

BMDS 3.0 Analysis Report

GWTX1413

For

GWTX1413 - 39 Week Oral Administration in Beagle Dogs

28.07.2022 09:58:47

Analysis Info

Analysis Name: GWTX1413

Analysis Description: C:\bmds3201\BMDS3201

Model Type: Dichotomous

Selected Models:

- Frequentist Log-Probit (restricted)

Option Sets:

- Option Set #1
 - Risk Type: Extra Risk
 - BMR: 0.1
 - Confidence Level: 0.95
 - Background: Estimated

Data

GWTX1413 - 39 Week Oral Administration in Beagle Dogs		
Source: FDA (2018)		
CBD Dose	N	Incidence
mg/kg bw/day	males + females combined	Liver (hepatocyte hypertrophy)
0	8	1
10	8	5
50	8	7
100	8	8

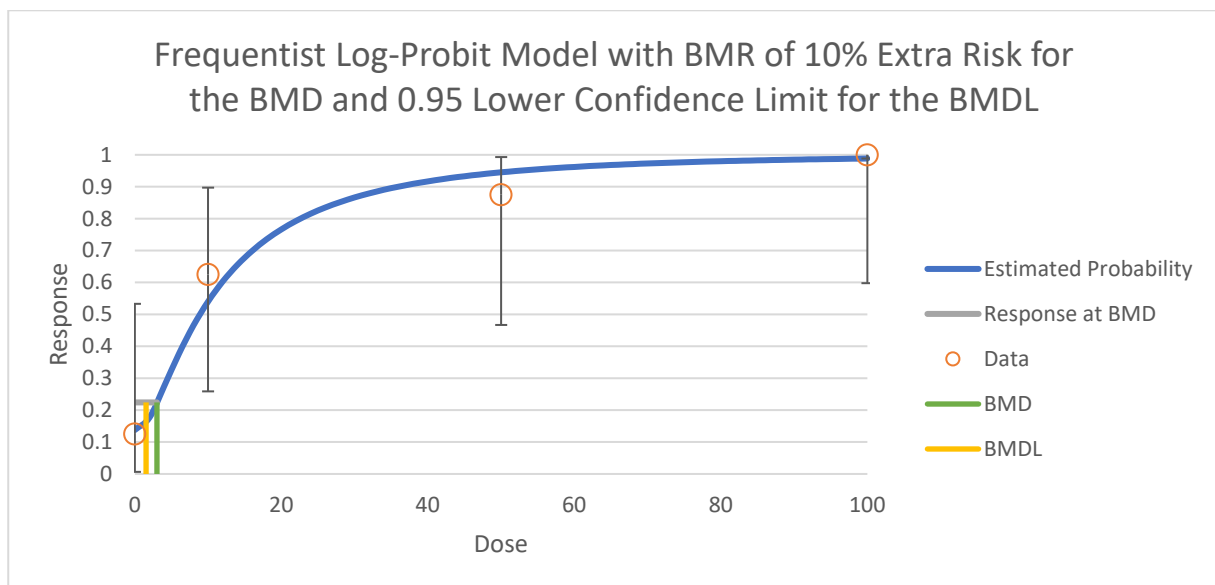
Frequentist Log-Probit Restricted Option Set #1

User Input					
Info		Model Options		Model Data	
Model	frequentist Log-Probit v1.1	Risk Type	Extra Risk	Dependent Variable	mg/kg bw/day
Dataset Name	GWTX1413 - 39 Week Oral Administration in Beagle Dogs	BMR	0.1	Independent Variable	Liver (hepatocyte hypertrophy)
User notes	Source: FDA (2018)	Confidence Level	0.95	Total # of Observations	4
		Background	Estimated		

Model Results																	
<table> <tr> <th colspan="2">Benchmark Dose</th></tr> <tr> <td>BMD</td><td>3.014237495</td></tr> <tr> <td>BMDL</td><td>1.517906631</td></tr> <tr> <td>BMDU</td><td>9.827687863</td></tr> <tr> <td>AIC</td><td>27.64123367</td></tr> <tr> <td>P-value</td><td>0.577102751</td></tr> <tr> <td>D.O.F.</td><td>2</td></tr> <tr> <td>Chi²</td><td>1.0994699</td></tr> </table>		Benchmark Dose		BMD	3.014237495	BMDL	1.517906631	BMDU	9.827687863	AIC	27.64123367	P-value	0.577102751	D.O.F.	2	Chi ²	1.0994699
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Goodness of Fit					
Dose	Estimated Probability	Expected	Observed	Size	Scaled Residual
0	0.137835074	1.102680589	1	8	-0.10531
10	0.54063746	4.325099683	5	8	0.4788106
50	0.9453689	7.562951202	7	8	-0.8758
100	0.988619282	7.908954253	8	8	0.3034697

Analysis of Deviance					
Model	Log Likelihood	# of Parameters	Deviance	Test d.f.	P Value
Full Model	-11.32082849	4	-	-	NA
Fitted Model	-11.82061683	2	0.9995767	2	0.606659
Reduced Model	-20.5917297	1	18.5418024	3	0.00034



Summary of Results

Option set #1 (Hover for details)											
Model	Analysis Type	Restriction	RiskType	BMD	BMDL	BMDU	P Value	AIC	Unnormalized Log Posterior Probability	BMDS Recommendation	BMDS Recommendation Notes
Log-Probit*	frequentist	Restricted	Extra Risk	3.014237	1.517907	9.8276879	0.5771028	27.64123367	-	Viable - Recommended	<p>Lowest AIC</p> <p>BMD 3x lower than lowest non-zero dose</p> <p>BMDL 3x lower than lowest non-zero dose</p>

*Selected model in bold; scaled residuals for selected model for doses 0, 10, 50, 100 were -0.105309684630889, 0.478810629656141, -0.875800382261093, 0.303469671400525 [units], respectively.

