FAQs ERS Document Development: Frequently Asked Questions

➢ Clinical Practice Guideline or Statement?

Ask yourself: do I want to make recommendations for clinical practice? If yes, you should aim to produce a clinical practice guideline and be prepared to follow a vigorous methodological process.

	Clinical Practice Guideline	Statement
Multidisciplinary and representative development group	☑	☑
PICO formulation	Detailed	To represent topics and sub-topics covered
Review of the literature	Systematic	Comprehensive
Assessment of the quality of evidence	☑	✘
Provide recommendations and their strength	☑	✘

Clinical practice guidelines are statements that **include recommendations** intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options. The ERS strongly recommends the use of the GRADE approach in their guidelines.

Statements, on the other hand, are descriptive of current practice and research evidence on a subject. They should also be based on a well-conducted literature search; however, as a formal grading of the evidence and degree of recommendations is not undertaken, they **cannot contain recommendations for clinical practice**.

➢ Clinical Practice Guideline or Technical Standards?

Ask yourself: do I want to answer "how to perform" a technology or a test, or do I rather want to answer "what to perform"?

This is a question that often arises, especially since some Task Force proposals contain both clinical and technology assessment questions in their scope. Clinical Practice Guidelines and Technical Standards refer, in fact, in two completely distinct types of documents.

If you want to focus on the application of a technology or a test to patient care (e.g. compare tests or identify populations for which a technology or a test might be more appropriate) and you want to make recommendations for patient care, you **should develop a clinical practice guideline** and follow the methods accordingly.

Otherwise, if you want to purely assess the technology or a test itself (e.g how to perform, validity, calibration, standardization, etc.) you **should develop a technical standards** document and refrain from addressing/make recommendations for issues that focus on clinical practice.

➢ What if there is very scarce evidence/ no good evidence for our subject? Can we still produce a clinical practice guideline?

YES! The amount and type of available data does NOT determine the type of your document.

The GRADE approach is applicable to any kind of evidence and not only to randomised controlled trials. It can be also applied to observational studies (cohort studies, case control, and case series).

When the evidence to answer a question about interventions comes from non-randomised studies, the confidence with their results should decrease due to inherent limitations of this type of data. As long as you are transparent and explicit about the identified evidence, you can use any type of data to reach recommendations.

The GRADE approach is applicable to prognostic questions and diagnostic questions. Appropriate designs to answers these questions typically include non-randomised studies which can provide high quality evidence provided that they are free of methodological limitations.

➢ Why do we need to have a TF member who is experienced with the GRADE approach/ evidence-based medicine?

Producing Clinical Practice Guidelines consists of following a rigorous evidence-based methodology. To ensure that all the steps of the process are followed and that the quality of the final document is high, a TF member has to have the methodological overview of the document.

It is preferable that this member has experience using the GRADE approach; if this is not feasible, the chairs of the TF should aim to include a member that has documented experience, at least, in evidence-based medicine and systematic reviews. This person will work closely with the ERS Methodologist to ensure that all the methodological requirements are met.

➢ How can we find someone with methodological expertise to include in our TF?

First, consider asking at your university/institution. Are there people who have experience in GRADE and/or evidence-based medicine (systematic reviews, meta-analyses etc.) and who might be interested in becoming members of the TF?

Consider including ERS junior members, as they might have the time and motivation needed to work on the TF. Make sure you acknowledge their contribution and give them ownership of their work by having them as co-authors of the guideline.

➢ How the ERS can help us?

ERS has two in-house Methodologists who can provide guidance through all the different steps of developing your document.

The ERS Methodologist will be working closely with the TF member who is responsible for the methodology, in order to make sure that all the essential requirements of the GRADE approach are met and any problems are promptly solved. However, the ERS Methodologist will NOT be performing the literature review and evidence synthesis for your project.

➢ Where can I learn more about the GRADE approach?

We list relevant resources, references and links in our website.

➢ Where can I see an example of a Guideline that was produced according to the ERS rules?

European Respiratory Society guidelines for the diagnosis of primary ciliary dyskinesia
http://erj.ersjournals.com/content/early/2016/11/11/13993003.01090-2016