

**Data Handling Plan (DHP) for Tinnitus Research Initiative (TRI):
Instructions for entering data into the TRI database**

ID: TRI-DHP

Version: V07 (English)

Date: May 9th, 2011

Author: Yvonne Eberl, Florian Zeman

**Review: Susanne Staudinger, Michael Koller, Michael Landgrebe, Berthold
Langguth**

Definition:

An important prerequisite for obtaining valid study results is the correct data entry of CRF records into a study database. The Data Handling Plan (DHP) improves the quality of data entries by providing study-specific instructions for entering data into a database. Queries occurring during data entry that are sent to the principal investigator are recorded in a query form (QF).

Data Handling Plan (DHP)

1. Text boxes to be filled in by the principal investigator

1.1 Unreadable or incomprehensible data entries

If a data entry made by a principal investigator is unreadable or incomprehensible, it will be documented in the query form (QF) that will be sent to the appropriate centre. The variable in the data base remains blank until the query is answered. The response will be entered into the database and marked as 'replied-to' in the QF. In case of further discrepancies, a new query has to be issued.

1.2 Implausible data entry

If a data entry is implausible, i.e. if a notice error is generated by the system or the implausibility is recognised by a data entry clerk, a new query is generated and recorded in the QF. In the meantime, the variable remains blank. The response will be entered into the database upon receipt of the query and marked as 'replied-to' in the QF.

1.3 Incomplete entry of dates

Principally, a new query has to be generated for the incomplete entries of dates. The actual text box for the date remains blank until receipt of the answered query. Each step has to be documented in the QF. If values are irreconstructable or the principal investigator has already documented the missing value on the CRF (also see 1.4), please proceed as follows:

Rounding up missing values:

(only in forms: concomitant medication, comorbidity, adverse events)

- Only value for 'day' is missing: leave day blank
and mark the box "unspecified"
- Values for 'day' and 'month' are missing: leave day and month blank
+ variable date is incomplete = tick off and mark the box "unspecified"
- Value for 'month' is missing: leave month blank
+ variable date is incomplete = tick off and mark the box "unspecified"
- Implausible date: leave date variable blank
+ variable date is incomplete = tick off
- Date is missing entirely: leave date variable blank
+ query to principal investigator

See 2.3. for date specifications in patient questionnaires.

1.4 Missing values:

Two lines of actions are possible for missing values:

- **Actual missing values:**
No entry into the text box; variable → generation of query
- **Confirmed missing values:** No entry into the text box; variable, but marking of the missing value by the physician (e.g. n.d., not done; n.a., not applicable)

Numeric text boxes require documentation of the following values:

- Audiometry / frequency: 999
- Audiometry / tinnitus matching:
 - If no interval but a figure is given, this figure has to be documented in both text boxes (from, to).
 - If no figure is given, although tinnitus matching has been carried out, please enter the figure 99999.
- Audiometry / minimal masking level: 999. If MML has been carried out but is not definable, please enter the figure 888.
- Audiometry / duration of residual inhibition: -1

- If a particular centre is known and confirmed to measure only certain ranges in audiometry, no query needs to be sent, and the missing value can be marked as a confirmed missing value.
- Statements on loss of hearing in audiometry refer to the frequency range from 125 Hz to 8 Hz only.
- Tinnitus matching
 - If the CRF states „left > right“ or „right > left“, please tick off „on both sides“ in the database.
 - The item „sound“ in the CRF has to be documented as „sinusoidal sound“ in the database.
 - The item „swooshing sound“ in the CRF has to be documented as „BBR“ (Broad Band) in the database.
 - If the CRF does not show any entry for tinnitus matching, no data should be entered into the database. „Not determinable“ should only be marked in the database if ticked off on the CRF.
 - If more than one sound is mentioned in the CRF, please enter data as follows:
 - Sound & swooshing sound in the CRF: enter „sinusoidal sound“.
 - Narrow band & broad band in the CRF: enter „broad band“.
- Please enter „not done“ in the text boxes.

2. Text boxes and questionnaires to be filled in by patients

2.1 More than one answer is given:

If more than one answer is given in a questionnaire, the worst option has to be documented (no queries are generated for patient questionnaires):

- Tinnitus handicap inventory: „worst“ value: yes
- TBF12: „worst“ value: often
- Tinnitus severity: „worst“ value: „extreme“ in question 1; „value 10“ in all others

- BDI: „worst“ value: 3
- WHOQOL: „worst“ value: 1
- Tinnitus questionnaire: „worst“ value: „3“ in questions 1, 7, 32, 40, 44, 49, 52; „1“ in all others

In case of multiple answers for TSCHQ:

- Question 9 „Where do you notice Tinnitus?“ Please enter the foremost or topmost cross into the database.
- Question 14 „Does the tinnitus sound like a tone or rather like noise?“: In case of multiple answers enter „other perception“. Exception: If „tonal“ and „crickets“ are ticked, enter „tonal“.

Tip:

- ⇒ Discrepancies on pages filled in by the principal investigator will generate a query.
- ⇒ Answers that cannot be divided into „worse“ or „better“ are decided upon on a case-by-case-basis. In case of contradicting answers, none of the options will be entered.

2.2 Missing entry:

For patient questionnaires, no query will be generated, and the text box remains blank.

2.3 Missing or incomplete date values in the TSCHQ

In case of an incomplete or missing value for date in question 5 *Start of tinnitus: When did you first notice the symptoms of tinnitus?*, please proceed as follows:

- Only the value for day is missing: 15.months.year
+ selection of radiobutton "missing value for day"
- Values for day and month are missing: 1.7.year
+ selection of radiobutton "missing values for day and month"
- Specification: xy years ago: count back from date of visit and enter the calculated date: 1.7.year
+ selection of radiobutton "missing value for day and month"

- Specification: xy months ago: count back from date of visit and enter the calculated date: 15.month.year
+ selection of radiobutton "missing value for day"
- If the value for the entire date is missing: leave date variable blank

3. Data entry is technically impossible:

Please contact database administrator or send a query to the principal investigator.

4. Differing documentation of units:

In case of differing units, please round up to the unit used in the CRF before data entry. Conversion tables are available on the internet, for example at <http://www.chemie.fu-berlin.de/chemistry/general/units.html> (principally: **1 kHz = 1000 Hz**)

5. Entry status:

The text box „quality assurance, input state” requires the entry status of the patient at the following occasions:

- Data entry is finished: If each page of the CRF available has been entered.
- Patient is a drop-out with premature study termination: If no CRFs for the last visit exist (not follow-up).
- Patient is completely validated: If all queries have been answered and the respective data entered into the data base.

6. Self-evident corrections

Previously to data entry, any discrepancies and abnormalities will be discussed with the project coordinator; corrections can then be made accordingly on one's own accord. All corrections have to be documented in a list that is passed on to the project coordinator. A query will be generated if there is the slightest doubt about a data entry.

7. Final visit

The different durations of the studies may result in some missing visits between baseline visit and final visit. Here, visits need to be documented in chronological order (visit 1 to 3, week 2 to 8). The last visit will be documented under final visit (previously termed week 12), the follow-up visit under follow-up (previously termed week 16).

8. Treatment codes

If a treatment code is not standardized and the actual code has to be typed in, the following format has to be used:

Center ID (3 numbers) - Treatment ID (3 numbers) (_ _ _ - _ _ _)

For example:

Center: Regensburg (ID 001), Treatment: Mirtazapin (ID 002)

→ Treatment code: 001-002