

e-Detail Aid Submission Best Practices

As electronic APSs have become more and more common, we at the PAAB have seen a wide range in how these are submitted.

In order to facilitate the review of electronic APSs, we are providing a guide comprised of best practices for clear and complete submissions. Adoption of these best practices may lead to speedier reviews and fewer resubmissions.

The initial submission for an electronic APS should include:

- an information architecture (IA) showing how the APS is organized and linkages between sections
- a copydeck and user flow
- a layout (if a layout cannot be provided at initial submission, a detailed wireframe for the different pages in the APS)

The following is an example of an information architecture and select copy pages for an iPad detail aid. Please see the sticky notes for feature highlights.

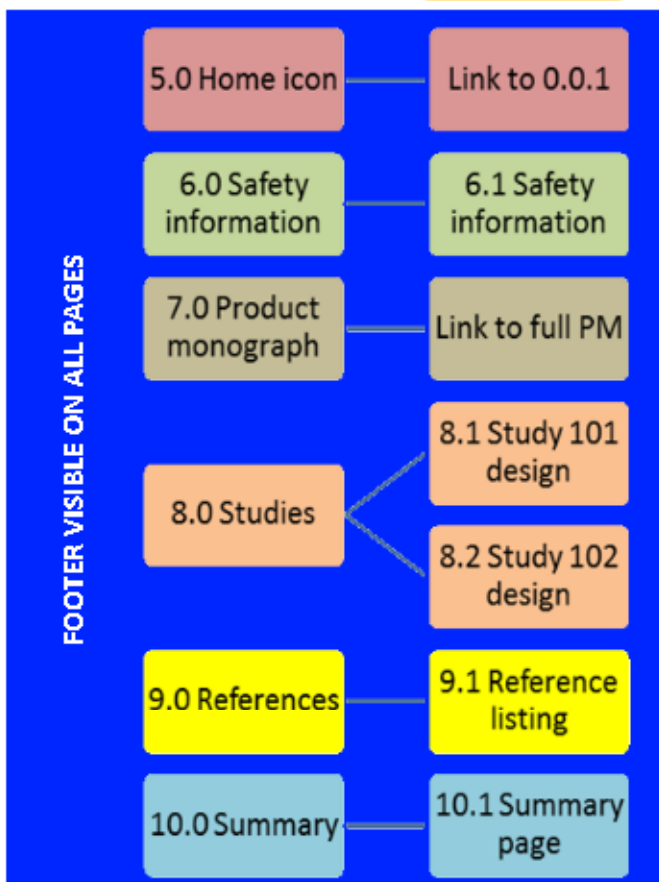
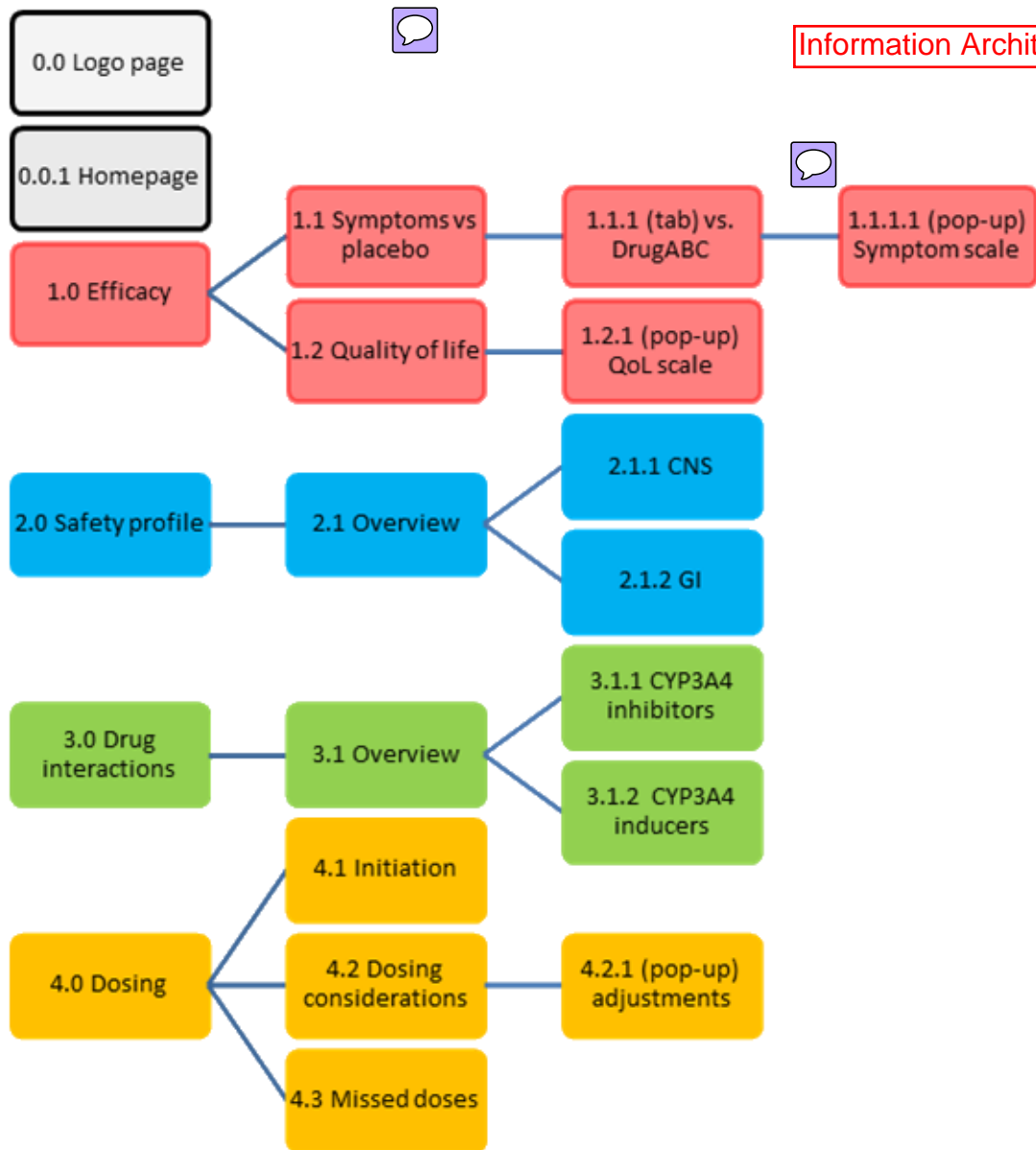



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For internal direction only; will not be included in final APS

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LEGEND: (image) (text) (button) (action)


Footer: visible at all times



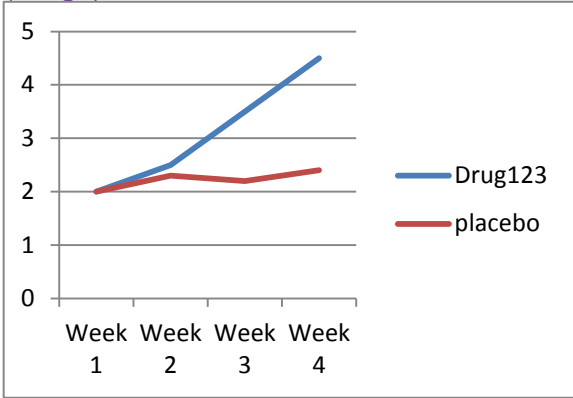
(image: home icon)	Tap opens 0.0.1
(image: menu icon)	Tap opens pop-up menu
Safety information	Tap opens 6.1
Product monograph	Tap directs user to product monograph weblink
Studies	Tap opens 8.1
References	Tap opens 9.1
(image: Drug123 logo)	Tap opens 10.1

Pop-up menu: opens from a tap on all pages

Efficacy	Tap opens 1.1	
	Sub-menu:	
	Symptoms	Tap opens 1.1
	Quality of life	Tap opens 1.2
Safety profile	Tap opens 2.1	
Drug interactions	Tap opens 3.1	
Dosing	Tap opens 4.1	
	Sub menu:	
	Initiation	Tap opens 4.1
	Dosing considerations	Tap opens 4.2
	Missed doses	Tap opens 4.3
Summary	Tap opens 10.1	

	Section	1.1 Symptoms vs. placebo
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	CONTENT
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TEXT & IMAGES	<p>Demonstrated efficacy for symptoms</p> <p>(tab 1) Symptoms vs. placebo</p> <p>(tab 2) Symptoms vs. DrugABC</p> <p>(chart title) Mean change in symptom score (LOCF)</p> <p>(image)</p>  <table border="1" style="margin-left: 20px;"> <caption>Data from Symptom Score Graph</caption> <thead> <tr> <th>Week</th> <th>Drug123</th> <th>placebo</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>2.0</td> <td>2.0</td> </tr> <tr> <td>2</td> <td>2.5</td> <td>2.2</td> </tr> <tr> <td>3</td> <td>3.5</td> <td>2.2</td> </tr> <tr> <td>4</td> <td>4.5</td> <td>2.4</td> </tr> </tbody> </table> <p>(qualifiers) LOCF: last observation carried forward</p>	Week	Drug123	placebo	1	2.0	2.0	2	2.5	2.2	3	3.5	2.2	4	4.5	2.4
Week	Drug123	placebo														
1	2.0	2.0														
2	2.5	2.2														
3	3.5	2.2														
4	4.5	2.4														

BUTTONS	(tab 1) Symptoms vs. placebo	Inactive 
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BUTTONS	(tab 2) Symptoms vs. DrugABC	Tap opens 1.1.1
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ACTIONS	Swipe left	Opens 1.1.1.1 
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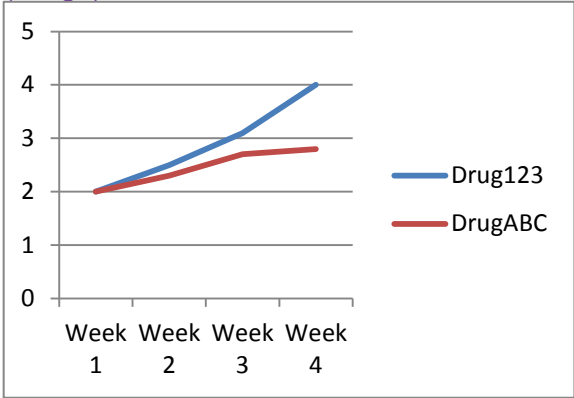
ACTIONS	Swipe right	Opens 8.1
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ACTIONS	Tap on graph	Expands graph to full page (tap again to close)
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NOTES	<ul style="list-style-type: none"> Footer visible on all pages Similar to 1.1.1 	
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Section	1.1.1 Symptoms vs. DrugABC
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CONTENT	
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TEXT & IMAGES	<p>Demonstrated efficacy for symptoms</p> <p>(tab 1) Symptoms vs. placebo</p> <p>(tab 2) Symptoms vs. DrugABC</p> <p>(chart title) Mean change in symptom score (LOCF)</p> <p>(image)</p>  <p>(qualifiers) LOCF: last observation carried forward</p>	
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BUTTONS	(tab 1) Symptoms vs. placebo	Tap opens 1.1
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BUTTONS	(tab 2) Symptoms vs. DrugABC	Inactive
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ACTIONS	Swipe left	Opens 1.1.1.1
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ACTIONS	Swipe right	Opens 8.2
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ACTIONS	Tap on graph	Expands graph to full screen (tap again to close)
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NOTES	<ul style="list-style-type: none"> Footer visible on all pages Similar to 1.1 	
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Section	1.1.1.1 Symptom scale (pop-up)
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CONTENT		
TEXT & IMAGES	<p>Symptom scale</p> <p>This scale evaluates:</p> <ul style="list-style-type: none"> • Symptom 1 • Symptom 2 • Symptom 3 • Symptom 4 • Symptom 5 • Symptom 6 	
BUTTONS	X	Closes this pop-up
NOTES	<ul style="list-style-type: none"> • Footer visible on all pages 	