



# INTRODUCTION TO PATIENT-REPORTED OUTCOMES (PROs) SUCH AS HEALTH-RELATED QUALITY OF LIFE, TREATMENT SATISFACTION, ETC

**Stockholm**

**Wenesday,  
March 3**

**08:30-12:15**

**Methods and  
Clinical  
Applications**



## *Translation Requirements*

*The Experience of Mapi Research  
Institute*

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Mapi Research Institute, France





# The context

**Growing Interest in PRO**



**Development of Instruments...  
in only one language (UK/US English)**



**Need for Adaptation for use in other countries  
(clinical trials - clinical practice)**



**Cultural adaptation**



# The context

- ❖ Official guidelines: none
- ❖ Recommendations drafted by ERIQA  
(in collaboration with Mapi Research Institute),  
and ISPOR SIG (2003)



# Definitions

## Cultural Adaptation



Two phases



**I**

**Linguistic Validation  
(translation)**



**II**

**Psychometric Validation  
(reliability, validity,  
responsiveness to change)**



# Definitions

## Linguistic Validation

Passage of the questionnaire from the "source" language to the "target" language

### Two requirements

- ✓ Equivalence between "source" and "target" versions
- ✓ Use of a language accessible to everybody

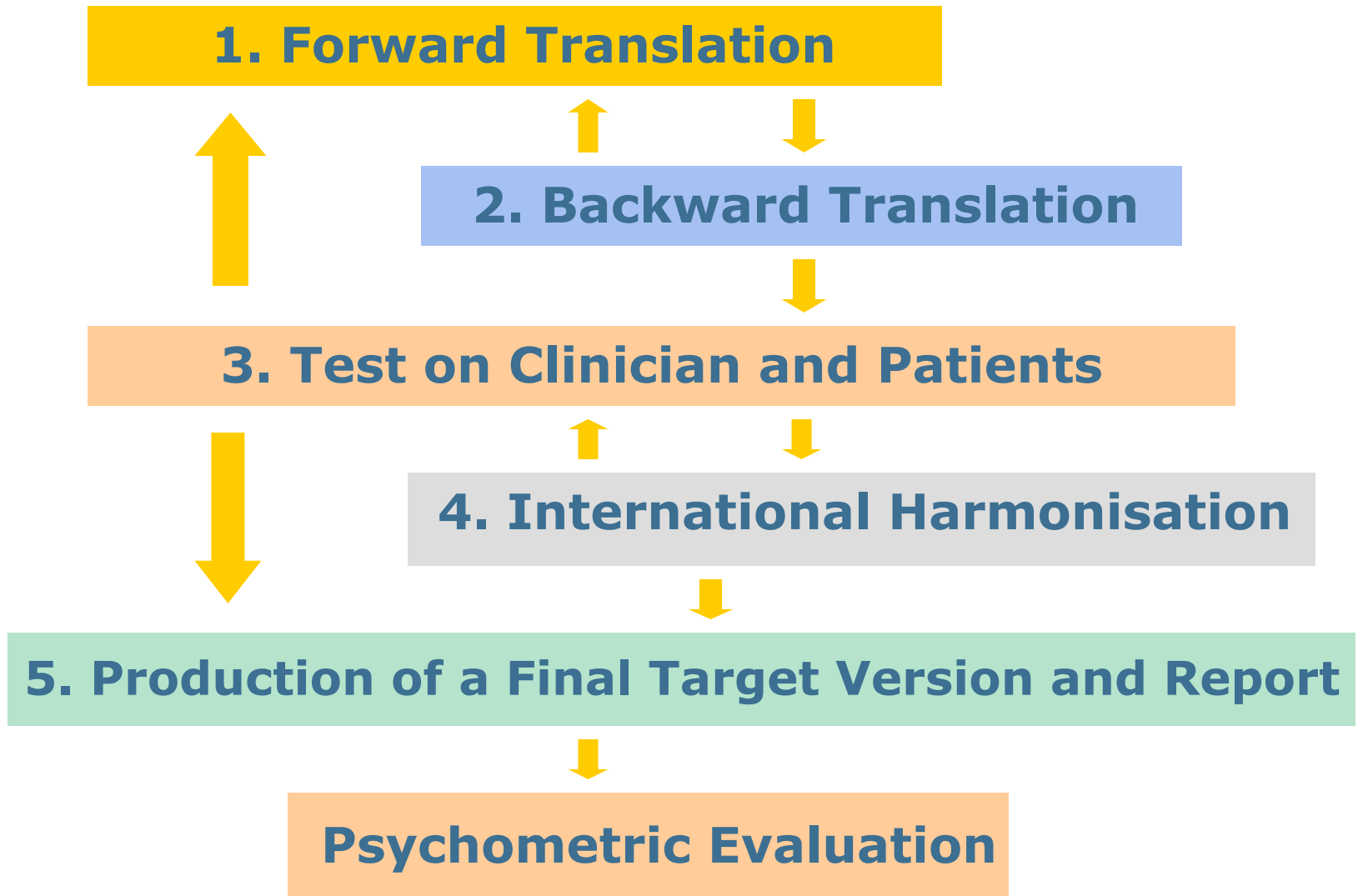
### Six Steps

- ✓ Forward Translation
- ✓ Backward Translation
- ✓ Test
- ✓ International Harmonisation
- ✓ Proof-reading
- ✓ Report



# Methodology: Steps

16 weeks





# Methodology: Players

Author



Co-ordinating Center



**Local team**

Consultant

« Forward » translators

« Backward » translator

Clinician

Patients

**Local team**

Consultant

« Forward » translators

« Backward » translator

Clinician

Patients

**Local team**

Consultant

« Forward » translators

« Backward » translator

Clinician

Patients

**15 participants per language version**



# Forward Step

Source



Conceptual definition of each item

*Author*



1 "forward"  
translation

1 "forward"  
translation

*Professional  
Translators*



Version 1

*Consultant*



Report

*Consultant  
Coordinating Center*





# Examples

*Swedish => UK English -> For use in the US*

*Disease area: Angina Pectoris*

**Original**

En kortare promenad (ungefär 2 km)  
A short walk (about 2 km)

**Final UK version**

Short walk (about a mile)

**Test on  
American population**

One mile is not a short walk !!

**Problem**

What is important? "1 mile" or "short walk"?



# Examples

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**Test on  
American population**

One mile is not a short walk !!

**Problem**

What is important? "1 mile" or "short walk"?

**Contact with  
author**



Concept = short walk

**Final American  
version**

Short walk (several blocks)



# Backward Step

**Version 1**



**1/ 2 "backward"  
translation(s)**

*Professional  
Translators*



**Comparison with original questionnaire**

*Consultant  
Coordinating Center*



**Report**



**Version 2**

*Consultant  
Coordinating Center*



# Examples

Danish -> Finnish -- Existing UK version used to help

Questionnaire = Danish Prostate Symptom Score

DAN-PSS-1

*Q2A: Do you consider your urinary stream as:  
Normal / Weak / Very weak / Dribbling*

**Problem** BT of response choices 2 & 3 =  
"slowly /very slowly" instead of "weakly/very  
weakly".

**Solution** "hitaasti" (slowly) and "hyvin hitaasti" (very  
slowly) were changed for "heikosti" (weakly)  
and "hyvin heikosti" (very weakly).



# Test on Clinician and Patients

Version 2



Review by a clinician/expert in the field

*Clinician*



Version 3



Patient interviews/Cognitive Debriefing  
- Filling out of the questionnaire  
- analysis of the interpretation of each item

*Consultant*



Report



Version 4

*Consultant  
Coordinating Center*



# Examples

## Original: Canadian English -- Title: 'Parent/Guardian Asthma Questionnaire' (Asthma)

All translations of the word 'guardian' were checked during cognitive debriefing to ensure that they were easily understood and commonly used by respondents.

- *'Questionnaire for parent/guardian about asthma'* in Afrikaans
- *'Questionnaire for parents/tutors of children with asthma'* in Argentinean Spanish
- *'Questionnaire for parents or (persons) responsible of patients with asthma'* in Chilean Spanish
- *'Questionnaire about asthma for parent/guardian'* in Chinese for Hong-Kong
- *'Questionnaire for parents/substituted parents of patients with asthma'* in Colombian Spanish
- *'Questionnaire for parents/tutors of patients with asthma'* in Costa Rican Spanish
- *'Parent/guardian asthma questionnaire'* in Danish
- *'Questionnaire for parents/guardians of asthmatic patients'* in Mexican Spanish
- *'Questionnaire for parents/tutors of patients with asthma'* in Peruvian Spanish



# International Harmonization

**Version 4**



**IH Meeting:**

- Comparison by group of languages
- Checking of concepts

*Professional Translators  
Coordinating Center*



**Control by Consultant**



**Report**

*Consultant  
Coordinating Center*



**Version 5**



# Examples

French → UK English, US English, Canadian English

## Quality of Life Questionnaire for Functional Digestive Disorders (FDDQL)

**Original** Item 13: "La moindre aggravation de vos douleurs ou de votre transit intestinal vous a-t-elle angoissé(e) ?"

**Problem** Although very commonly used in France, the phrase "transit intestinal" (referring to the progression of foods inside the intestines) was particularly difficult to render in all the languages.

**Solution** UK English = bowel function  
US English = intestinal activity  
Canadian English = bowel activities





# Proof-reading & Final Report

Version 5



Proof-reading

*Natives in Target Language*



Control by Coordinating Center



Report



Final Version

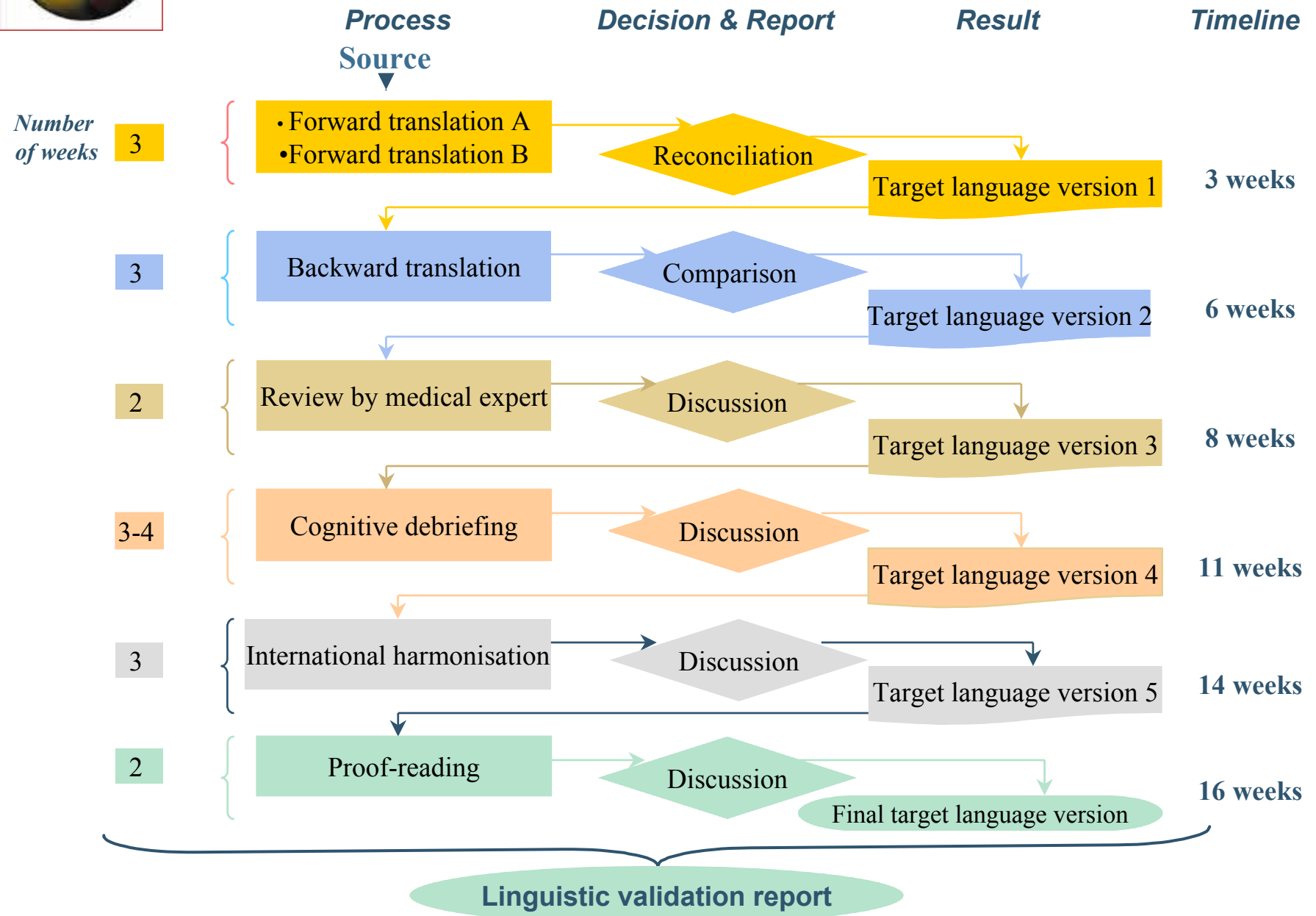


Final Report

*Coordinating Center*



# Timeline for Translation





# Conclusions

- ❖ **Translating a PRO measure is a not an easy process**

- ❖ **Recommendations**

- ❖ « Do what you said you would do »

- ❖ « Provide evidence of what you have done »

**= 4Ts Rule**

- ❖ Thoughtfulness

- ❖ Timing

- ❖ Training

- ❖ Transparency



Lead to a 5th one

**Trust**