

Beauty is in the eye of the
beholder, or is it?

ASPIRE Protocol Team Meeting

Cape Town

28 October 2013

318-30009-1

- 26 year old
- Para3, youngest child 3 year
- Contraception – Jadelle
- Moderate alcohol intake prior to study participation
- Enrolled on 19 Nov 2012, normal liver function
- M6 follow-up visit, grade 1 raised AST and grade 1 raised ALT

Follow-up Results

Date Visit code	AST 10-30 IU/l	ALT 5-44 IU/l	GGT 13-60 IU/l	Comments
02 MAY 13 06.0	55 Grade 1	90 Grade 1		Asymptomatic AEs 002 and 003 reported
30 MAY 13 07.0	66 Grade 1	94 Grade 1		Asymptomatic
06 JUN 13 07.1	114 Grade 2	186 Grade 2		Asymptomatic Status of AEs 002 and 003 updated to AEs 004 and 005
27 JUN 13 08.0	159 Grade 3	259 Grade 3	68 Not gradable	What next?

Benjamin Franklin

Beauty and folly are old companions

The Plot Thickens...

- IoR informed by nurse that participant was extremely light in complexion.
- On probing, ppt remarked *“Oh, I use 2 types of skin-lightening creams everyday... over the whole body... I even ask my cousin to apply the cream at the back for me!”*
- *“I am the only dark-skinned person in my family and so I am the only one who is not beautiful... One worrying thing is that the creams are so strong, our palms are turning orange.”*
- Creams smuggled into the country by informal traders

What Next?

- Asymptomatic
- **Product hold** instituted per clinician's discretion.
- **PSRT Query**
- Product last used on 01 JUL 13
- Hydroquinone last used on 01 JUL 13
- Status of AEs 004 and 005 updated to AEs 006 and 007

Date	AST	ALT	Comments
Visit code	10-30	5-44	
	IU/l	IU/l	
02 JUL 13 08.2	231 Grade 3	394 Grade 3	Asymptomatic Continued on product hold.
17 JUL 13 09.0	45 Grade 1	94 Grade 1	Asymptomatic Normal renal function test results Resumed product For review at visit 10.0
27 AUG 13 10.0	79 Grade 2	118 Grade 2	Asymptomatic. Denies drug/alcohol, herbal preparation ingestion. No possible hepatotoxin identified Denies continued hydroquinone use - no longer light skinned as she was. No other cutaneous or systemic manifestations of hydroquinone use apparent at the moment.
25 SEP 13 11.0	31 Not gradable	41 Normal	Asymptomatic, AEs 006 and 007 resolved Site staff compliment her on how beautiful she is looking
21 OCT 13 12.0	42 Grade 1	53 Not	Asymptomatic, New AE Site staff compliment her on how beautiful she is

Thank You

- *It is amazing how complete is the delusion that beauty is goodness!* – Leo Tolstoy
- However, in this case, is the hydroquinone the real culprit?
- The question remains:
Related or not related?