



TRIAL STATISTICIANS' INTERIM REPORT

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REPORT IDENTIFICATION

Report ID:	PIP-007	Date of Report:	09/11/202x
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The validity of the actual clinical research data presented below is the responsibility of the reporting Site.

INDIVIDUALS – SUMMARY

Subject ID:	4430006	Research Site:	4430
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Subject Allocated Dose:	300mg
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Compliance % rate to date (if known):	100%
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Treatment duration to date (weeks):	4 weeks
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Treatment Tolerability during study period:	Tolerated
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Subject AEs

AE NUMBER	1	2
SUBJECT	4430xxxx	4430xxxx
CTCAE TERM	Bloating	Periorbital oedema
ONSET DATE OF AE	12/10/2021 00:00	18/10/2021 00:00
CTCAE SEVERITY	Grade 2	Grade 1
STUDY DRUG DOSE	300mg	300mg
CAUSALITY/RELATIONSHIP	Possibly	Probably
ACTION TAKEN	None	None
NOTES	NA	NA

OVERALL – SUMMARY

Treated Subjects to date:	7									
Reported AEs to date:	16									
CTCAE Grades (all subjects):	Grade 1:	10	Grade 2:	6	Grade 3:	0	Grade 4:	0	Grade 5:	0

Table 1: Posterior estimates of dose toxicity

Posterior estimates of Toxicities	Dose			
	100	200	300	400
Mean	0.062101	0.10756	0.173566	0.339353
SD	0.078016	0.103578	0.128406	0.155218
Median	0.033793	0.076431	0.146085	0.330407
Plug-in Estimate*	0.02442	0.059729	0.121478**	0.297119

* Plug-in estimate denotes the toxicity estimate using the mean posterior estimation of the model parameter plugged into the toxicity model. This is the metric used to decide the next recommended dose.

** Current estimation of HTD

Table 2: Credible intervals of posterior estimates of dose toxicity

Quantile	Dose			
	100	200	300	400
2.50%	0.000324	0.002248	0.010445	0.072351
10%	0.002273	0.00985	0.031547	0.136718
25%	0.01064	0.03179	0.07579	0.226451
50%	0.033793	0.076431	0.146085	0.330407
75%	0.082657	0.150707	0.242765	0.44263
97.50%	0.292767	0.393596	0.497817	0.669264

Figure 1: Current estimation of the Dose toxicity curve.

Posterior p(DLT) quantiles: 2.5%, 25%, 50%, 75%, 97.5%
Points = p(DLT) estimates; Diamond = recommended dose

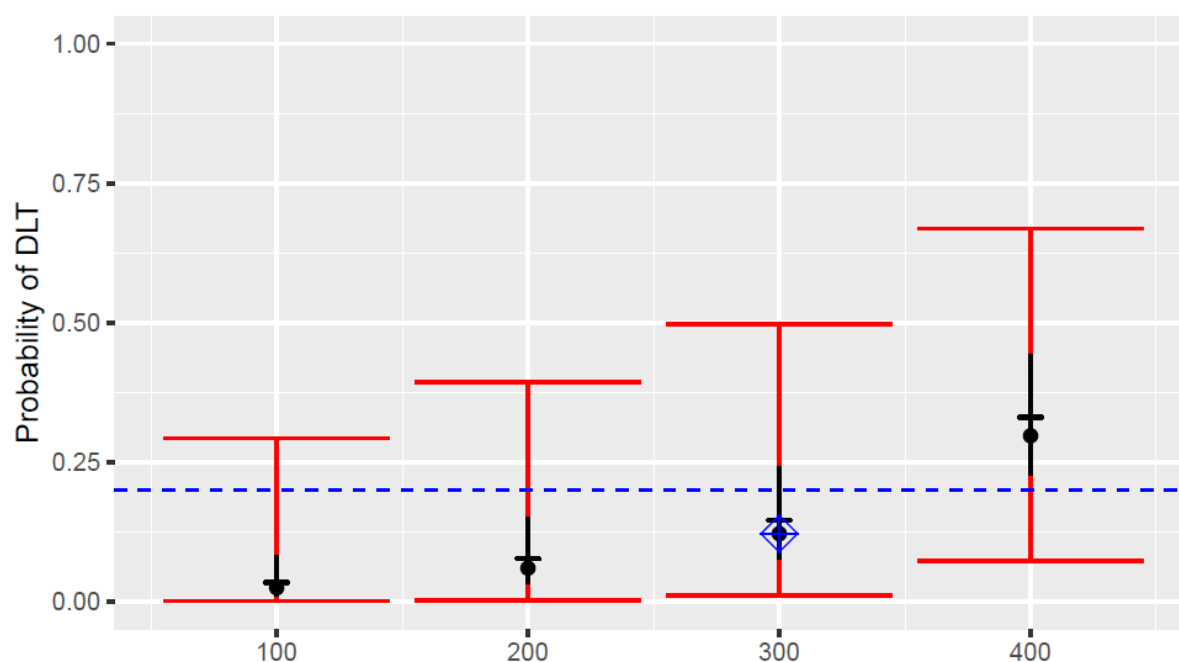
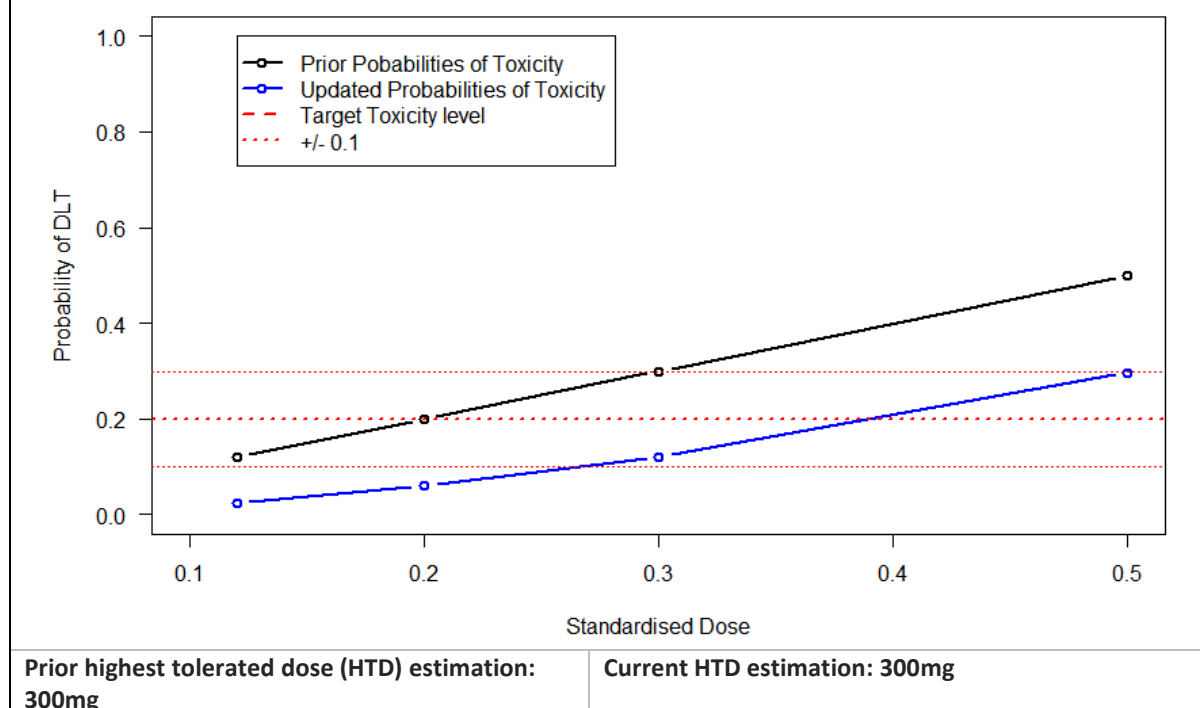


Figure 2: Simplified dose/toxicity showing our prior guess and updated toxicities.



OUTCOME:

Subsequent subject

XXXXXXX

The current best estimation of the HTD is 300mg. We recommend the next patient is remains on 300mg.
Confirmation needed by independent DMC and TSC.

APPROVAL

To my knowledge, the content of this report is correct:

Sofia S. Villar

(full name)

26/05/20xx

(signature)

(date)

This report can be signed electronically to avoid delay.