Authorship rules for publications of data collected by the CrescNet growth network

1. Preliminary remarks

Scientific work is subject to legal and professional regulations, rules of conduct such as the Declaration of Helsinki and professional standards. The recommendations on good clinical practice adopted by the DFG are intended to prevent scientific misconduct. (1)

CrescNet is a network in paediatrics for the early detection of disorders of growth and weight development and for the documentation of the course of treatment when a growth disorder has been detected. The network is based at the Department of Paediatrics and Adolescent Medicine at Leipzig University Hospital. The core of the network is a central register maintained at the medical computer centre of the Leipzig University. Partners in the network are paediatric and adolescent medical facilities in primary and specialised care, with growth and weight development being the focus of data collection. Participation in the network is based on the commitment to quality assurance through the conclusion of a cooperation agreement with the Medical Faculty of the Leipzig University.

The authorship of scientific publications that use data from the CrescNet Register in the context of quality assurance in paediatrics is regulated below.

2. Tasks of CrescNet

CrescNet has the task of promoting quality assurance in patient care in the field of growth and weight development disorders. A major contribution to this is the establishment of a feedback system for percentile deviations to partners in primary care.

CrescNet supports scientific work in the field of growth disorders by maintaining various modules that enable the documentation of growth-related clinical parameters, such as phenotypic manifestations of concomitant symptoms, laboratory values, etc., and can be analysed in relation to diagnosis. CrescNet thus supports the development of guidelines.

3. Access to the data and evaluation projects

In addition to quality assurance, publications and other scientific projects are supported by the database. The participating centres have committed themselves to joint responsibility for the protection of the collected data in the cooperation agreement with the medical faculty of the Leipzig University.

Valid data protection regulations (GDPR) must be complied with. **The informed consent of the legal guardians** (Informed Consent Form CrescNet) must be kept in the patient file. For data protection reasons, the original data will remain at the participating centre; only anonymised data will be used and published for statistical analyses. The analysing institutions secure the respective data status used for the analysis. A data set to be used for a scientific question is generated at the CrescNet site in Leipzig and made available to the requesting scientist via a **project agreement (can be found in the CrescNet application under Documents > Proposal for project agreement)**.

Evaluations in the context of scientific analyses are carried out in accordance with the explanations in the application for a scientific project (see point 5).

In principle, the participating centres always have access to their collected data within the framework of quality assurance in paediatrics, which themselves regularly contribute to the development of the data pool.

Epidemiological/scientific questions can be dealt with by CrescNet partners after a project plan has been drawn up and presented to the CrescNet advisory board (see point 5). External researchers only have access to the data in co-operation with one or more CrescNet partners, and only with the express approval of the CrescNet Advisory Board.

4. Publications

The structure of quality assurance in paediatrics means that data is collected on a multicentre basis. As many people are involved for this reason, the selection and ranking of authors can be difficult. In principle, the authors of a scientific publication should be those, but only those, who have made a significant contribution to the conception and planning or to the analysis and interpretation of the data and to the formulation of the manuscript and who have agreed to publication. Inclusion of documented patients in a study/project does not necessarily lead to co-authorship. In all publications that deal with studies/project questions, all participating clinics should be listed in the addendum, possibly also stating the number of fully documented patients and the responsible physician.

With regard to the order of authors, the first author is usually the person who wrote the manuscript. The study/project leader can claim the position of last author if he/she is not already the first author. If several study/project leaders are involved in a study, they agree on the last authorship according to the extent of their involvement. The other authors are named and ranked by the studies/project leaders involved in the study/project.

The corresponding author is usually the main project leader. Doctoral students are to be considered as co-authors if the results of their dissertation are part of the publication.

All publications based on the data collection of the CrescNet registry must be labelled with a reference to the CrescNet network.

5. Application for a scientific project

Each application is based on a written project outline (CrescNet **project agreement**)

- Title of the project
- Background (why should this evaluation take place, what previous knowledge/data and possibly own preliminary work exists),
- Question formulated as a scientific hypothesis
- Method (statistical design),
- Information about the persons involved
- · Information on the time frame,
- Information on the planned publication of the data (congresses, publication, authorship)
- Information on financial support for the project, in particular support from third parties (e.g. industry)

In principle, the outline should be formulated in such a way that it clearly fulfils the requirements for acceptance as a scientific publication. The outline can be submitted to the project coordinator CrescNet (info@crescnet.org) at any time via the project agreement.

Scientific analyses should primarily be formulated and coordinated by active participants in the database. If external persons or institutions or pharmaceutical companies make enquiries, these projects must be led by active users and the CrescNet advisory board must be informed in advance. Adequate funding of the expenditure is necessary.

6. Composition of the CrescNet Advisory Board

The members of the CrescNet Advisory Board are scientifically recognised experts from the field of paediatrics.

The committee is made up of the following members.

- 1. Leipzig University CrescNet:
 - Scientific director
 - CrescNet project coordination
 - CrescNet technical management database
- 2. Cooperating specialist centres

 International representatives from sub-project Achondroplasia and other skeletal dysplasias

Interested partners should have the opportunity to participate in the advisory board. Each institution should be represented by one person. Interested parties shall express their interest in participating in project coordination of CrescNet. A decision on participation (addition, replacement) shall be made by the existing advisory board team. A total number of 10 members should not be exceeded.

7. Tasks of the CrescNet advisory board

To promote trusting cooperation between all participants and minimise bureaucracy.

- Pre-selection on the basis of the project outlines
- Coordination of the presentation and discussion
- Awarding the project
- Monitoring the implementation; if there is a lack of activity, the project award can be withdrawn
- Contacts and agreements on coordination before submitting abstracts for congresses (national or international). In the interests of all those involved, critical consideration must be given to the possible negative consequences of the publication for the group as a whole (e.g. abuse in the competition for patients).
- Information on the current status of the project and data density according to project proposals at annual reports to the participating centers

Literature

- (1) Principles for safeguarding good scientific practice (DFG recommendations)
- (2) Guidelines for authorship in international journals (http://icmje.org)

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Annexes

Annex 1 ICF CrescNet

Annex 2 Proposal for project agreement Annex 3 Guide to the project agreement

Annex 4 Technical and organizational measures data protection of the register