The design

The use of the exclamation mark is intended to capture the user's attention.

The diamond was selected as it is commonly recognized as a standard caution sign. It intuitively establishes that the copy requires additional caution to draw the reader to the explanatory notes and act as a reminder on subsequent spreads.

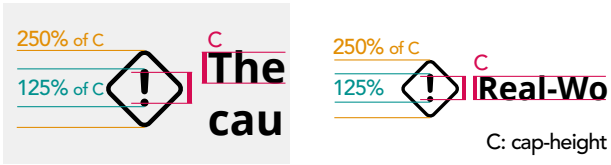
PAAB has provided guidance in the design section while intentionally avoiding overly prescriptive direction based on industry feedback. Note: The information that must appear in the Attention Icon formatting space should remain clearly distinct from any other content. If a design variation affects this clarity or separation, PAAB will request changes to maintain the integrity of the Attention Icon and advertising standards.

Recommended icon use

Minimum size

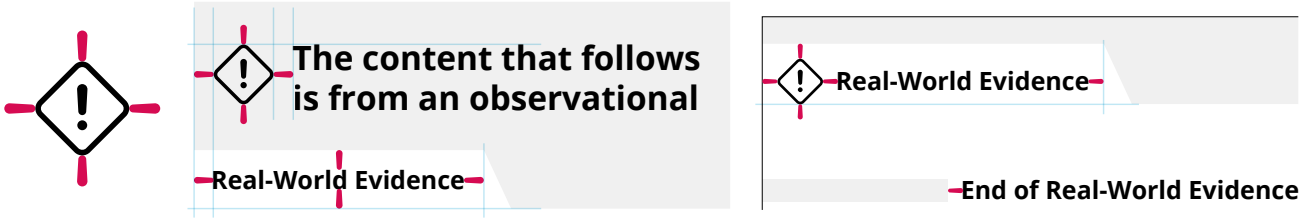
The icon should be scaled to a minimum of 250% of the copy cap-height in the corresponding box, which makes the exclamation mark 125% bigger than the cap-height. PAAB will base the calculation on the larger of the text in the copy or the text in images (e.g., graphics). For an explanation of cap-height, see Guidance on Indication and Fair Balance Font Size.

NOTE: This is a minimum, not a standard size. The icon must be large enough to always stand out in the presentation.



Clear space

The minimum clear space surrounding the icon is equivalent to the height of the exclamation point, without its point.
The clear space around the text in the TAB corresponds to the same minimum clearance as the icon. The "Real-World Evidence" or "Real-World Data" text in the TAB has to respect a ratio of 75% of the body copy and has to be easily legible. When the RWE/RWD icon is placed inside the TAB, the clearance is based on the icon's dimensions (see image below). The RWE/RWD icon is aligned with the top of the first line when placed next to a paragraph, or centered with the height of a single-line of text.



Icon dos and don’ts

PREFFERED use

Always use the black version when accompanying the disclaimer in the grey box.

WHEN NECESSARY
use a knockout

The icon on the **TAB** can be black or white, whichever creates greater contrast against the tab colour.

DO NOT add colours

Only the black and white icons will be considered to avoid any misleading implications associated to a product’s brand book.

DO NOT rotate or scale

The octagon is as wide as it is large. It should keep its proportions at all time.

In use

The explanatory statement next to the RWE icon uses the same font size as the copy, and is bolded black. The font size is the same as regular copy.

The content that follows is from an observational study. It should be interpreted cautiously as it is not a randomized controlled trial or in the Product Monograph.

Real-World Evidence

The grey header colour composition is **C0 M0 Y0 K8**.

Duis autem vel eum iriure dolor

The headline has equal or reduced prominence to the main headline of the APS when the APS containes other headlines.

In hendrerit in vulputate velit esse molestie consequat, vel illum dolore eu feugiat nulla facilisis at vero eros et accumsan.

Key study limitations

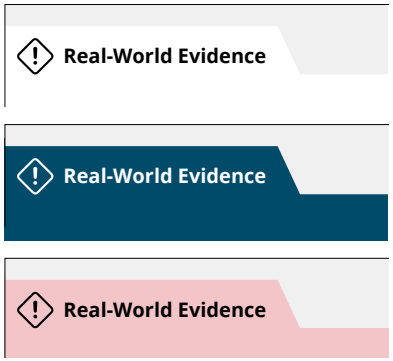
Key limitations perspiciatis unde omnis iste natus error sit voluptatem accusantium doloremque laudantium, totam rem aperiam. Duis autem vel eum iriure dolor in hendrerit in vulputate velit esse molestie consequat, vel illum dolore eu feugiat nulla facilisis at vero eros et accumsan et iusto odio dignissim qui blandit praesent luptatum zzril delenit augue duis dolore te feugait nulla facilisi.

The key study limitations are introduced with a bolded and underlined "Key Study Limitations" subhead. The font size is a minimum of 75% of the body copy and easily legible. The headline and copy may appear in brand colours as long as prominence, clarity, or legibility are not reduced.

End of Real-World Evidence

The **Grey Closing Bar** indicates where the RWE presentation ends; the line colour composition is C0 M0 Y0 K8. The closing copy text must be bolded and 75% of the main body text.

In use



The **TAB** can be presented on white background or brand-colour background.

The guiding principles are that it must clearly denote a visual framing of the content between the grey header and the grey closing bar. Reviewers will request adaptation if visual elements impede clear visual framing. The tab can be white or brand colours. If choosing to use brand colours, ensure that contrast is high.

Text size must bea minimum 75% of body copy. In instances where the size of the tool or copy renders it difficult to read easily, the Reviewer may request increased sizing to ensure the integrity of the Attention Icon formatting.

Copy on the tab should be reflective of the nature of the data within the Attention Icon presentation.

The following is an evolving list:

- Real World Evidence
- Subjective Endpoint + Open-Label
- Post-Hoc Data*
- Non-Canadian Formulation
- Non-Validated Endpoint*

The preferred presentation of the TAB has a 25° angle. However, for technical and aesthetic reasons, it will appear in a rectangular TAB when presented in an email or on a fax (see next page).

*For consideration in rare diseases

In use

SHALLOW SPACE

The content that follows is from an observational study. It should be interpreted cautiously as it is not a randomized controlled trial or in the Product Monograph.

Real-World Evidence

Duis autem vel eum iriure dolor

In hendrerit in et accumsan.

Key study limitations

Key Study limitations perspiciatis unde omnis iste natus error sit voluptatem accusantium doloremque laudantium, totam rem aperiam.

End of Real-World Evidence

FAX

The content that follows is from an observational study. It should be interpreted cautiously as it is not a randomized controlled trial or in the Product Monograph.

Real-World Evidence

Duis autem vel eum iriure dolor

In hendrerit in et accumsan.

Key study limitations

Key Study limitations perspiciatis unde omnis iste natus error sit voluptatem accusantium doloremque laudantium, totam rem aperiam.

End of Real-World Evidence

To allow maximum legibility when designing a fax, the content is placed in a white box with a black stroke and the text colour is C0 M0 Y0 K100.

EMAIL

The content that follows is from an observational study. It should be interpreted cautiously as it is not a randomized controlled trial or in the Product Monograph.

Real-World Evidence

Duis autem vel eum iriure dolor

In hendrerit in vulputate velit esse molestie consequat, vel illum dolore eu feugiat nulla facilisis at vero eros et accumsan.

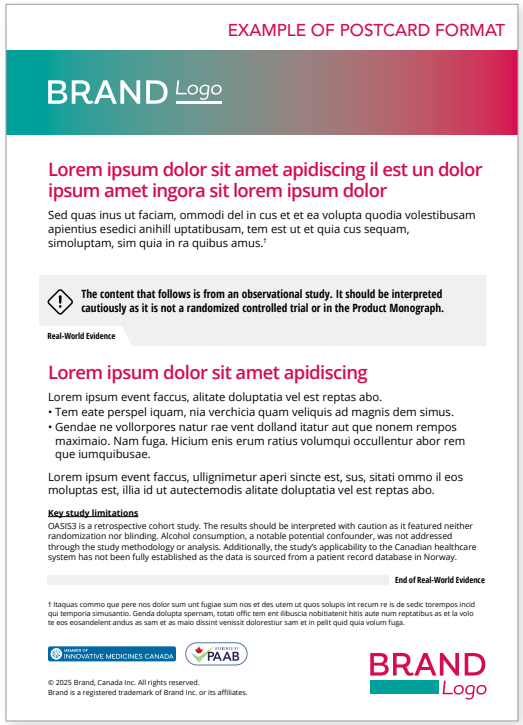
Key study limitations

Key limitations perspiciatis unde omnis iste natus error sit voluptatem accusantium doloremque laudantium, totam rem aperiam.

End of Real-World Evidence

The TAB loses the angle for programming reasons.

Postcard example



EXAMPLE OF POSTCARD FORMAT

BRAND Logo

The icon is aligned with the main content

Lorem ipsum dolor sit amet apidiscing il est un dolor ipsum amet ingora sit lorem ipsum dolor

Sed quas inus ut faciam, ommodi del in cus et et ea volupta quodia volestibusam apientius esedici anihill uptatibusam, tem est ut et quia cus sequam, simoluptam, sim quia in ra quibus amus.†

Minimum 250% of the main body copy cap-height

The content that follows is from an observational study. It should be interpreted cautiously as it is not a randomized controlled trial or in the Product Monograph.

Real-World Evidence

Lorem ipsum dolor sit amet apidiscing

Lorem ipsum event faccus, alitate doluptatia vel est reptas abo.

- Tem eate perspel iquam, nia verchicia quam veliquis ad magnis dem simus.
- Gendae ne vollorpores natur rae vent dolland itatur aut que nonem rempos maximaio. Nam fuga. Hicium enis erum ratius volumqui occullentur abor rem que iumquibusae.

Lorem ipsum event faccus, ullignimetur aperi sincte est, sus, sitati ommo il eos moluptas est, illia id ut autectemodis alitate doluptatia vel est reptas abo.

Key study limitations

OASIS3 is a retrospective cohort study. The results should be interpreted with caution as it featured neither randomization nor blinding. Alcohol consumption, a notable potential confounder, was not addressed through the study methodology or analysis. Additionally, the study's applicability to the Canadian healthcare system has not been fully established as the data is sourced from a patient record database in Norway.

End of Real-World Evidence

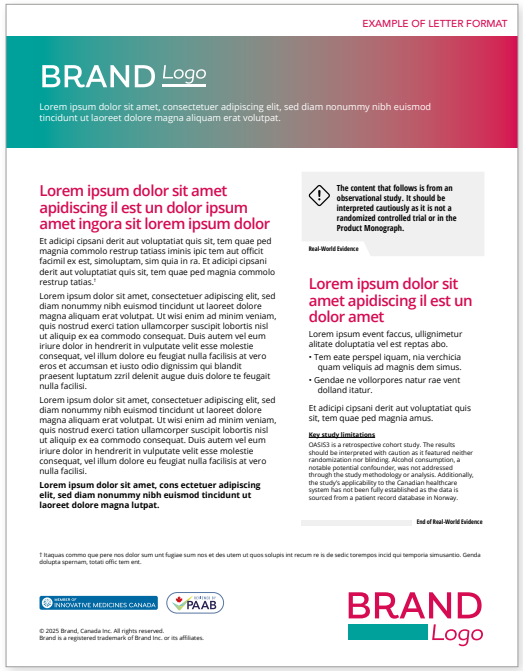
† Itaquas commo que pere nos dolor sum unt fugiae sum nos et des utem ut quos solupis int recum re is de sedic torempos incid qui temporia simusantio. Genda dolupta spernam, totati offic tem ent ilibuscia nobitiatenit hitis aute num reptatibus as et la volo te eos eosandelent andus as sam et as maio dissint venissit dolorestiur sam et in pelit quid quia volum fuga.

MEMBER OF INNOVATIVE MEDICINES CANADA

REVIEWED BY PAAB

BRAND Logo

Letter example


EXAMPLE OF LETTER FORMAT

BRAND Logo

Lorem ipsum dolor sit amet, consectetuer adipiscing elit, sed diam nonummy nibh euismod tincidunt ut laoreet dolore magna aliquam erat volutpat.

Lorem ipsum dolor sit amet apidiscing il est un dolor ipsum amet ingora sit lorem ipsum dolor

Et adicipi cipsani derit aut voluptatiat quis sit, tem quae ped magnia commolo restrup tatiass iminis ipic tem aut officit facimil ex est, simoluptam, sim quia in ra. Et adicipi cipsani derit aut voluptatiat quis sit, tem quae ped magnia commolo restrup tatias.†

Lorem ipsum dolor sit amet, consectetuer adipiscing elit, sed diam nonummy nibh euismod tincidunt ut laoreet dolore magna aliquam erat volutpat. Ut wisi enim ad minim veniam, quis nostrud exerci tation ullamcorper suscipit lobortis nisl ut aliquip ex ea commodo consequat. Duis autem vel eum iriure dolor in hendrerit in vulputate velit esse molestie consequat, vel illum dolore eu feugiat nulla facilisis at vero eros et accumsan et iusto odio dignissim qui blandit praesent luptatum zzril delenit augue duis dolore te feugait nulla facilisi.

Lorem ipsum dolor sit amet, consectetuer adipiscing elit, sed diam nonummy nibh euismod tincidunt ut laoreet dolore magna aliquam erat volutpat. Ut wisi enim ad minim veniam, quis nostrud exerci tation ullamcorper suscipit lobortis nisl ut aliquip ex ea commodo consequat. Duis autem vel eum iriure dolor in hendrerit in vulputate velit esse molestie consequat, vel illum dolore eu feugiat nulla facilisis at vero nulla facilisi.

Lorem ipsum dolor sit amet, cons ectetuer adipiscing elit, sed diam nonummy nibh euismod tincidunt ut laoreet dolore magna lutpat.

The content that follows is from an observational study. It should be interpreted cautiously as it is not a randomized controlled trial or in the Product Monograph.

Real-World Evidence

Lorem ipsum dolor sit amet apidiscing il est un dolor amet

Lorem ipsum event faccus, ullignimetur alitate doluptatia vel est reptas abo.

- Tem eate perspel iquam, nia verchicia quam veliquis ad magnis dem simus.
- Gendae ne vollorpores natur rae vent dolland itatur.

Et adicipi cipsani derit aut voluptatiat quis sit, tem quae ped magnia amus.

Key study limitations

OASIS3 is a retrospective cohort study. The results should be interpreted with caution as it featured neither randomization nor blinding. Alcohol consumption, a notable potential confounder, was not addressed through the study methodology or analysis. Additionally, the study's applicability to the Canadian healthcare system has not been fully established as the data is sourced from a patient record database in Norway.

End of Real-World Evidence

† Itaquas commo que pere nos dolor sum unt fugiae sum nos et des utem ut quos solupis int recum re is de sedic torempos incid qui temporia simusantio. Genda dolupta spernam, totati offic tem ent.

MEMBER OF INNOVATIVE MEDICINES CANADA

REVIEWED BY PAAB

BRAND Logo

EXAMPLE OF LETTER FORMAT

BRAND Logo

Lorem ipsum dolor sit amet, consectetuer adipiscing elit, sed diam nonummy nibh euismod tincidunt ut laoreet dolore magna aliquam erat volutpat.

The text in the box is aligned with the main content

Lorem ipsum dolor sit amet apidiscing il est un dolor ipsum amet ingora sit lorem ipsum dolor

Et adicipi cipsani derit aut voluptatiat quis sit, tem quae ped magnia commolo restrup tatiass iminis ipic tem aut officit facimil ex est, simoluptam, sim quia in ra. Et adicipi cipsani derit aut voluptatiat quis sit, tem quae ped magnia commolo restrup tatias.†

Lorem ipsum dolor sit amet, consectetuer adipiscing elit, sed diam nonummy nibh euismod tincidunt ut laoreet dolore magna aliquam erat volutpat. Ut wisi enim ad minim veniam, quis nostrud exerci tation ullamcorper suscipit lobortis nisl ut aliquip ex ea commodo consequat. Duis autem vel eum iriure dolor in hendrerit in vulputate velit esse molestie consequat, vel illum dolore eu feugiat nulla facilisis at vero eros et accumsan et iusto odio dignissim qui blandit praesent luptatum zzril delenit augue duis dolore te feugait nulla facilisi.

Lorem ipsum dolor sit amet, consectetuer adipiscing elit, sed diam nonummy nibh euismod tincidunt ut laoreet dolore magna aliquam erat volutpat. Ut wisi enim ad minim veniam, quis nostrud exerci tation ullamcorper suscipit lobortis nisl ut aliquip ex ea commodo consequat. Duis autem vel eum iriure dolor in hendrerit in vulputate velit esse molestie consequat, vel illum dolore eu feugiat nulla facilisis at vero nulla facilisi.

Lorem ipsum dolor sit amet, cons ectetuer adipiscing elit, sed diam nonummy nibh euismod tincidunt ut laoreet dolore magna lutpat.

The content that follows is from an observational study. It should be interpreted cautiously as it is not a randomized controlled trial or in the Product Monograph.

Real-World Evidence

Lorem ipsum dolor sit amet apidiscing il est un dolor amet

Lorem ipsum event faccus, ullignimetur alitate doluptatia vel est reptas abo.

- Tem eate perspel iquam, nia verchicia quam veliquis ad magnis dem simus.
- Gendae ne vollorpores natur rae vent dolland itatur.

Et adicipi cipsani derit aut voluptatiat quis sit, tem quae ped magnia amus.

Key study limitations

OASIS3 is a retrospective cohort study. The results should be interpreted with caution as it featured neither randomization nor blinding. Alcohol consumption, a notable potential confounder, was not addressed through the study methodology or analysis. Additionally, the study's applicability to the Canadian healthcare system has not been fully established as the data is sourced from a patient record database in Norway.

End of Real-World Evidence

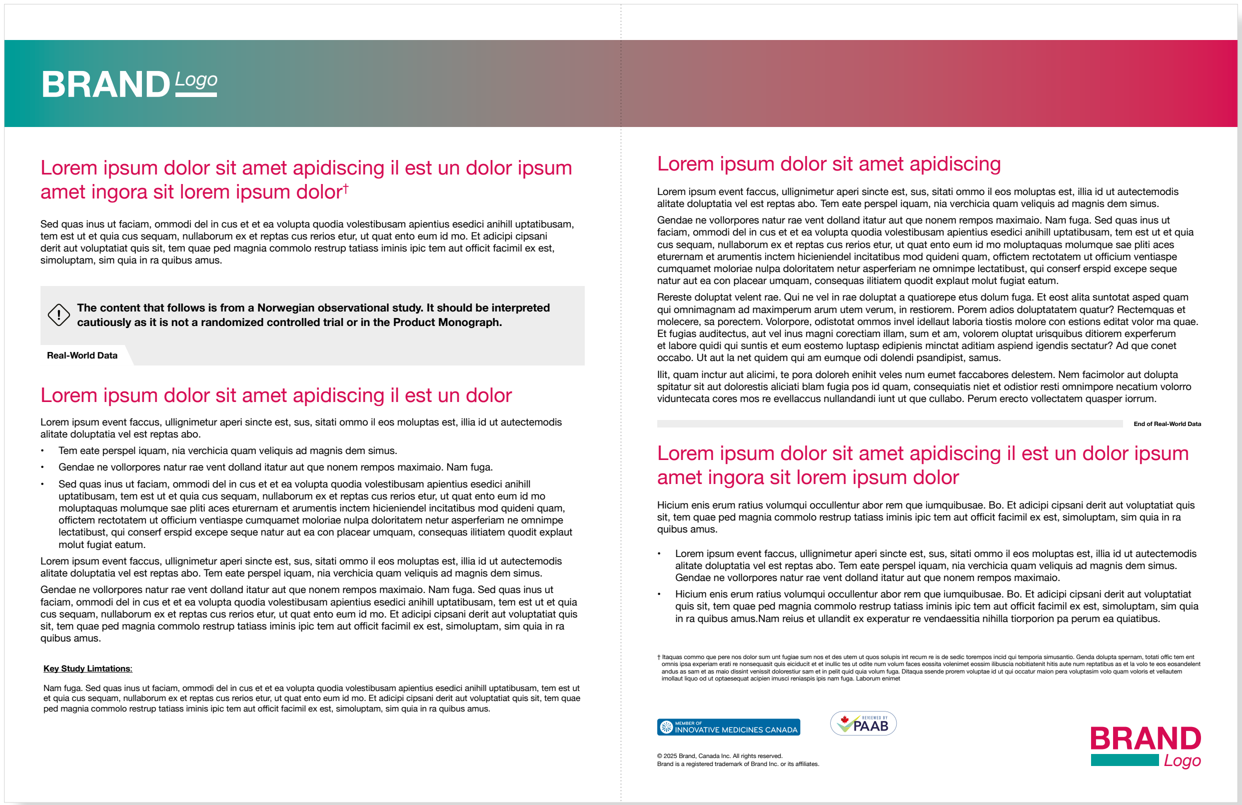
† Itaquas commo que pere nos dolor sum unt fugiae sum nos et des utem ut quos solupis int recum re is de sedic torempos incid qui temporia simusantio. Genda dolupta spernam, totati offic tem ent.

MEMBER OF INNOVATIVE MEDICINES CANADA

REVIEWED BY PAAB

BRAND Logo

Brochure example


BRAND Logo

Lorem ipsum dolor sit amet apidiscing il est un dolor ipsum amet ingora sit lorem ipsum dolor†

Sed quas inus ut faciam, ommodi del in cus et et ea volupta quodia volestibusam apientius esedici anihill uptatibusam, tem est ut et quia cus sequam, nullaborum ex et reptas cus rerios etur, ut quat ento eum id mo. Et adicipi cipsani derit aut voluptatiat quis sit, tem quae ped magnia commolo restrup tatiass iminis ipic tem aut officit facimil ex est, simoluptam, sim quia in ra quibus amus.

The content that follows is from a Norwegian observational study. It should be interpreted cautiously as it is not a randomized controlled trial or in the Product Monograph.

Real-World Data

Lorem ipsum dolor sit amet apidiscing il est un dolor

Lorem ipsum event faccus, ullignimetur aperi sincte est, sus, sitati ommo il eos moluptas est, illia id ut autectemodis alitate doluptatia vel est reptas abo.

- Tem eate perspel iquam, nia verchicia quam veliquis ad magnis dem simus.
- Gendae ne vollorpores natur rae vent dolland itatur aut que nonem rempos maximaio. Nam fuga.
- Sed quas inus ut faciam, ommodi del in cus et et ea volupta quodia volestibusam apientius esedici anihill uptatibusam, tem est ut et quia cus sequam, nullaborum ex et reptas cus rerios etur, ut quat ento eum id mo moluptaquas molumque sae pliti aces eturernam et arumentis inctem hicieniendel incitatibus mod quideni quam, offictem rectotatem ut officium ventiaspe cumquamet moloriae nulpa doloritatem netur asperferiam ne omnimpe lectatibust, qui conserf erspid excepe seque natur aut ea con placear umquam, consequas illitatem quodit explaut molut fugiat eatum.

Lorem ipsum event faccus, ullignimetur aperi sincte est, sus, sitati ommo il eos moluptas est, illia id ut autectemodis alitate doluptatia vel est reptas abo. Tem eate perspel iquam, nia verchicia quam veliquis ad magnis dem simus.

Gendae ne vollorpores natur rae vent dolland itatur aut que nonem rempos maximaio. Nam fuga. Sed quas inus ut faciam, ommodi del in cus et et ea volupta quodia volestibusam apientius esedici anihill uptatibusam, tem est ut et quia cus sequam, nullaborum ex et reptas cus rerios etur, ut quat ento eum id mo. Et adicipi cipsani derit aut voluptatiat quis sit, tem quae ped magnia commolo restrup tatiass iminis ipic tem aut officit facimil ex est, simoluptam, sim quia in ra quibus amus.

Key Study Limtations:

Nam fuga. Sed quas inus ut faciam, ommodi del in cus et et ea volupta quodia volestibusam apientius esedici anihill uptatibusam, tem est ut et quia cus sequam, nullaborum ex et reptas cus rerios etur, ut quat ento eum id mo. Et adicipi cipsani derit aut voluptatiat quis sit, tem quae ped magnia commolo restrup tatiass iminis ipic tem aut officit facimil ex est, simoluptam, sim quia in ra quibus amus.

Lorem ipsum dolor sit amet apidiscing

Lorem ipsum event faccus, ullignimetur aperi sincte est, sus, sitati ommo il eos moluptas est, illia id ut autectemodis alitate doluptatia vel est reptas abo. Tem eate perspel iquam, nia verchicia quam veliquis ad magnis dem simus.

Gendae ne vollorpores natur rae vent dolland itatur aut que nonem rempos maximaio. Nam fuga. Sed quas inus ut faciam, ommodi del in cus et et ea volupta quodia volestibusam apientius esedici anihill uptatibusam, tem est ut et quia cus sequam, nullaborum ex et reptas cus rerios etur, ut quat ento eum id mo moluptaquas molumque sae pliti aces eturernam et arumentis inctem hicieniendel incitatibus mod quideni quam, offictem rectotatem ut officium ventiaspe cumquamet moloriae nulpa doloritatem netur asperferiam ne omnimpe lectatibust, qui conserf erspid excepe seque natur aut ea con placear umquam, consequas illitatem quodit explaut molut fugiat eatum.

Rereste doluptat velent rae. Qui ne vel in rae doluptat a quatiorepe etus dolum fuga. Et eost alita suntotat asped quam qui omnimagnam ad maximperum arum utem verum, in restiorem. Porem adios doluptatem quatur? Rectemquas et molecere, sa porectem. Volorpore, odistotat ommos invel idellaut laboria tiostis molore con estions editat volor ma quae. Et fugias auditectus, aut vel inus magni corectiam illam, sum et am, volorem oluptat urisquibus ditiorem experferum et labore quidi qui suntis et eum eostemo luptasp edipienis minctat aditiam aspiend igendis sectatur? Ad que conet occabo. Ut aut la net quidem qui am eumque odi dolendi psandipist, samus.

Ilit, quam inctur aut alicimi, te pora doloreh enihit veles num eumet faccabores delestem. Nem facimolor aut dolupta spitatur sit aut dolorestis aliciati blam fugia pos id quam, consequiatis niet et odistior resti omnimpore necatium volorro viduntecata cores mos re evellaccus nullandandi iunt ut que cullabo. Perum erecto vollectatem quasper iorrum.

End of Real-World Data

Lorem ipsum dolor sit amet apidiscing il est un dolor ipsum amet ingora sit lorem ipsum dolor

Hicium enis erum ratius volumqui occullentur abor rem que iumquibusae. Bo. Et adicipi cipsani derit aut voluptatiat quis sit, tem quae ped magnia commolo restrup tatiass iminis ipic tem aut officit facimil ex est, simoluptam, sim quia in ra quibus amus.

- Lorem ipsum event faccus, ullignimetur aperi sincte est, sus, sitati ommo il eos moluptas est, illia id ut autectemodis alitate doluptatia vel est reptas abo. Tem eate perspel iquam, nia verchicia quam veliquis ad magnis dem simus. Gendae ne vollorpores natur rae vent dolland itatur aut que nonem rempos maximaio.
- Hicium enis erum ratius volumqui occullentur abor rem que iumquibusae. Bo. Et adicipi cipsani derit aut voluptatiat quis sit, tem quae ped magnia commolo restrup tatiass iminis ipic tem aut officit facimil ex est, simoluptam, sim quia in ra quibus amus.Nam reius et ullandit ex experatur re vendaessitia nihilla tiorporion pa perum ea quiatibus.

† Itaquas commo que pere nos dolor sum unt fugiae sum nos et des utem ut quos solupis int recum re is de sedic torempos incid qui temporia simusantio. Genda dolupta spernam, totati offic tem ent omnis ipsa experiam erati re nonsequasit quis eiciducit et et inullic tes ut odite num volum faces eossita volenimet eossim ilibuscia nobitiatenit hitis aute num reptatibus as et la volo te eos eosandelent andus as sam et as maio dissint venissit dolorestiur sam et in pelit quid quia volum fuga. Ditaqua ssende prorem voluptae id ut qui occatur maion pera voluptasim volo quam voloris et vellautem imollaut liquo od ut optaesequat acipien imusci reniaspis ipis nam fuga. Laborum enimet

MEMBER OF INNOVATIVE MEDICINES CANADA

REVIEWED BY PAAB

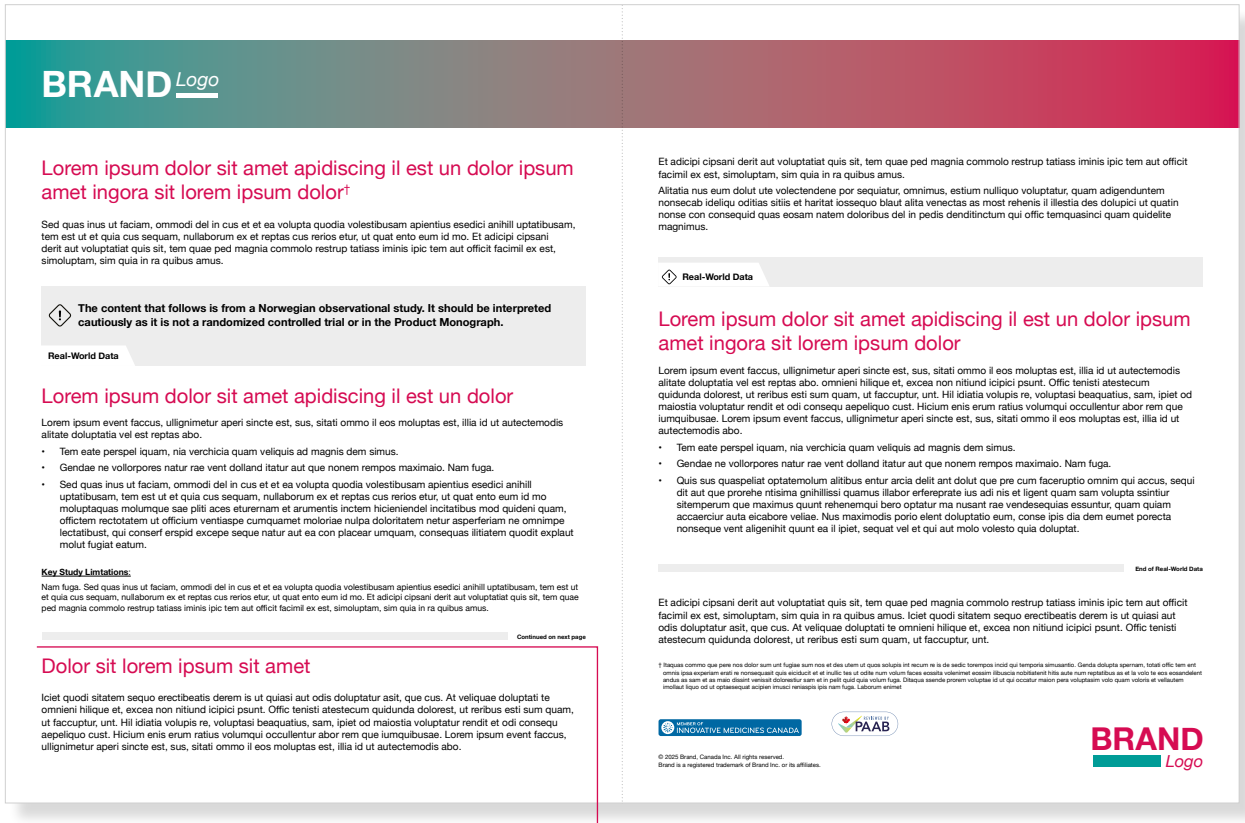
© 2025 Brand, Canada Inc. All rights reserved.
Brand is a registered trademark of Brand Inc. or its affiliates.

BRAND Logo

How to present the RWE/RWD content in a spread, **without interruption**:

1. When the data appears across more than one spread (side by side pages) without interruption, the abbreviated grey tab header is not required.
2. Key study limitations require disclosure.
3. Presence of the closing grey bar is required, where appropriate.

Brochure example



BRAND Logo

Lorem ipsum dolor sit amet apidiscing il est un dolor ipsum amet ingora sit lorem ipsum dolor†

Sed quas inus ut faciam, ommodi del in cus et et ea volupta quodia volestibusam apientius esedici anihill uptatibusam, tem est ut et et quia cus sequam, nullaborum ex et reptas cus rerios etur, ut quat ento eum id mo. Et adicipi cipsani derit aut voluptatiat quis sit, tem quae ped magnia commolo restrup tatiass iminis ipic tem aut officit facimil ex est, simoluptam, sim quia in ra quibus amus.

The content that follows is from a Norwegian observational study. It should be interpreted cautiously as it is not a randomized controlled trial or in the Product Monograph.

Real-World Data

Lorem ipsum dolor sit amet apidiscing il est un dolor

Lorem ipsum event faccus, ullignimetur aperi sincte est, sus, sitati ommo il eos moluptas est, illia id ut autectemodis alitate doluptatia vel est reptas abo.

- Tem eate perspel iquam, nia verchicia quam veliquis ad magnis dem simus.
- Gendae ne vollorpores natur rae vent dolland itatur aut que nonem rempos maximaio. Nam fuga.
- Sed quas inus ut faciam, ommodi del in cus et et ea volupta quodia volestibusam apientius esedici anihill uptatibusam, tem est ut et et quia cus sequam, nullaborum ex et reptas cus rerios etur, ut quat ento eum id mo moluptaquas molumque sae pliti aces eturernam et arumentis inctem hicieniendel incitatibus mod quideni quam, officitem rectotatem ut officium ventiaspe cumquamet moloriae nulpa doloritatem netur asperferiam ne omnimpe lectatibust, qui conserf erspid excepe seque natur aut ea con placear umquam, consequas ilitiatem quodit explaut molut fugiat eatum.

Key Study Limtations:

Nam fuga. Sed quas inus ut faciam, ommodi del in cus et et ea volupta quodia volestibusam apientius esedici anihill uptatibusam, tem est ut et et quia cus sequam, nullaborum ex et reptas cus rerios etur, ut quat ento eum id mo. Et adicipi cipsani derit aut voluptatiat quis sit, tem quae ped magnia commolo restrup tatiass iminis ipic tem aut officit facimil ex est, simoluptam, sim quia in ra quibus amus.

Continued on next page

Dolor sit lorem ipsum sit amet

Iciet quodi sitatem sequo erectibeatis derem is ut quiasi aut odis doluptatur asit, que cus. At veliquae doluptati te omnieni hilique et, excea non nitiund icipici psunt. Offic tenisti atestecum quidunda dolorest, ut reribus esti sum quam, ut faccuptur, unt. Hil idiatia volupis re, voluptasi beaquatius, sam, ipiet od maiostia voluptatur rendit et odi consequ aepeliquo cust. Hicium enis erum ratius volumqui occullentur abor rem que iumquibusae. Lorem ipsum event faccus, ullignimetur aperi sincte est, sus, sitati ommo il eos moluptas est, illia id ut autectemodis abo.

Et adicipi cipsani derit aut voluptatiat quis sit, tem quae ped magnia commolo restrup tatiass iminis ipic tem aut officit facimil ex est, simoluptam, sim quia in ra quibus amus.

Alitatia nus eum dolut ute volectendene por sequiatur, omnimus, estium nulliquo voluptatur, quam adigenduntem nonsecab ideliqu oditias sitiis et haritat iossequo blaut alita venectas as most rehenis il illestia des dolupici ut quatin nonse con consequid quas eosam natem doloribus del in pedis denditinctum qui offic temquasinci quam quidelite magnimus.

Real-World Data

Lorem ipsum dolor sit amet apidiscing il est un dolor ipsum amet ingora sit lorem ipsum dolor

Lorem ipsum event faccus, ullignimetur aperi sincte est, sus, sitati ommo il eos moluptas est, illia id ut autectemodis alitate doluptatia vel est reptas abo. omnieni hilique et, excea non nitiund icipici psunt. Offic tenisti atestecum quidunda dolorest, ut reribus esti sum quam, ut faccuptur, unt. Hil idiatia volupis re, voluptasi beaquatius, sam, ipiet od maiostia voluptatur rendit et odi consequ aepeliquo cust. Hicium enis erum ratius volumqui occullentur abor rem que iumquibusae. Lorem ipsum event faccus, ullignimetur aperi sincte est, sus, sitati ommo il eos moluptas est, illia id ut autectemodis abo.

- Tem eate perspel iquam, nia verchicia quam veliquis ad magnis dem simus.
- Gendae ne vollorpores natur rae vent dolland itatur aut que nonem rempos maximaio. Nam fuga.
- Quis sus quaspeliat optatemolum alitibus entur arcia delit ant dolut que pre cum faceruptio omnim qui accus, sequi dit aut que prorehe ntisima gnihillissi quamus illabor erfereprate ius adi nis et ligent quam sam volupta ssintiur sitemperum que maximus quunt rehenemqui bero optatur ma nusant rae vendesequias essuntur, quam quiam accaerciur auta eicabore veliae. Nus maximodis porio elent doluptatio eum, conse ipis dia dem eumet porecta nonseque vent aligenihit quunt ea il ipiet, sequat vel et qui aut molo volesto quia doluptat.

End of Real-World Data

Et adicipi cipsani derit aut voluptatiat quis sit, tem quae ped magnia commolo restrup tatiass iminis ipic tem aut officit facimil ex est, simoluptam, sim quia in ra quibus amus. Iciet quodi sitatem sequo erectibeatis derem is ut quiasi aut odis doluptatur asit, que cus. At veliquae doluptati te omnieni hilique et, excea non nitiund icipici psunt. Offic tenisti atestecum quidunda dolorest, ut reribus esti sum quam, ut faccuptur, unt.

† Itaquas commo que pere nos dolor sum unt fugiae sum nos et des utem ut quos solupis int recum re is de sedic torempos incid qui temporia simusanto. Ganda doluptа sperram, totati offic tem ent omnis ipsa excperiam entil re nonsequasd quis eicidiucit et et inullic tes ut odite num volum faces ecestia voleninet ecssim libuacia nobitiatenti hitis aute num reptatibus as et la voto te ecs ecsandelent andus as sam et as maio disaint venisat dolorestiur sam et in pelit quid quia volum fuga. Ditaqua ssende prorem voluptae id ut qui occatur maion para voluptasim volo quam voloris et vellautem imollaut liquo od ut optaesequt acipien imuaci reriaspis ipis nam fuga. Luborum enimet

MEMBER OF INNOVATIVE MEDICINES CANADA

LISTED BY PAAB

BRAND Logo

Grey closing bar discloses that the RWE/RWD presentation will be continued on a separate page.

How to present the RWE/RWD content in a spread, **with interruption**:

1. Presence of the abbreviated grey tab header is required.
2. Key study limitations should appear with or prior to the first set of results.
3. Presence of grey closing bar is required.

NOTE: When the path through which the reader accesses the data is or can be non-linear, the explanatory statement and key study limitations may have to be repeated unless functionality is added to ensure the reader has to pass through the initial presentation prior to accessing later sections.

Double RWE/RWD example

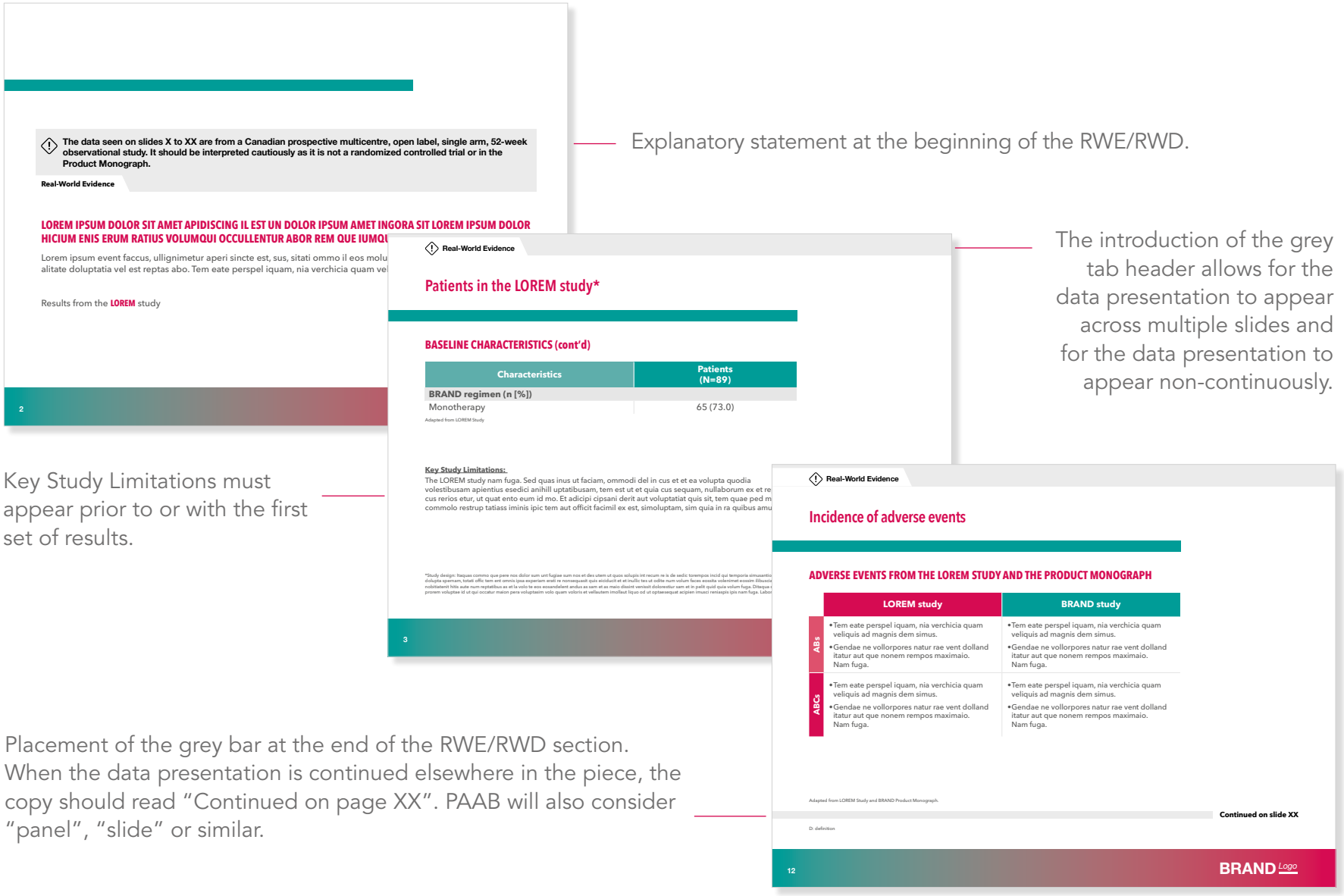
When there are more than one RWE/RWD presentation requiring the use of the Attention icon, each presentation must be self-contained.

Presentations cannot appear in the same Attention Icon formatting space. They must be separate and distinct.

1. Different RWE/RWD presentations require distinct separation.
2. Presence of their own respective grey disclosure tabs, explanatory statement and key study limitations are required.
3. Presence of separate grey closing bars are required.

Visual Aid:
Multi-page example (1/2)

How to present the RWE/RWD content in an APS, **with interruption**.



Explanatory statement at the beginning of the RWE/RWD.

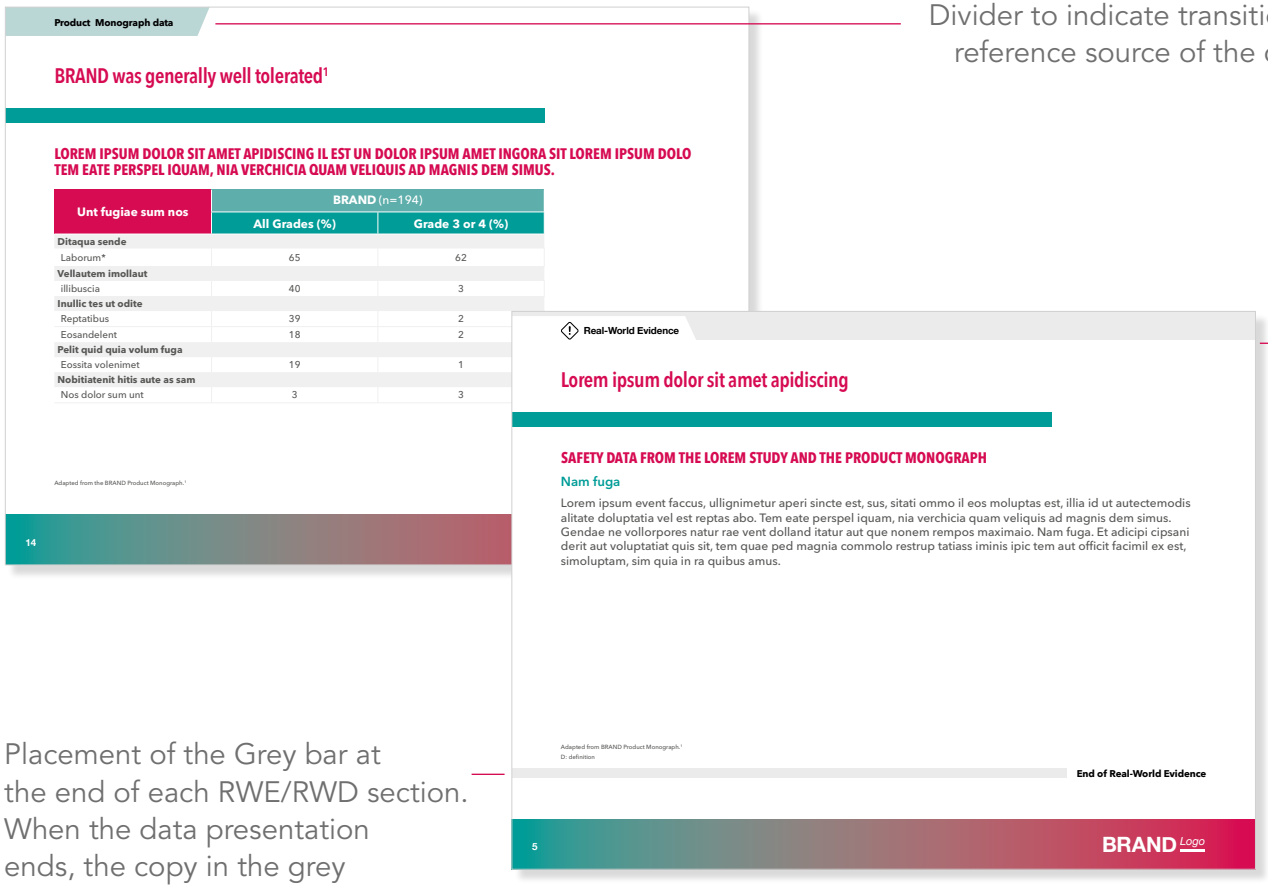
The introduction of the grey tab header allows for the data presentation to appear across multiple slides and for the data presentation to appear non-continuously.

Key Study Limitations must appear prior to or with the first set of results.

Placement of the grey bar at the end of the RWE/RWD section. When the data presentation is continued elsewhere in the piece, the copy should read "Continued on page XX". PAAB will also consider "panel", "slide" or similar.

Visual Aid: Multi-page example (2/2)

How to present the RWE/RWD content in an APS, **with interruption**.



Product Monograph data

BRAND was generally well tolerated[1]

LOREM IPSUM DOLOR SIT AMET APIDISCING IL EST UN DOLOR IPSUM AMET INGORA SIT LOREM IPSUM DOLO TEM EATE PERSPEL IQUAM, NIA VERCHICIA QUAM VELIQUIS AD MAGNIS DEM SIMUS.

Unt fugiae sum nos	BRAND (n=194)	
	All Grades (%)	Grade 3 or 4 (%)
Ditaqua sende		
Laborum*	65	62
Vellautem imollaut		
illibuscia	40	3
Inullic tes ut odite		
Reptatibus	39	2
Eosandelent	18	2
Pelit quid quia volum fuga		
Eossita volenimet	19	1
Nobitiatenit hitis aute as sam		
Nos dolor sum unt	3	3

Adapted from the BRAND Product Monograph.[1]

14

Real-World Evidence

Lorem ipsum dolor sit amet apidiscing

SAFETY DATA FROM THE LOREM STUDY AND THE PRODUCT MONOGRAPH

Nam fuga

Lorem ipsum event faccus, ullignimetur aperi sincte est, sus, sitati ommo il eos moluptas est, illia id ut autectemodis alitate doluptatia vel est reptas abo. Tem eate perspel iquam, nia verchicia quam veliquis ad magnis dem simus. Gendae ne vollorpores natur rae vent dolland itatur aut que nonem rempos maximaio. Nam fuga. Et adicipi cipsani derit aut voluptatiat quis sit, tem quae ped magnia commolo restrup tatiass iminis ipic tem aut officit facimil ex est, simoluptam, sim quia in ra quibus amus.

Adapted from BRAND Product Monograph.[1]
D: definition

End of Real-World Evidence

5

BRAND Logo

Divider to indicate transition and identify the reference source of the content presented.

The TAB is reintroduced after the interruption.

Placement of the Grey bar at the end of each RWE/RWD section. When the data presentation ends, the copy in the grey closing bar should read "End of Real-World Evidence".

The nature of the data should match what was presented on the opening tab and tab throughout. For example, "End of Real-World Data".

REMEMBER: If functionality is added to allow the user to move in a non-linear manner through the piece, the explanatory statement and key study limitations may have to be repeated.

Fax and Black and White layout Examples

BRAND *Logo*

Lorem ipsum dolor sit amet, consectetuer adipiscing elit, dolore magna aliquam erat volutpat.

Lorem ipsum dolor sit amet apidiscing il est un dolor ipsum amet ingora sit lorem ipsum dolor

Et adicipi cipsani derit aut voluptatiat quis sit, tem quae ped magnia commolo restrup tatiass iminis ipic tem aut officit facimil ex est, simoluptam, sim quia in ra. Et adicipi cipsani derit aut voluptatiat quis sit, tem quae ped magnia commolo restrup tatias.†

Lorem ipsum dolor sit amet, consectetuer adipiscing elit, sed diam nonummy nibh euismod tincidunt ut laoreet dolore magna aliquam erat volutpat. Ut wisi enim ad minim veniam, quis nostrud exerci tation ullamcorper suscipit lobortis nisl ut aliquip ex ea commodo consequat. Duis autem vel eum iriure dolor in hendrerit in vulputate velit esse molestie consequat, vel illum dolore eu feugiat nulla facilisis at vero eros et accumsan et iusto odio dignissim qui blandit praesent luptatum zzril delenit augue duis dolore te feugait nulla facilisi.

Lorem ipsum dolor sit amet, consectetuer adipiscing elit, sed diam nonummy nibh euismod tincidunt ut laoreet dolore magna aliquam erat volutpat. Ut wisi enim ad minim veniam, quis nostrud exerci tation ullamcorper suscipit lobortis nisl ut aliquip ex ea commodo consequat. Duis autem vel eum iriure dolor in hendrerit in vulputate velit esse molestie consequat, vel illum dolore eu feugiat nulla facilisis at vero nulla facilisi.

Lorem ipsum dolor sit amet, cons ectetuer adipiscing elit, sed diam nonummy nibh euismod tincidunt ut laoreet dolore magna lutpat.

The content that follows is from an observational study. It should be interpreted cautiously as it is not a randomized controlled trial or in the Product Monograph.

Real-World Evidence

Lorem ipsum dolor sit amet apidiscing il est un dolor amet

Lorem ipsum event faccus, ullignimetur alitate doluptatia vel est reptas abo.

- Tem eate perspel iquam, nia verchicia quam veliquis ad magnis dem simus.
- Gendae ne vollorpores natur rae vent dolland itatur.

Et adicipi cipsani derit aut voluptatiat quis sit, tem quae ped magnia amus.

Key study limitations

OASIS3 is a retrospective cohort study. The results should be interpreted with caution as it featured neither randomization nor blinding. Alcohol consumption, a notable potential confounder, was not addressed through the study methodology or analysis. Additionally, the study's applicability to the Canadian healthcare system has not been fully established as the data is sourced from a patient record database in Norway.

End of Real-World Evidence

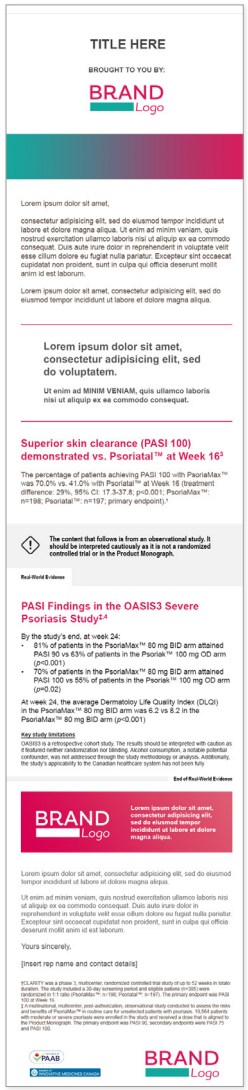
† Itaquas commo que pere nos dolor sum unt fugiae sum nos et des utem ut quos solupis int recum re is de sedic torempos incid qui temporia simusantio. Genda dolupta spernam, totati offic tem ent.

MEMBER OF INNOVATIVE MEDICINES CANADA

REVIEWED BY PAAB

BRAND *Logo*

Digitizing RWE/RWD Data*†


TITLE HERE

BROUGHT TO YOU BY:

BRAND Logo

Lorem ipsum dolor sit amet,

consectetur adipisicing elit, sed do eiusmod tempor incididunt ut labore et dolore magna aliqua. Ut enim ad minim veniam, quis nostrud exercitation ullamco laboris nisi ut aliquip ex ea commodo consequat. Duis aute irure dolor in reprehenderit in voluptate velit esse cillum dolore eu fugiat nulla pariatur. Excepteur sint occaecat cupidatat non proident, sunt in culpa qui officia deserunt mollit anim id est laborum.

Lorem ipsum dolor sit amet, consectetur adipisicing elit, sed do eiusmod tempor incididunt ut labore et dolore magna aliqua.

Lorem ipsum dolor sit amet, consectetur adipisicing elit, sed do voluptatem.

Ut enim ad MINIM VENIAM, quis ullamco laboris nisi ut aliquip ex ea commodo consequat.

Superior skin clearance (PASI 100) demonstrated vs. Psoriatal™ at Week 16[3]

The percentage of patients achieving PASI 100 with PsoriaMax™ was 70.0% vs. 41.0% with Psoriatal™ at Week 16 (treatment difference: 29%, 95% CI: 17.3-37.8; p<0.001; PsoriaMax™: n=198; Psoriatal™: n=197; primary endpoint).†

The content that follows is from an observational study. It should be interpreted cautiously as it is not a randomized controlled trial or in the Product Monograph.

Real-World Evidence

PASI Findings in the OASIS3 Severe Psoriasis Study[‡,4]

By the study's end, at week 24:

- 81% of patients in the PsoriaMax™ 80 mg BID arm attained PASI 90 vs 63% of patients in the Psoriak™ 100 mg OD arm (*p*<0.001)
- 70% of patients in the PsoriaMax™ 80 mg BID arm attained PASI 100 vs 55% of patients in the Psoriak™ 100 mg OD arm (*p*=0.02)

At week 24, the average Dermatoloy Life Quality Index (DLQI) in the PsoriaMax™ 80 mg BID arm was 6.2 vs 8.2 in the PsoriaMax™ 80 mg BID arm (*p*<0.001)

Key study limitations

OASIS3 is a retrospective cohort study. The results should be interpreted with caution as it featured neither randomization nor blinding. Alcohol consumption, a notable potential confounder, was not addressed through the study methodology or analysis. Additionally, the study's applicability to the Canadian healthcare system has not been fully

End of Real-World Evidence

BRAND Logo — Lorem ipsum dolor sit amet, consectetur adipisicing elit, sed do eiusmod tempor incididunt ut labore et dolore magna aliqua.

Lorem ipsum dolor sit amet, consectetur adipisicing elit, sed do eiusmod tempor incididunt ut labore et dolore magna aliqua.

Ut enim ad minim veniam, quis nostrud exercitation ullamco laboris nisi ut aliquip ex ea commodo consequat. Duis aute irure dolor in reprehenderit in voluptate velit esse cillum dolore eu fugiat nulla pariatur. Excepteur sint occaecat cupidatat non proident, sunt in culpa qui officia deserunt mollit anim id est laborum.

Yours sincerely,

[Insert rep name and contact details]

PAAB

BRAND Logo

In an email and mobile layout, the grey area can cover the whole width or remain boxed. For the purposes of emails which are mobile optimized, the tab may be placed in the center to allow for responsive design.

*Grey boxes bleed all the way to the edges on email and mobile templates only.
†Study parameters can appear anywhere on the spread or through a digital link. The footnote would elaborate on the study description. The sponsor may include additional features of the study (i.e., not limited to limitations); these should be presented in a neutral/non-promotional tone.

ACKNOWLEDGEMENTS

PAAB would like to thank the RWE Committee members for their time and invaluable contributions to the development of the original version of this guidance.

Amyn Sayani (AstraZeneca)
Chrysanthy Christopoulos (Lemieux Bédard)
Jefferson Tea (Takeda)
Manushvi Gupta (Reckitt Health & VMS Canada)
Matt Slipek (Havas Health and You)
Nina Hemery (Fisika)
Virginie Giroux (Merck)

This version of the guidance includes major updates to formatting in response to other stakeholder feedback to improve clarity. PAAB would like to thank Maven, Lemieux Bedard and bMod for their collaboration.

PAAB would also like to thank Lemieux Bédard for their design services for this document.

GLOSSARY

Health product

A substance or mixture of substances manufactured, sold or represented by a specific manufacturer for in vivo use in the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical state, or the symptoms thereof; or in restoring, correcting or modifying function(s) in humans. This includes: drugs listed on all schedules of the Food & Drugs Act and Regulations that have a Drug Identification Number (DIN) assigned by Health Canada; and Natural Health Products that includes traditional herbal medicines; traditional Chinese, Ayurvedic (East Indian) and Native North American medicine; homeopathic preparations; and vitamin and mineral supplements that have a Health Canada assigned NPN or DIN-HM and "pharmaceutical products".

This excludes medical devices and cosmetics (except for therapeutic cosmetics) as defined in the Food and Drugs Act and Regulations; products used for in vitro diagnosis of conditions, both normal (pregnancy test kits) or in connection with disordered states of health (blood glucose monitoring devices for diabetes, contact lens solutions, etc.); and food and vitamins being promoted purely for the maintenance of normal health.

Marketing benefit claims

A statement that is designed to promote the sale of a health product. It often highlights a specific product attribute i.e., "longer lasting" or "tastes great".

A promotional statement designed to inform about the product's availability and benefits so as to form/alter the audience's opinion of the medication. It can be explicit (i.e., text) or implicit (i.e., images), comparative or non-comparative. It can relate to pharmacological or non-pharmacological properties of the product.

Not all statements about a product are "marketing claims of benefit". Common examples of product messaging which are not considered marketing benefit claims include product reconstitution instructions, monitoring instructions, dosing modifications for special populations and storage instructions when these are presented as instructions/burdens rather than features/ benefits (i.e., presented to instruct rather than alter/form the audience's opinion of the medication in a positive way). How a statement is framed can sometimes affect whether it is a marketing benefit claim. For example, the copy "Arbace: Convenience of a single daily dose" is a marketing benefit claim, while "Patients should be instructed to take a single dose daily at the same time each day" is not.

GLOSSARY

APS

Advertising/Promotional Systems

PSP or PAP

Patient Support Program or Patient Assistance Program

Programs that exist to provide patients with timely access to medication, information, and resources intended to help patients stay on track of their therapy.

Real-World Data (RWD)

Real world data are data relating to patient status and/or the delivery of health care routinely collected from a variety of sources in real-world settings.

Real-World Evidence (RWE)

Real world evidence is the evidence regarding the usage, and potential benefits or risks, of a medical product derived from analysis of real-world data.