Appendix C

EXAMPLE of a Study Summary Sheet

(Note: A Study Summary Sheet was generated for each of n=138 studies from the 130 references. Copies are available from the authors upon request.)
# STUDY SUMMARY SHEET

**CITATION**  REF: 122  
**YEAR:** 1996  
**AUTHORS:** Veerman A, Chanlon JF  
**TITLE:** Fexofenadine's effects, alone and with alcohol, on actual driving and psychomotor performance.  
**SOURCE:** J Allergy Clin Immunol  
**VOL. PP:** 101:300-311  
**ALCOHOL?** Y  
**Comments:** Train sep day, Clemastine 2mg bid (h.s., AM day) coded as 3mg Acute & 4mg R; F120,24hCAM, so A; F120xd, F60xd, so R: 240, 120mg; fexa improved drive & attentional stl impair; but sig impair CTTI  

**METHOD**  
- **Blind:** DB  
- **Design:** Cross x  
- **No. (n):** 24  
- **Sex (m):** 12  
- **Age (M):** 21-45  
- **Population:** Healthy Volunteers  
- **Postdrug:**  
- **Test duration:** Acute, Repeat, Residual  
- **Alerting effects:** Yes  

**RESULTS**  
**Task (or Subjective Sedation)** | **SCF** | **Task/Drug** | **A** | **R** | **Resid.**  
--- | --- | --- | --- | --- | ---  
1 Critical Tracking (CTT) - **SCF** (5 trials) | BCR | V. brief | X | YES |  
2 Critical Tracking (CTT) - **SCF** (5 trials) | BCR | V. brief | X | NO |  
3 Reaction Time, Choice (CTT), vs (L/R w. dr 9C | V. brief | X | NO | NO |  
4 Reaction Time, Choice (CTT), vs (L/R w. dr 9C | V. brief | X | NO | NO |  
5 Vigilance - Sustained attention - **SCF** (40m  | 45 min | X | NO | NO |  
6 Vigilance - Sustained attention - **SCF** (40m | 45 min | X | NO | NO |  
7 Driving - Actual, Highway drive | 1R | - | YES |  
8 Driving - Actual, Highway drive | 1R | - 1 hr | |  

**RESULTS**  
**Task (or Subjective Sedation)** | **SCF** | **Task/Drug** | **A** | **R** | **Resid.**  
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1 Critical Tracking (CTT) - **SCF** (5 trials) | BCR | V. brief | X | YES |  
2 Critical Tracking (CTT) - **SCF** (5 trials) | BCR | V. brief | X | NO |  
3 Reaction Time, Choice (CTT), vs (L/R w. dr 9C | V. brief | X | NO | NO |  
4 Reaction Time, Choice (CTT), vs (L/R w. dr 9C | V. brief | X | NO | NO |  
5 Vigilance - Sustained attention - **SCF** (40m  | 45 min | X | NO | NO |  
6 Vigilance - Sustained attention - **SCF** (40m | 45 min | X | NO | NO |  
7 Driving - Actual, Highway drive | 1R | - | YES |  
8 Driving - Actual, Highway drive | 1R | - 1 hr | |  

**CODES:**  
- **Bind:** DB - Double-blind  
- **SS:** Single-blind  
- **PC:** Positive Control  
- **Coded for 10 key drugs or other 1st (D) or 2nd (M) generation H1-antagonists or Misc. drugs (M)  
- **Dosing:** A=Acute, R=Repeted, Resid=Residual effects  

**SCF:** Skill Category:  
- 1=Driving & Flying  
- 2=Psychometric  
- 3=Reaction  
- 4=Visual Attention  
- 5=Cognitive Skills  
- 6=OHD-Attention  
- 7=Motor  
- 8=Hand-eye  
- 9=Reaction Time  
- 10=Physiological (BB, EES, ERP)  
- 11=Subjective Sedation  

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**HMACMW Antihistamines & Driving Review for DOT.** FILE: C:\GMAM-M:\CWDOT-REVIEWS\CWDOT-DATA wb3 03/31/90 04:13:38 PM Page 1 of 2
RESULTS - Continued... COMMENTS for each line of study results:

<table>
<thead>
<tr>
<th>RESULTS TASK (or Subjective SEDATION)</th>
<th>SQF</th>
<th>A</th>
<th>B</th>
<th>Resid.</th>
<th>COMMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>CRITICAL TRACKING (CTT) -- SCR (5 min)</td>
<td>60Y</td>
<td>X</td>
<td></td>
<td></td>
<td>CTT; C3 -acute sig (Day 1 AM dose, and h.s. dose: C2mg bx); F120,240 = AM doses both sig impair</td>
</tr>
<tr>
<td>CRITICAL TRACKING (CTT) -- SCR (5 min)</td>
<td>60Y</td>
<td>X</td>
<td></td>
<td></td>
<td>CTT: n.s. Day 4; but alc sig impaired, and C and F240 (AM dose) &lt; alc sig &gt; alc alone</td>
</tr>
<tr>
<td>REACTION TIME, Choice (CRT): Var (LET v. distractor) 9C</td>
<td>60Y</td>
<td>X</td>
<td></td>
<td></td>
<td>ORT: n.s any time or drug dose; but alc sig impaired</td>
</tr>
<tr>
<td>REACTION TIME, Choice (CRT): Var (LET v. distractor) 9C</td>
<td>60Y</td>
<td>X</td>
<td></td>
<td></td>
<td>ORT: n.s any time or drug dose; but alc sig impaired</td>
</tr>
<tr>
<td>VIGILANCE - Sustained Attention -- SCR (40min)</td>
<td>7</td>
<td></td>
<td></td>
<td></td>
<td>VIG: n.s. any time or drug dose, but C trend impair Day 1(p &lt; .075); alc sig impaired</td>
</tr>
<tr>
<td>VIGILANCE - Sustained Attention -- SCR (40min)</td>
<td>7</td>
<td></td>
<td></td>
<td></td>
<td>VIG: n.s. any time or drug dose, but C trend impair Day 1(p &lt; .075); alc sig impaired</td>
</tr>
<tr>
<td>DRIVING - Actual, Highway circuit</td>
<td>1R</td>
<td>X</td>
<td></td>
<td></td>
<td>DRIVE: C sig impaired Day 1&amp;4; n.s. T effect on Day 1</td>
</tr>
<tr>
<td>DRIVING - Actual, Highway circuit</td>
<td>1R</td>
<td>X</td>
<td></td>
<td></td>
<td>DRIVE: C sig impaired Day 1&amp;4, T240mg (h.s/AM) sig improved driving Day 4 &amp; F240 (both dose reg) sig atten alc impair</td>
</tr>
</tbody>
</table>