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

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