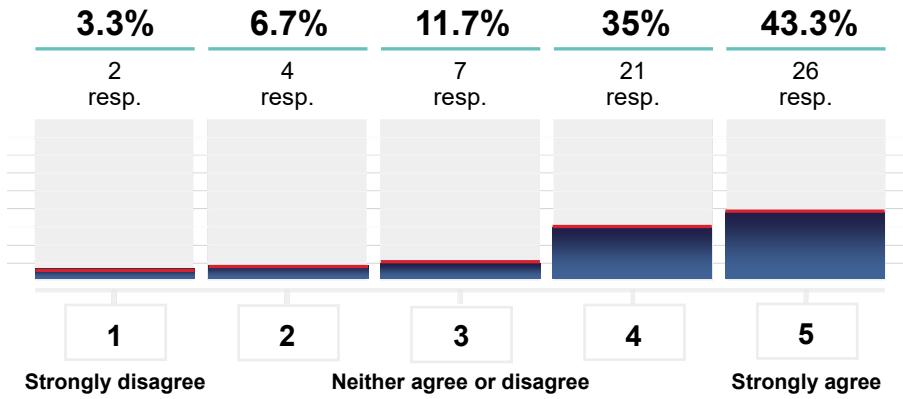
"Does not really symbolize care or caution but more like it commands attention"

"I think the ! symbol is quite universal as a 'hey there! hold up! read me!'"

RWE Visual Presentation

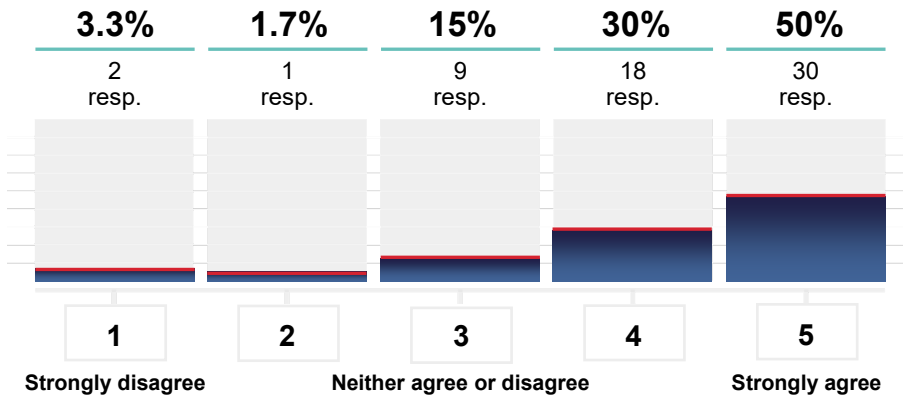
Please rate the following icon on how effectively it would draw your attention to the explanatory statement shown previously

(60 out of 60 people answered this question)



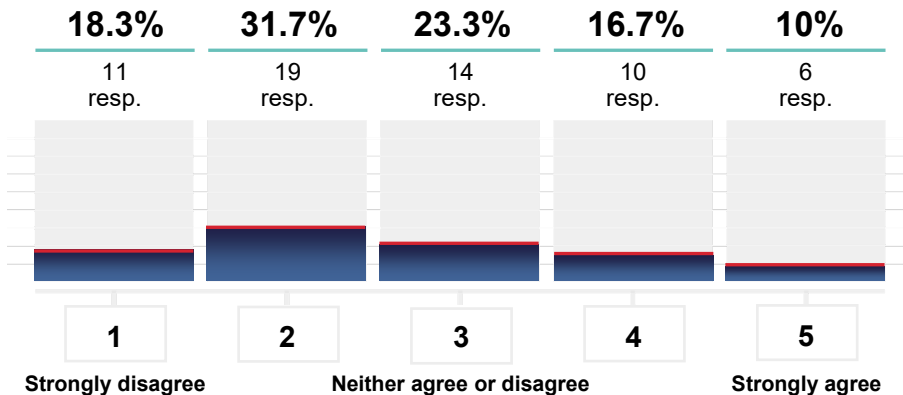
Please rate the following icon on how effectively it would draw your attention to the explanatory statement shown previously.

(60 out of 60 people answered this question)



Please rate the following icon on how effectively it would draw your attention to the explanatory statement shown previously.

(60 out of 60 people answered this question)



RWE Visual Presentation

Please rank the icons in order of your preference.

1 being your favourite, 3 being your least.

Participants ranked the icons in order of preference as noted below:

1

72% (n = 43)



2

20% (n = 12)



3

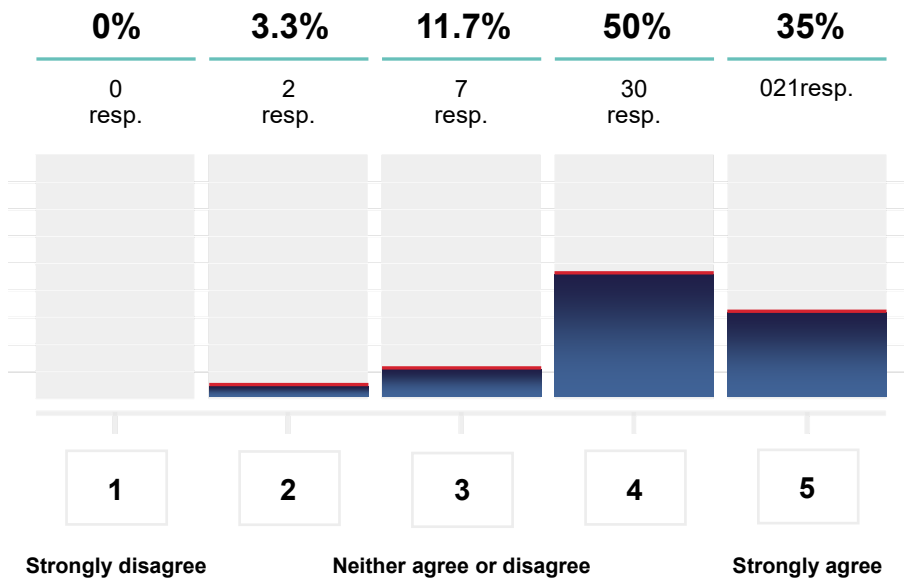
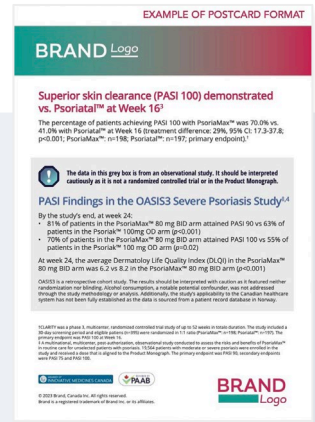
8% (n = 5)



RWE Visual Presentation

Based on the collective measures being proposed, I can easily identify information that should be interpreted with care and caution.

(60 out of 60 people answered this question)



Participants indicated that the aggregate measures facilitated the necessary caution for the examination of the content. They further emphasized the efficacy of the specific elements and their synergistic combination, while also providing suggestions for subsequent refinements.

Theme 1: Effective Visual Differentiation. N = 7

Visual cues, like shading, icons, and distinct boxes, enable better distinction of important information. Several doctors appreciate how visual differentiation, whether through icons, boxes, or shading, distinguishes the critical content from other parts of the advertisement. This distinction allows them to readily identify the content requiring careful interpretation.

"Everything in the 'box' looks different from the rest of the page."

Theme 2: Suggested Enhancements for Improved Clarity. N = 8

Doctors recommend certain enhancements like selective bolding, colour changes, and font differentiation to ensure critical content is highlighted effectively. While the doctors acknowledge the advertisement's effectiveness, they also provide constructive feedback on areas of improvement, particularly around font, text size, and colour to further emphasize the critical data.

"I actually think that the 1st sentence of section 3 should be bolded and in the same text as the '!' statement."

Theme 3: Recognition of Comprehensive Design Elements. N = 6

Doctors acknowledge the combination of design elements, including icons, text size, shading, and explanatory notes, work together to emphasize important content. Several comments underline a broad recognition of the multifaceted design approach in the advertisement, including shading, highlighting, and larger text, which collectively draws attention and aids in comprehension.

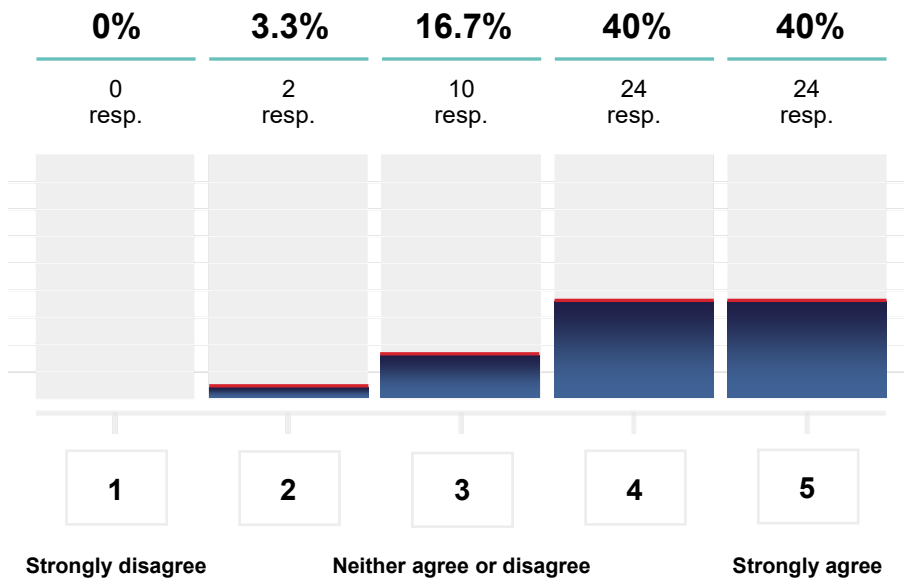
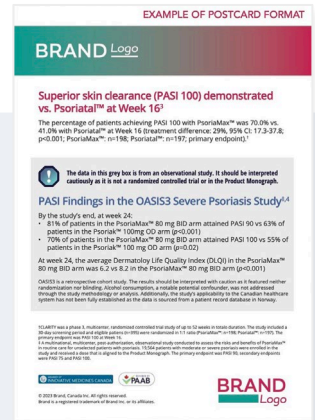
"I can easily identify information that should be interpreted with care and caution because the text is boxed, and the exclamation point icon is present."

RWE Visual Presentation

Based on the collective measures being proposed,

I can quickly differentiate the types of content being presented and this is an important time saving consideration for me.

(60 out of 60 people answered this question)



Participants agreed that presenting the RWE data in this format enabled them to quickly differentiate RWE from gold standard RCT data.

Theme 1: Clarity and Conciseness of Presentation. N = 9

Doctors appreciate the clear and concise layout, which aids in quick information processing for clinical decision-making. Expansion on title: The majority of doctors appreciate the streamlined presentation of the advertisement. The clear and concise nature of the information helps them easily identify the relevant content, making it simpler to apply in their clinical decision-making.

"Information presented in a concise and well-constructed manner."

Theme 2: Effective Differentiation Through Design. N = 7

Design elements such as colour differentiation, font sizes, and distinct segments make the content readily distinguishable. Doctors recognize the use of various design elements that help in differentiating between different types of content. This differentiation is essential for them to quickly identify and understand the presented information.

"I can efficiently differentiate the types of content being presented due to the distinct presentation styles, such as boxed paragraphs, light backgrounds (including those within the box), and the logical item order."

Theme 3: Highlighted Critical Information for Quick Reference. N = 6

Doctors value the ability to immediately identify where the critical information lies, ensuring they're well-informed during decision-making. Many doctors pointed out that the advertisement effectively highlights essential details, allowing them to be better informed. Such features are especially valuable when doctors need to make quick clinical decisions based on the presented information.

Yes. This is very helpful to identify immediately where to read the critical information and what exactly I need to be aware of when applying the information to my clinical decision making."

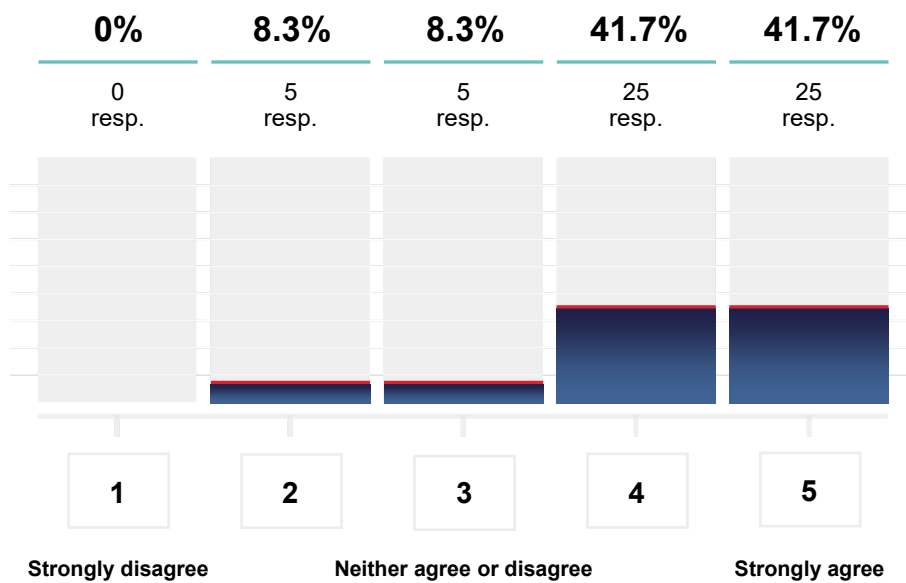
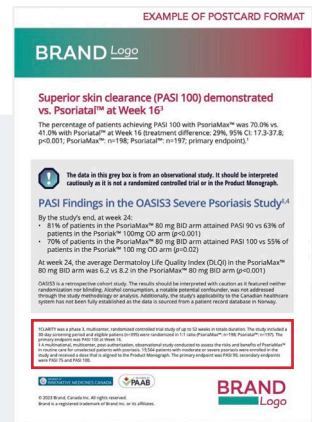
2

RWE Base Requirements

Transparent RWE Disclosures

The published paper contains sufficient methodologic information, and clearly states the findings and any limitations of the methodology and findings.

(60 out of 60 people answered this question)



Participants agreed that this presentation of RWE successfully states any limitations of the methodology.

Theme 1: Emphasis on Transparency & Completeness. N = 6

Doctors highlighted the importance of a complete and transparent presentation of study limitations, methodology, and findings for accurate application and critical for determining how to apply the knowledge to patient care effectively.

Theme 2: Clarity & Conciseness of Information. N = 5

Doctors value clear, succinct, and easy-to-understand summaries of study specifics, which aid in quick understanding and decision-making. The doctors have highlighted the need for clear and concise information, particularly about the study type, sample size, and variables tested. This makes the data more digestible and aids in its effective application.

Theme 3: Importance of Knowledge Contextualization. N = 4

Doctors emphasize the significance of understanding the broader context in which a study is conducted, including comparisons to other studies, for better comprehension and application. Some doctors noted that while they need clear findings and limitations from a single study, understanding how these findings fit within the larger body of evidence or relate to other studies is equally crucial.

"...limitations were well mentioned, with bias of the study identified. This is important before applying knowledge to patient care."

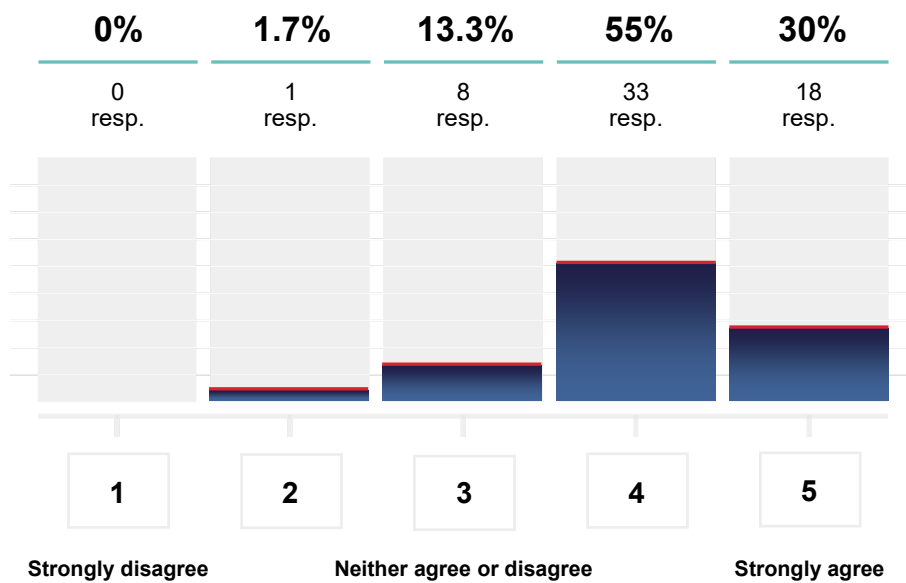
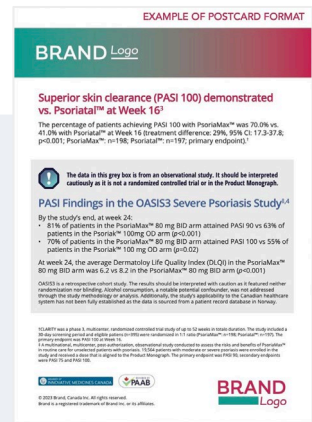
"Excellent succinct information about the type of study, how many people, variable being tested etc."

"I need to know what kind of data I am working with in order to place a weight/significance on the new research to help guide decision making."

Transparent RWE Disclosures

The methodology is predefined in the publication, and any amendments to the methodology are clearly justified (e.g. required for additional scientific merit).

(60 out of 60 people answered this question)



Doctors agreed that this presentation of the methodology is clearly justified in the visual presentation.

Theme 1: Clarity & Presentation of Methodology. N = 7

Doctors emphasize the importance of having a clear, predefined, and well-presented methodology. This ensures that the research is unbiased, sound, can be critically assessed, and is easily understandable.

"It is important to disclose all details re methodology so that the reader can critically assess the data that are being presented to support a promo claim in the piece."

Theme 2: Application to Clinical Practice. N = 3

The methodology and the quality of research directly influence clinical decision-making. High-quality research is preferred as it provides more accurate and applicable insights for patient care.

"High quality research will always trump low quality research for clinical decision making."

Theme 3: Concerns about Changes & Bias. N = 4

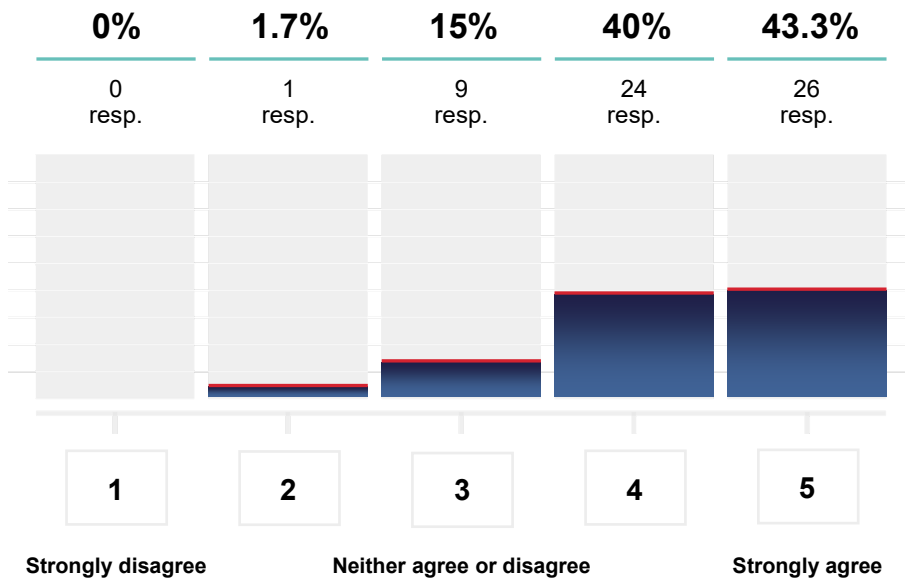
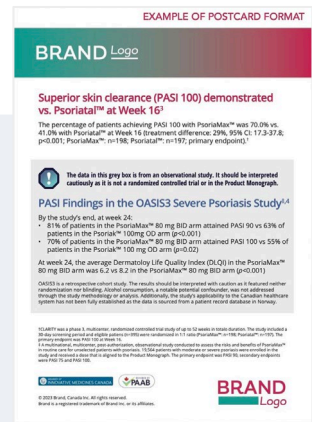
Any changes to the predefined methodology can lead to misinterpretation of data and potential biases. Such changes need to be justified and examined with caution.

"Changes to the methodology could also lead to misinterpretation of the data. If the changes and comments identify potential alternative benefits compared to the primary outcomes, the data needs to be re-examined with caution and would warrant further or another study to identify whether said changes were actually real."

Transparent RWE Disclosures

The data are collected from empirical observation (as opposed to sponsor-influenced modelling).

(60 out of 60 people answered this question)



The doctors' comments, emphasized the importance of unbiased data, the need for clarity in presentation, and the preference for empirical evidence over modelling.

Theme 1: Importance of Unbiased Data. N = 8

Doctors emphasize the criticality of unbiased data collection and interpretation. They believe that empirical evidence, as opposed to sponsor-influenced modelling, offers a more reliable and ethical approach to data analysis.

".....sponsors have their agenda & goals & ways to interpret data which may not always be beneficial or the exact truth."

Theme 2: Empirical Evidence Over Modelling. N = 6

There's a strong preference for empirical evidence over sponsor-influenced modelling. Doctors believe that empirical data, derived from real-world observations, is more valuable and trustworthy in scientific research.

"There is a place and use-cases for modelling, however empirical evidence is key."

Theme 3: Clarity & Presentation. N = 3

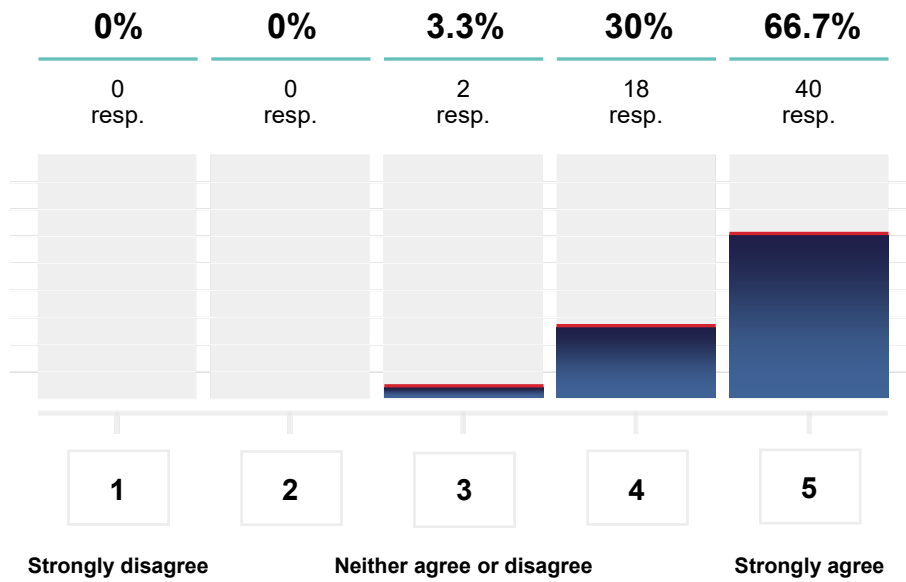
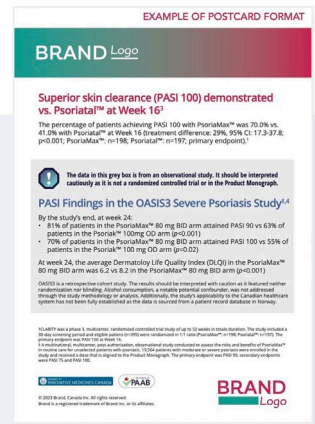
Doctors highlight the need for clarity in the presentation of data and terms. Clear definitions and tables can enhance understanding and interpretation, ensuring that the data's significance is easily grasped.

"Needs to be put in table to make it easier for the reader to understand."

Transparent RWE Disclosures

It is important to know about currently available real-world evidence.

(60 out of 60 people answered this question)



Doctors value RWE for its ability to complement RCTs by offering broader insights, its role in gauging drug performance in real-world scenarios, and its presentation in easily digestible formats for quick reference and deeper exploration.

Theme 1: RWE as a Comprehensive & Complementary Tool to RCTs. N = 5

Doctors view RWE as a valuable supplement to randomized controlled trials (RCTs), offering insights that might not be captured in a controlled environment and providing a broader perspective, especially when RCTs might not be fully generalizable.

"RWE is sometimes all we have - and it's important to acknowledge this, while understanding its limitations."

Theme 2: RWE's Role in Understanding Drug Performance in Real-World Settings. N = 6

Doctors emphasize the importance of RWE in understanding how drugs perform outside of clinical trials, especially when considering their effectiveness and potential side effects in diverse populations.

"It is vital to understand the expected performance of a drug in the real world, as drug effectiveness tends to decrease outside clinical trials."

Theme 3: Ease of Access & Digestibility of RWE. N = 4

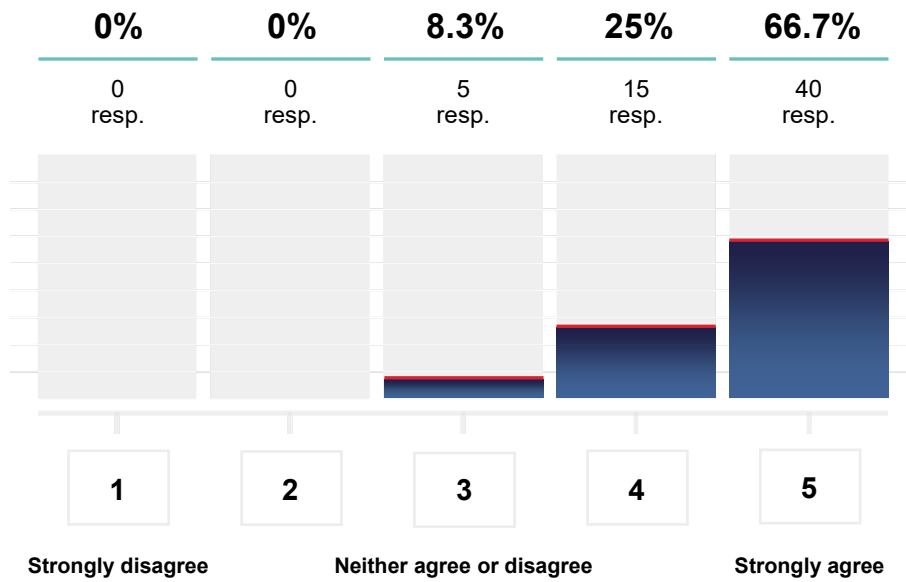
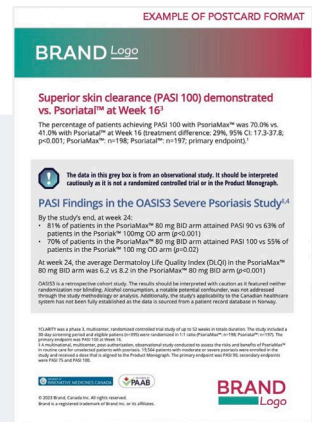
Doctors value the presentation of RWE in easily digestible formats, such as infographics, which allow for quick insights and further exploration if desired.

"There are so many new studies, new treatment options, etc., so when a mini-infographic is created that delivers a brief snapshot of a study, it is exciting as the new evidence is easily digested and if the clinician wants to read more about it, they can easily look up the study."

Transparent RWE Disclosures

Real world evidence is useful to me in my practice.

(60 out of 60 people answered this question)



These themes capture the essence of the doctors' comments, emphasizing the real-world applicability of RWE, its role as a complement to controlled trials, its importance in evidence-based decision-making, and its ability to keep pace with current practice.

Theme 1: Real-World Applicability N = 5

Doctors value RWE because it reflects the realities of clinical practice. They believe that RWE provides insights that are directly applicable to real patients with genuine health concerns, making it more relevant than controlled trials in many scenarios.

"We live in the real world and have real patients with real diseases that need real meds."

Theme 2: Complement to Controlled Trials. N = 6

While randomized controlled trials (RCTs) are considered the gold standard, doctors appreciate RWE for capturing data not always evident in RCTs. They believe RWE offers a broader perspective, especially when certain populations are excluded from controlled studies.

"It is nice to know how likely is a treatment going to be effective, NN2, clinically significant results, new treatments with great results etc. This way if a patient asks about it, I can give them an evidence-based answer."

Theme 3: Keeping Pace with Current Practices. N = 4

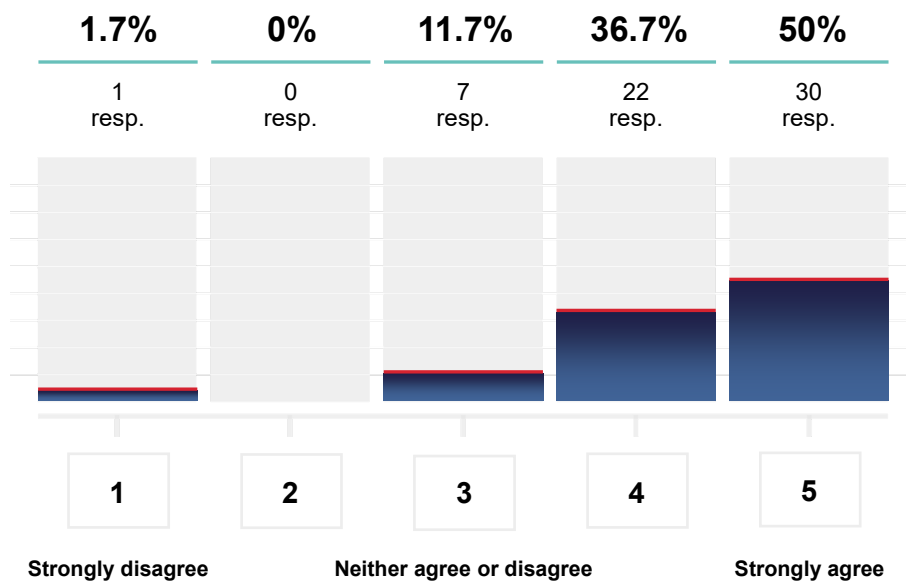
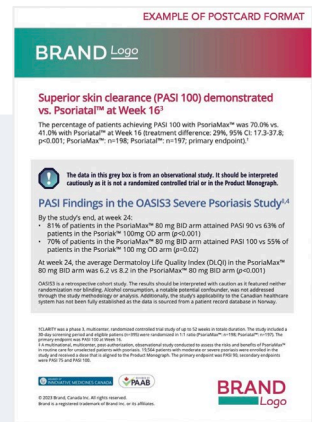
Doctors highlight that RWE helps them stay updated with current practices, especially when guidelines lag behind. They believe RWE offers insights into medication tolerability, patient follow-up, and other evolving aspects of patient care.

"Current guidelines are often behind on current practice which changes based on real-world evidence of medication tolerability, patient follow up etc."

Transparent RWE Disclosures

The addition of real world evidence that meets defined base requirements for evidence increases the utility and value of advertising.

(60 out of 60 people answered this question)



Doctors overall appreciate the value of Real World Evidence in drug advertising overall.

Theme 1: Reflective of Real-World Practice & Informed Decision Making. N = 10

Doctors appreciate RWE because it mirrors their actual practice experiences and provides additional insights beyond traditional data, aiding in more informed clinical decision-making.

"RWE is valuable as it offers additional information beyond what is normally reported in the Product Monograph and clinical investigation report, as it is commonly collected from a large number of individuals and diverse patient populations."

Theme 2: Enhanced Credibility & Trustworthiness. N = 5

Doctors believe that the inclusion of real-world evidence (RWE) in advertising can enhance the credibility and trustworthiness of the information presented.

"Real world evidence is key for any advertising."

Theme 3: Need for a Balanced View on RWE & Traditional Data. N = 3

While doctors recognize the value of RWE, they also emphasize the importance of not overshadowing gold standard data from trials.

"I would rather see gold standard data from trials than distracting/diluting RWE unless it is unique and truly fills a gap in our understanding of the trial data."

Appendix 1

Participants contributed from the following institutions:

BC Children's Hospital
Canadian Red Cross
CancerCare Manitoba
CHUQ (Quebec University...)
CMPA
Community
Credit Valley Family Health Team
Cross Cancer Institute
Dentistry On King
Dr Dallas Med Prof Corp
Dr. Kingsley R. Lee Inc.
First Town Dental
fondation-de-l-ordre-des-dentistes-
du-québec
Fraser Health Authority
Halton Healthcare
Heartlake health centre
Hotel-dieu de sherbrooke
Luna Rx Pharmacy
McGill University
McMaster
Medicine Hat Adult Addiction &
Mental Health Clinic
Neuroperforma

Niagara Health
North Bay
North York General Hospital
North-eastern University College of
Professional Studies
Ottawa Department of Medicine
Perceiv AI
Princess Margaret Hospital/UHN
Purposemed
Region of Peel
RI-MUHC - Glen site - Centre for
Innovative Medicine
Royal Columbian
Southlake regional health centre
Sunnybrook health science centre
The Hospital for Sick Children
The Neuro (Montreal Neurological
Institute-Hospital)
The Simkin Centre; Shared Health
Manitoba
University Health Network
University of Saskatchewan
University of Toronto
Wascana rehabilitation

Thank You

