An Industry Perspective on **Guidelines for Translation and Cultural Adaptation**

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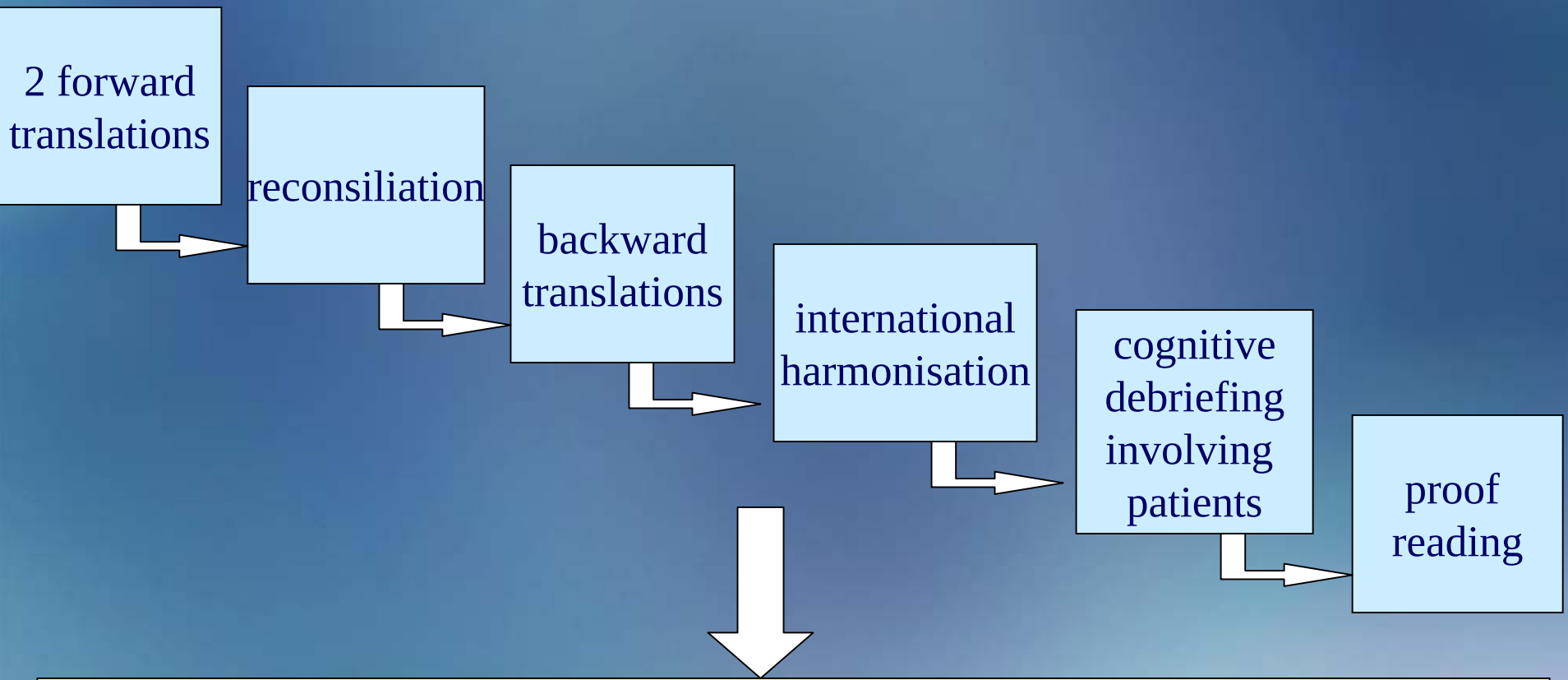
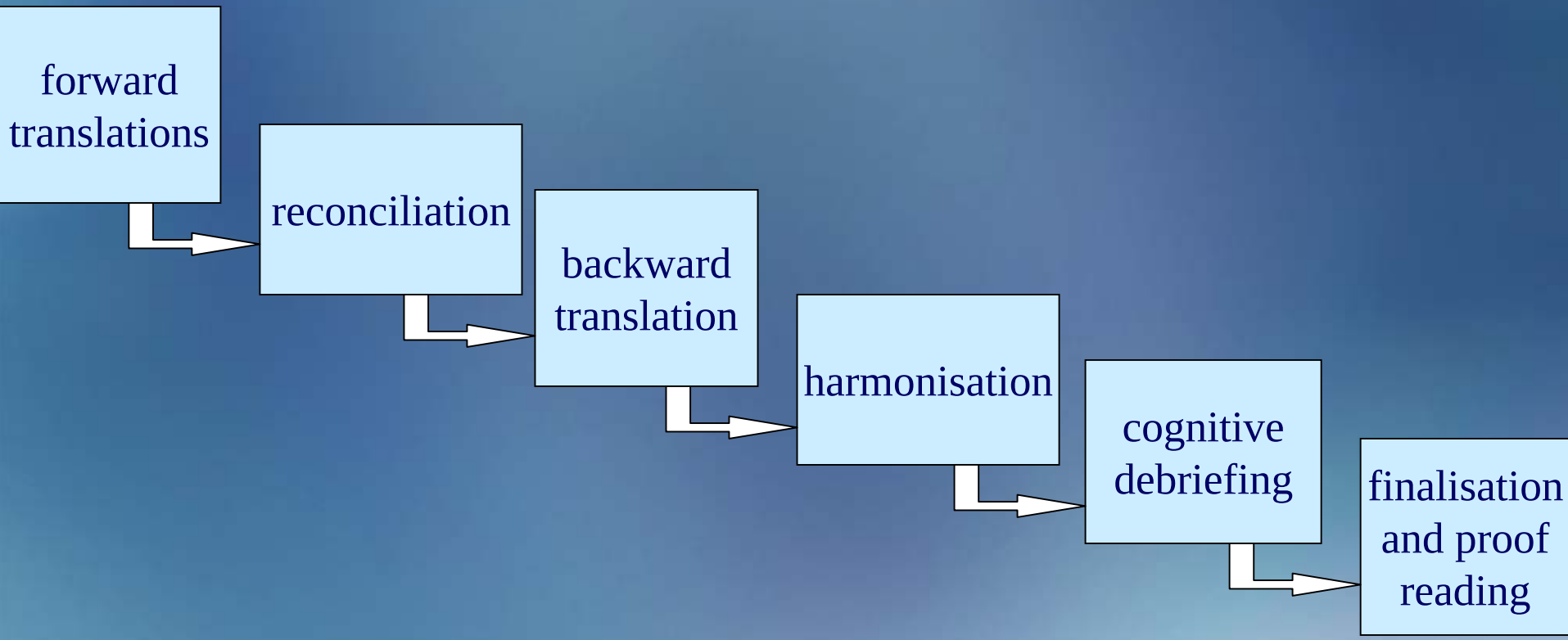
ERIQA Recommendations

Aim: Ensure the same meaning of the original concept in all translations



Psychometrics for translated questionnaires (reliability and validity)
for each country and language or groups of countries with similar culture

ISPOR Recommendations



Psychometric data from one population cannot be generalised to another population, but specific guidance has not been published yet

Practicalities of Clinical Trials

- Many trials are primarily designed to answer Regulatory requirements
- For disease-specific instruments, there are few accepted “gold standards”
- Short time intervals from design of study to patient inclusion
- Countries are added during course of study
- Multinational trials often recruit small samples per country

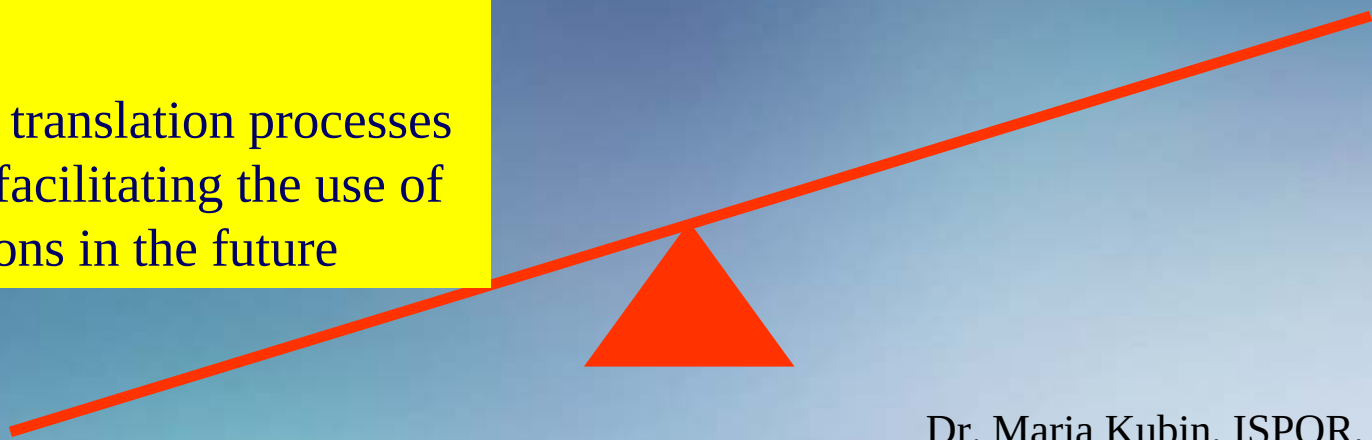
Guidelines

Advantages

- Standards for the assessment of HRQOL are based on scientific rationale
- Collaboration of experts from ISPOR, ISOQOL, ERIQA, PhRMA-HOC resulted in harmonised, uniform recommendations
- Enhance recognition of HRQOL as endpoint
- Heterogeneity of translation processes will be reduced, facilitating the use of existing translations in the future

Disadvantages

- Raises the hurdle in terms of time and budget needed for measurement of QOL
- Practicalities of validation need consideration
- How much validation evidence is enough?



Conclusions and Recommendations

- ☠ Great initiative that helped federating scientists, clinicians, regulators, pharmaceutical industry
- ↑ Continue to develop **uniform** international standards
- ↑ Keep guidance flexible to needs of an evolving discipline
- ↑ Bridge scientific goals and practical constraints
- ↑ Provide guidance on unresolved methodological issues