ERN GENTURIS GUIDELINE GROUP TERMS OF REFERENCE VERSION 3.0

1. INTRODUCTION

1.1 The ERN GENTURIS Network proposes the clinical area and the rare genturis syndrome where a guideline should be developed. The Executive Committee Plus makes the final decision on which guidelines are prioritized for developing.

1.2 The GENTURIS network will receive an invite to indicate their interest to participate in the Guideline Group. The ERN GENTURIS Network Board or the relevant Thematic Group may suggest the experts for the Core Working Group. The Core Working Group is a group of experts who have profound expertise in the disease and (if possible) experience in guideline development. They will be the operational arm of the Guideline Group.

1.3 The Core Working Group will appoint a leader who will be the Chair of the Core Working Group, as well as of the Guideline Group. The leader should be a representative from a ERN GENTURIS Full Member or Affiliated Partner (ERN GENTURIS HCP).

1.4 The Core Working Group will nominate internal and external experts, including patient representatives as members of the Guideline Group.

1.5 The Guideline Groupe will oversee and advise on the development of specific guidelines in the Network's area of expertise. For each genturis disease a separate Guideline Group will be established; Each Guideline Group shall be known as the **[Disease name] Guideline Group**.

1.6 Guideline Groups have devolved responsibility from the Network Board and will act as a working group that report, through the Guideline Group's Chair to ERN GENTURIS Network Board for approval and exception reporting.

2. CORE WORKING GROUP MEMBERSHIP

2.1 The GENTURIS network will receive an invite to indicate their interest to participate in the Guideline Group. The ERN GENTURIS Network Board or the relevant Thematic Group may suggest the experts for the Core Working Group who will lead on the research and writing of the guideline. The Core Working Group should consist of:

- Experts who have profound expertise in the disease and (if possible) experience in guideline development;
- Approximately 3 to 8 people. If possible, a patient representative should be included in the Core Working Group as well;
- From at least 2 ERN GENTURIS HCPs from at least 2 Member States with expertise in the ERN GENTURIS thematic group to which the genturis disease belongs[1].

2.2 The Core Working Group is part of the Guideline Group.

[1] The HCP is recognised as an expert in Thematic Group following an application and assessment process, which includes proof of national endorsement as an expert centre as well as national endorsement for the application, a positive assessment by the ERN Board, and validation of the positive assessment by the ERN Board of Member States.

2.3 The Core Working Group will appoint a leader who will be the Chair of the Core Working Group, as well as of the Guideline Group. The leader should be a representative from a ERN GENTURIS Full Member or Affiliated Partner (ERN GENTURIS HCP).

2.4 The Core Working Group will be the operational arm of the Guideline Group and will engage with the Guideline Group for advice on the scope of the guideline, research carried out and in writing the guidelines and recommendations.

2.5 The Core Working Group will engage with the Guideline Group, either virtually or face to face, to secure consensus for recommendations.

3. MEMBERSHIP GUIDELINE GROUP

3.1 The Core Working Group makes a **list with all specialties**/areas, from which experts and patient representatives can be identified, that should be included in the guideline and revise the list of MDT disciplines when required.

3.2 The Core Working Group will identify experts **who are respected in their field of expertise** for each specialty and identify and select them based on the following considerations:

- Consideration on which countries have a recognised guideline and consideration of which experts are experienced in writing guidelines;
- Experts from ERN GENTURIS, preferably with experience in writing guidelines;
- Experts from other ERNs where there is any overlap in scope, preferably with experience in writing guidelines;
- External people from Europe, who should be endorsed by a professional society, preferably with experience in writing guidelines;
- External people from outside Europe if necessary, and only if expertise cannot be found in Europe, preferably with experience in writing guidelines;
- Representative of relevant professional societies should be involved.

3.3 The Guideline Group will consist of representatives from:

- Minimum representation from 4-5 Member States, of which a minimum of 3 HCPs of ERN GENTURIS with expertise in the ERN GENTURIS thematic group to which the genturis disease belongs[1];
- Minimum of two patient representatives with experience of or representing the clinical areas of the guideline, if possible; and linking back to the wider patient community when required.

3.4 Specific criteria for membership shall normally include:

- Established record of involvement in specialist clinical practice in the genturis on which the guideline will focus;
- Commitment to engage with ERN GENTURIS and the Guideline Group, and to respond to requests in a timely manner;
- Good communicator with command of written and oral English;
- Ability to attend real or virtual meetings of the Guideline Group.

3.5 Definition of final composition of the Guideline Group will be kept by the Core Working Group and (one of the ERN GENTURIS) Project Manager(s) and will take into account appropriate diversity and representation necessary to deliver the Guideline Group's remit. Disclosure statements have to be

filled out for all members of the Guideline Group. Members of the Guideline Group will be co-authors of the guideline, in which the Core Working Group will occupy first and last authorships. ERN GENTURIS will be added in the title and in the acknowledgement of the journal publication. If possible, the phrase "on behalf of European Reference Network for Genetic Tumour Risk Syndromes" will be added to the author list or affiliations to ERN GENTURIS will be added.

3.6 Members shall be appointed for the duration of the project timeline to develop the guideline.

4. PATIENT INVOLVEMENT

4.1 The Core Working Group will establish a Patient Advisory Group (PAG) of at least two patient representatives that have experience in the clinical area of the guideline, if possible.

4.2 The PAG will appoint a chair, who will be present as representative of the PAG in Core Working Group meetings.

4.3 The PAG will advise on the scope, target population, clinical questions, the guideline aims, and to address and rate the outcomes in terms of their importance.

4.4 The PAG will review the evidence and recommendations, undertaking a patient centered literature review or survey the patient community where there are gaps in evidence, ensuring their views on the balance of benefit and harm of the recommendations are considered by the Core Working Group.

4.5 The PAG will develop a lay persons' guide or information of the guideline.

5. PURPOSE

The purpose of the Guideline Group is to:

5.1 Oversee the writing of and the publication of the guideline and its recommendations;

5.2 Provide specialist advice on a new guideline scope – population, intervention, comparator and outcomes;

5.3 Review and grade published and unpublished evidence as described in the guideline development policy, mainly performed by the Core Working Group;

5.4 Secure consensus on recommendations and clinical opinion where there are gaps in published evidence through an evidence-based approach (e.g.: Delphi) as described in the guideline development policy;

5.5 Review patient and lay-person information and guidelines;

5.6 Advise and communicate with wider stakeholders when agreed, maintaining links with national and European societies;

5.7 Promote the guideline developed by ERN GENTURIS on conferences, (virtual) meetings and workshops and thereby promoting high quality patient care and engagement;

5.8 Oversee the review and update of the guidelines and their recommendations.

6. REPORTING AND ASSURANCE ARRANGEMENTS

The Guideline Group shall:

6.1 Work effectively with the Core Working Group and Network Coordinator & ERN GENTURIS HCPs;

6.2 Report formally, regularly and on a timely basis to the ERN GENTURIS Network Board and Network Coordinator on the Guideline Group's activities.

7. MANAGERIAL AND ADMINISTRATIVE SUPPORT

7.1 Administration and secretarial support will be provided by Network Coordinator's Management Team.

8. CORE WORKING GROUP MEETIG

8.1 Meetings with the Core Working Group shall be held once a month. Communication via email should occur regularly.

8.2 Meetings should be held as video or teleconference where possible.

9. GUIDELINE GROUP MEETING

9.1 Meetings with the Guideline Group shall be held as the Chair of the Guideline Group deems necessary. Communication with the Guideline Group via email should occur regularly, but definitely when finalizing the scope, draft recommendations and draft guideline.

9.2 Meetings should be held as video or teleconference where possible.

10. RELATIONSHIPS AND ACCOUNTABILITIES WITH THE NETWORK BOARD AND ITS COMMITTEES

10.1 The Guideline Group is directly accountable to the ERN GENTURIS Network Board for its performance in exercising the functions set out in these terms of reference.

10.2 The Guideline Group shall embed the ERN GENTURIS corporate standards, priorities and requirements, e.g. equality and human rights through the conduct of its business.

11. REVIEW

11.1 These Terms of Reference shall be reviewed periodically by the Network Coordinator's Management Team with reference to the ERN GENTURIS Network Board.