

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 1998

AUTHORS Vermeeren A, O'Hanlon JF

TITLE Fexofenadine's effects, alone and with alcohol, on actual driving and psychomotor performance.

SOURCE J Allergy Clin Immunol

VOL:PP 101: 306-311

ALCOHOL? Y [N=No, Y=Yes] IF study also included ALCOHOL treatment, coded results below reflect No Alcohol (or Placebo drink) conditions for test of drug alone effects

METHOD Blind PC+ DESIGN Ss (n) Males (n) AGES 21-45 AGE (M) 31.5 ± 8.5 Population Healthy volunteers PostDose 1.5h perf, +3drive TEST duration 1hr perf, 1hr drive Acute Repeat Day 1 Day4, 5+alc Residual Alerting effects? For 240mg improve drive & attenuate alc impair.

COMMENTS: Train: sep day, clemastine 2mg bid (h.s., AM day1) coded as 3mg Acute & 4mg R; F120,240AM, so A; F120bid, F60bid, so R; 240, 120mg, feso improved drive & attenuated alc impair, but sig impair CTI

RESULTS: DID STUDY SHOW STATISTICALLY SIGNIFICANT IMPAIRMENT (relative to Placebo) as function of DRUG (and DOSE) SHOWN BELOW?

| RESULTS | TASK (or Subjective Sedation) | SC# | Instr/DUR | A | R | Resid. | D1: CHLORPHENIRAMINE | | | D2: CLEMASTINE | | | D3: DIPHENHYDRAMINE | | | D4: HYDROXYZINE | | | D5: TRIPOLIDINE | | | | |
|---------|---|-----|-----------|---|---|--------|----------------------|-----|------|----------------|-----|-----|---------------------|-----|-----|-----------------|------|------|-----------------|------|------|------|------|
| | | | | | | | 2.0mg | 5.0 | 10mg | 10mg | 2mg | 2mg | 5mg | 2mg | 5mg | 10mg | 20mg | 20mg | 30mg | 50mg | 50mg | 50mg | 50mg |
| 1 | CRITICAL TRACKING (CTT) - -SCTI (5 trials) | 8Ct | v. brief | X | X | | YES | | | | | | | | | | | | | | | | |
| 2 | CRITICAL TRACKING (CTT) - -SCTI (5 trials) | 8Ct | v. brief | | X | | NO | | | | | | | | | | | | | | | | |
| 3 | REACTION TIME, Choice (CRT); Vs (LSR w. dr) | 9C | v. brief | X | X | | NO | | | | | | | | | | | | | | | | |
| 4 | REACTION TIME, Choice (CRT); Vs (LSR w. dr) | 9C | v. brief | X | X | | NO | | | | | | | | | | | | | | | | |
| 5 | VIGILANCE - Sustained Attention - -SCTI (45m) | 7 | 45 min | X | X | | NO | | | | | | | | | | | | | | | | |
| 6 | VIGILANCE - Sustained Attention - -SCTI (45m) | 7 | 45 min | X | X | | NO | | | | | | | | | | | | | | | | |
| 7 | DRIVING - Actual, Highway circuit | 1R | - 1hr | X | X | | YES | | | | | | | | | | | | | | | | |
| 8 | DRIVING - Actual, Highway circuit | 1R | - 1hr | X | X | | YES | | | | | | | | | | | | | | | | |

| RESULTS | TASK (or Subjective Sedation) | SC# | Instr/DUR | A | R | Resid. | M1: ASTEMIZOLE | | | M2: CETIRIZINE | | | M3: FEXOFENADINE/M4: LORATADINE | | | M5: TERFENADINE | | | | | | | |
|---------|---|-----|-----------|---|---|--------|----------------|------|------|----------------|------|------|---------------------------------|------|------|-----------------|------|------|------|-------|-------|--|--|
| | | | | | | | 10mg | 20mg | 30mg | 50mg | 10mg | 20mg | 30mg | 50mg | 10mg | 20mg | 30mg | 40mg | 60mg | 120mg | 240mg | | |
| 1 | CRITICAL TRACKING (CTT) - -SCTI (5 trials) | 8Ct | v. brief | X | X | | YES | | | | | | | | | | | | | | | | |
| 2 | CRITICAL TRACKING (CTT) - -SCTI (5 trials) | 8Ct | v. brief | | X | | NO | | | | | | | | | | | | | | | | |
| 3 | REACTION TIME, Choice (CRT); Vs (LSR w. dr) | 9C | v. brief | X | X | | NO | | | | | | | | | | | | | | | | |
| 4 | REACTION TIME, Choice (CRT); Vs (LSR w. dr) | 9C | v. brief | X | X | | NO | | | | | | | | | | | | | | | | |
| 5 | VIGILANCE - Sustained Attention - -SCTI (45m) | 7 | 45 min | X | X | | NO | | | | | | | | | | | | | | | | |
| 6 | VIGILANCE - Sustained Attention - -SCTI (45m) | 7 | 45 min | X | X | | NO | | | | | | | | | | | | | | | | |
| 7 | DRIVING - Actual, Highway circuit | 1R | - 1hr | X | X | | NO | | | | | | | | | | | | | | | | |
| 8 | DRIVING - Actual, Highway circuit | 1R | - 1hr | X | X | | NO | | | | | | | | | | | | | | | | |

CODES: Blind; DB=Double-blind, SB=Single-blind PC+: Positive control; Coded for 10 key drugs or other 1st (D) or 2nd (N) generation H1-antagonists or Misc. drugs (M) Dosing: A=Acute, R=Repeated, Resid=Residual effects
SC#: Skill Category: #1=Driving & Flying, 2=Psychomotor, 3=Perception, 4=Manual functions, 5=Cognitive Skills, 6=Divided Attention, 7=Vigilance, 8=Tracking, 9=Reaction Time, 10=Physiological (ASLT, EEG, ERP), 99=Subjective Sedation

CITATION

REF# 122
YEAR 1998

AUTHORS Vermeeren A, O'Hanlon JF

STUDY SUMMARY SHEET: Page 2 of 2

COMMENTS: n=24, driving & psychomotor perf, day1, 4 & aic day5, O'Hanlon, issue: Fex impair CTT acute dose, improve drive & attenuate aic impair, alerting effect?

RESULTS - Continued... COMMENTS for each line of study results:

| RESULTS | TASK (or Subjective SEDATION) | SC# | A | B | Resid. | COMMENTS: |
|---------|---|-----|---|---|--------|--|
| 1 | CRITICAL TRACKING (CTT) - SCRI (5 trials) | 8Cr | X | X | | CTT: C3 - acute sig (Day 1 AM dose, and h.s. dose: C2mg bid); F120,240 as AM doses both sig impair! |
| 2 | CRITICAL TRACKING (CTT) - SCRI (5 trials) | 8Cr | X | X | | CTT: n.s. Day4; but aic sig impaired, and C and F240 (AM dose) + aic sig > aic alone |
| 3 | REACTION TIME, Choice (CRT); Vs (LER w. distractor) | 9C | X | X | | CRT: n.s. any time or drug dose; but aic sig impaired |
| 4 | REACTION TIME, Choice (CRT); Vs (LER w. distractor) | 9C | X | X | | CRT: n.s. any time or drug dose; but aic sig impaired |
| 5 | VIOLANCE - Sustained Attention - SCRI (45min) | 7 | X | X | | VIG: n.s. any time or drug dose, but C trend impair Day1 (p=.075); aic sig impaired |
| 6 | VIOLANCE - Sustained Attention - SCRI (45min) | 7 | X | X | | VIG: n.s. any time or drug dose, but C trend impair Day1 (p=.075); aic sig impaired |
| 7 | DRIVING - Actual, Highway circuit | 1R | X | X | | DRIVE: C sig impaired Day 1&4; n.s. T effect on Day1 |
| 8 | DRIVING - Actual, Highway circuit | 1R | X | X | | DRIVE: C sig impaired Day 1&4; T240mg (h.s/AM) sig improved driving Day4 & F240 (both dose rega) sig atten aic impair! |
| 9 | | | | | | |
| 10 | | | | | | |
| 11 | | | | | | |
| 12 | | | | | | |
| 13 | | | | | | |
| 14 | | | | | | |
| 15 | | | | | | |
| 16 | | | | | | |
| 17 | | | | | | |
| 18 | | | | | | |