Minutes Database Meeting July 30, 2014, 09:00 – 17:00

Besprechungsraum Psychiatrische Institutsambulanz, Bezirksklinikum Regensburg

Moderation: Michael Landgrebe

AGENDA morning

09:00 – 09:15 Welcome – Round of introductions

09:15 – 9:30 COST-Action TINNET (Schlee)

09:30 – 9:45 Tinnitus Database: background (Landgrebe)

09:45 – 10:00 Database Structure (Zeman)

10:00 – 10:30 Database Programming and Development - Options and limits

(Pryss/Reichert)

10:30 – 11:00 Data merge (all)

11:00 – 11:30 Questionnaires (Langguth/Landgrebe)

11:30 – 12:00 Discussion

Dr. Ulrich Frick, Koeln DE, HS Doepfer, Psychologist, Statistician

Prof. Dr. Michael Koller, Regensburg, DE, Head of Center of Clinical Trials, University Hospital Regensburg

Daniela Krainer, Dipl.-Ing., Klagenfurt, Austria, raltec, College Kaernten,

Dr. Michael Landgrebe, Hausham, DE, Psychiatrist, Chief physician of Hospital St. Agatharied, leader TRI Tinnitus Subtyping project

Dr. Berthold Langguth, Regensburg DE, Psychiatrist and Neurologist, Head of psychiatric outpatients department University Hospital Regensburg at Bezirksklinikum

Astrid Lehner, Regensburg DE, Psychologist University Hospital Regensburg

Rüdiger Pryss, Ulm, DE, Database expert, University of Ulm

Dr. Martin Schecklmann, Regensburg, DE, Psychologist, Statistician

Dr. Winfried Schlee, Regensburg, DE, Psychologist, Scientific Research Coordinator, University Hospital Regensburg,

Susanne Staudinger, Regensburg, DE, Database Management, University Hospital Regensburg

Dr. Agnes Szczepek, Berlin DE, ENT, Dept of Otorinolaryngology, Charité Berlin

Florian Zeman, Regensburg, DE, co-head Center of Clinical Trials, University Hospital Regensburg

Yossi Arzouan from Israel had to last-minute cancel his participation

After the introduction Winny Schlee gave an overview over the general rules and the networking instruments of the European COST program. Then he presented the status quo of the BM1306 Action TINNET, the key personel, the list of participants and the upcoming activities.

Background and current status of the TRI Tinnitus database have been presented by Dr. Landgrebe, leader of the TRI Tinnitus Subtyping project and the TRI Tinnitus Database. Florian Zeman described the inner database structure and the possibilities of queries to the database.

It has become clear that the database in its current status cannot be used anymore but has to be rebuilt or modified in order to make the changed grades of the cooperating partners of TINNET (Pryss, University of Ulm). Target of the new programming should be the development of the database to an extremely flexible and modular system. Preferable would be a future development to the point of an expert system.

Winny Schlee described two bottlenecks of the project
1) how to collect for and to enter as much data as possible into the database
2) how to generate as much output as possible?

In order to deal with the first question, the existing confidential agreement has to be revised according to not only the privacy policy of most of the cooperating institutions. Furthermore the patients have to sign an informed consent about the storage of their pseudonymizised – or anonymizised – data in the database. In order to guarantee a high data quality it is necessary to define criteria how and what data should be collected and entered into the database. The need of defining standards applies also for data export. It has been suggested to prepare special SAPs for the TINNET group in cooperation with the TINNET workgroup V Outcome Measurements. Ethic aspects of Data sharing are in the responsibility of the single center.

A Steering Committee should decide which data are of high quality and which should be imported into the database. The admission of further/new items/variables (within the questionnaires, admission of imaging and/or audiological data) has also to be checked.

Professor Koller will suggest a score to assess the data quality. With this score we will also code if the data has been validated.

L U N C H B R E A K

AGENDA Afternoon

13:00 – 13:30 Tinnitus Database: Present – Future (survey among participating centers/countries) (Schlee)

13:30 – 14:30 Formulation and definition of possible research questions – aims of the workgroup, financial support, orders to other workgroups

14:30 – 15:00 Fixing of a time schedule and responsibilities

15:00 – 16:30 Rules of data sharing – scientific agreement for cooperating centers

16:30 – 17:00 Cooperation with other TINNET-workgroup

Date of the next Meeting

End of the Meeting – GROUP PHOTO

The TINNET-experts should describe what additional aspects have to be considered during the rebuilding / modification process of the database. The survey among the TINNET-experts should contain the following:

- description of the benefits if a center collects data for the database
- Expectations of the database
- Standards of data security
- Questions about ideas of how to finance the database: would I, a center/institution, pay for the database service
- Which new variables have to be added
- Description of current used statistical formats
- Modified scientific cooperation agreement and outline of the database
- Question about who of the cooperation center is the responsible person to sign the agreement
- How much is the number of cases of a center
- Does the center already have data, which could be entered into the database and, if yes, in which format?
- Which data? Clinical, genetic , sectional, longitudinal data?
- Possible research areas: influence of pharmacological, non-pharmacological, combined, socio-demographical methods…

Furthermore other TINNET workgroups should be asked for checking the standard CRF and to let the database workgroup know which variables are missing.

Tasks and responsibilities within the TINNET database workgroup

WHAT	WHO	WHEN
Scientific Cooperation Agreement and Outline	Michael Landgrebe	end of August
Appendix	Susanne Staudinger	End of August
Survey	Winny Schlee/Susanne Staudinger	September 15
Shipping of the survey	Susanne Staudinger	September 16
Database specification sheet	Ruediger Pryss/Susanne Staudinger	September 15
Generic database structure	Ruediger Pryss/Susanne Staudinger	September 15
Roadmap Database Management	Uli Frick/Michael Koller	October 30
Suggestions for a STSM Database	all	

Contact to other workgroups

WORKGROUP	WHO
Genetics	Agnes Szczepek
Imaging	Winny Schlee/Martin Schecklmann
Outcome Measurements	Uli Frick/Michael Koller
Clinical	Michael Landgrebe/Berthold Langguth

Questions for the workgroup representatives

WORKGROUP	WHAT
Clinical/Outcome	Which variables are missing within the standard CRF
	Which questionnaire that is classified as mandatory (A) should be classified as recommended (B) and vice versa
	Reassessment of the Consensus (consensus 1.1.) Which variables/items/questionnaires have proven themselves? Which variables/items/questionnaires are missing? Which variables/items/questionnaires should be deleted? Suggestions for users
	Fixing of standardized criteria for outcome measurements
A draft of consensus 1.1. should be discussed and approved at the 11th TRI Tinnitus Conference 2016 in London	

WORKGROUP	WHAT
Neuroimaging/Genetics	Are genetic data already available? Where?
	Suggestions for additional clinical characteristics that are relevant for genetic data collection respectively data analysis
	Draft of a grant application for a genetic project

Suggestions for the next database workgroup meeting together with a database workshop: end of January in Ulm, Germany, or Klagenfurt, Austria, with one or two invited speakers: Prof. Felix Naumann, Berlin, N.N.