

Analysis Guide

January 31, 2001

DATASET: SIDEEFF

Side effects (symptoms) data. One record per randomized participant per visit (collected at SV3, RI, IV1, IV2 and IV3). Use AN_ID as the participant ID for all Data Release Requests and for all analysis data sets that leave CHR.

| Variable | Description | Format | Range | Notes |
|-----------|----------------------------------|-----------|-------|--|
| AN_ID | id for analysis datasets | text | | Numeric portion of original alphanumeric ID. First digit identifies clinic site. |
| APPETITE | poor appetite | severity* | 1 - 4 | = 1 if did not occur, = 2 if mild, = 3 if moderate, = 4 if severe |
| BLOATING | bloating / uncomfortably full | severity* | 1 - 4 | included in GI symptoms, = 1 if did not occur, = 2 if mild, = 3 if moderate, = 4 if severe |
| CONSTIP | constipation | severity* | 1 - 4 | included in GI symptoms, = 1 if did not occur, = 2 if mild, = 3 if moderate, = 4 if severe |
| DIARRHEA | diarrhea / loose stools | severity* | 1 - 4 | included in GI symptoms, = 1 if did not occur, = 2 if mild, = 3 if moderate, = 4 if severe |
| DRY MOUTH | dry mouth | severity* | 1 - 4 | = 1 if did not occur, = 2 if mild, = 3 if moderate, = 4 if severe |
| EXTHIRST | excessive thirst | severity* | 1 - 4 | = 1 if did not occur, = 2 if mild, = 3 if moderate, = 4 if severe |
| FATIGUE | fatigue or low energy | severity* | 1 - 4 | = 1 if did not occur, = 2 if mild, = 3 if moderate, = 4 if severe |
| FELT | overall past two weeks | felt* | 1 - 5 | |
| HEADACHE | headache | severity* | 1 - 4 | = 1 if did not occur, = 2 if mild, = 3 if moderate, = 4 if severe |
| ITCHYSKI | itchy skin or hives | severity* | 1 - 4 | = 1 if did not occur, = 2 if mild, = 3 if moderate, = 4 if severe |
| LITEHEAD | lightheadedness when standing up | severity* | 1 - 4 | = 1 if did not occur, = 2 if mild, = 3 if moderate, = 4 if severe |
| NAUSEA | nausea or upset stomach | severity* | 1 - 4 | included in GI symptoms, = 1 if did not occur, = 2 if mild, = 3 if moderate, = 4 if severe |
| SERIOUS | serious illness in past month | yesnoft* | 1 - 4 | |
| STUFFNOS | stuffy nose | severity* | 1 - 4 | = 1 if did not occur, = 2 if mild, = 3 if moderate, = 4 if severe |
| TASTE | change in taste | severity* | 1 - 4 | = 1 if did not occur, = 2 if mild, = 3 if moderate, = 4 if severe |
| VISIT | visit | visittf* | 4 - 8 | = 4 if SV3, = 5 if RI, = 6 if IFP 1, = 7 if IFP 2, = 8 if IFP 3 |
| WHEEZING | wheezing | severity* | 1 - 4 | = 1 if did not occur, = 2 if mild, = 3 if moderate, = 4 if severe |

* custom format, see list of formats at end of this section.

Variable Formats

January 31, 2001

DATASET: SIDEEFF

| Dataset | Format: | Value Range: | Label: | |
|----------------|----------------|---------------------|-------------------|---------------|
| SIDEEFF | FELT | .. | NO ANSWER | |
| | | 1. | MUCH WORSE | |
| | | 2. | WORSE THAN USUAL | |
| | | 3. | THE SAME AS USUAL | |
| | | 4. | BETTER THAN USUAL | |
| | SEVERITY | SEVERITY | 5. | MUCH BETTER |
| | | | .. | NO ANSWER |
| | | | 1. | DID NOT OCCUR |
| | | | 2. | MILD |
| | VISITFT | VISITFT | 3. | MODERATE |
| | | | 4. | SEVERE |
| | | | 1. | PSV |
| | | | 2. | SV1 |
| | | | 3. | SV2 |
| | | | 4. | SV3 |
| 5. | | | RI | |
| YESNOFT | YESNOFT | 6. | INT1 | |
| | | 7. | INT2 | |
| | | 8. | INT3 | |
| | | 9. | COMPLT. FEEDING | |
| | | 0. | No | |
| | | 1. | Yes | |
| | | 2. | No | |
| | | 3. | Unsure | |

SideEff Dataset 10 Sample Observations

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| | | A | B | D | D | E | | H | I | L | | S | | W | | | | |
|----|-------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | P | L | C | I | R | X | F | E | T | I | S | T | H | | | | |
| | | P | O | O | A | Y | T | A | A | C | T | N | E | U | | | | |
| | A | E | A | N | R | M | H | T | D | H | E | A | R | F | | | | |
| | N | T | T | S | R | O | I | I | F | A | Y | H | U | I | | | | |
| O | | I | I | T | H | U | R | G | E | C | S | E | S | O | | | | |
| b | | T | N | I | E | T | S | U | L | H | K | A | E | U | | | | |
| s | D | E | G | P | A | H | T | E | T | E | I | D | A | S | | | | |
| | | S | S | E | T | G | | | | | | | | | | | | |
| 1 | 20847 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 3 | 1 | 1 | 1 | 1 | 2 | 1 | 1 | 4 | 1 |
| 2 | 20847 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 3 | 2 | 1 | 1 | 1 | 1 | 1 | 1 | 5 | 1 |
| 3 | 20847 | 1 | 2 | 1 | 1 | 2 | 1 | 1 | 5 | 1 | 1 | 1 | 1 | 2 | 1 | 1 | 6 | 1 |
| 4 | 20847 | 1 | 1 | 1 | 1 | 2 | 1 | 1 | 3 | 1 | 1 | 1 | 1 | 2 | 1 | 1 | 7 | 1 |
| 5 | 20847 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 3 | 1 | 1 | 1 | 1 | 2 | 1 | 1 | 8 | 1 |
| 6 | 10933 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 3 | 1 | 1 | 1 | 1 | 2 | 2 | 1 | 4 | 1 |
| 7 | 10933 | 2 | 2 | 2 | 2 | 2 | 3 | 2 | 3 | 1 | 2 | 1 | 1 | 2 | 3 | 1 | 5 | 1 |
| 8 | 10933 | 2 | 2 | 1 | 2 | 2 | 3 | 2 | 3 | 2 | 2 | 1 | 2 | 2 | 4 | 1 | 6 | 1 |
| 9 | 10933 | 3 | 2 | 3 | 3 | 2 | 2 | 2 | 3 | 3 | 2 | 3 | 3 | 2 | 3 | 1 | 7 | 2 |
| 10 | 10933 | 3 | 2 | 2 | 1 | 3 | 2 | 3 | 3 | 2 | 2 | 3 | 2 | 2 | 4 | 3 | 8 | 1 |

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