

Cultural learning implementing multi-national clinical trials

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Disclosure / conflicts of interest

I have an interest in relation to one or more organisations that could be perceived as a possible conflict of interest in the context of the subject of this presentation. The relationships are summarised below:

| <u>Interest</u> | <u>Name of organisation</u> |
|-----------------|--|
| Grant support | AB-Biotics, Alexza, Almirall, AstraZeneca, Bristol-Myers Squibb, Cephalon, Dainippon Sumitomo Pharma, Elan, Esteve, Ferrer, GlaxoSmithKline, Janssen-Cilag, Lilly, Lundbeck, Otsuka, Pfizer, Sanofi-aventis, Servier, Takeda, Telefónica |
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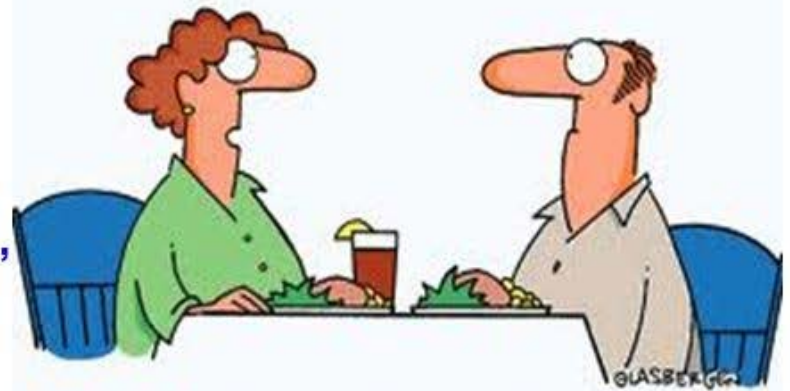
Cultural and language issues in clinical trials

- Baseline geographical/cultural differences
- Symptoms are expressed differently across cultures
- Validity of tools and questionnaires in different languages
- Unofficial co-official, and local languages
- Language variations
- Rater training (in their own language!)
- Centralized ratings
- Biomarkers

CULTURAL VARIATION

- The cultures of the world are very different.
- For example, there are approximately 240 different languages in the world today.
- In addition, the same language may have several variations.
 - British English, American English, Canadian English, and Australian English.

Γειά 喂 สวัสดี hello
안녕하세요 olá
Bonjour Hej Oi! Olá! ciao hola
Привіт guten tag
aloha
今日は goddag Chào ahn / Chào chi
こんにちは hallo Привет shalom



"This is the nicest conversation we've had in weeks.
Let's not spoil it by talking."

Co-official and local languages



The complexity of validating functional assessments across cultures

- Performance-based functional assessment: UPSA-B



1. Making appointments



2. Writing checks



3. Counting change

Sven Barnow · Nazli Balkir (Editors)

Cultural Variations *in* Psychopathology

From Research to Practice



HOGREFE 

The MADRS: Construct validity across cultures

1

APPARENT SADNESS

0 = No sadness

1

2 = Looks dispirited but does brighten up without difficulty

3

4 = Appears sad and unhappy most of time

5

6 = Looks miserable all the time. Extremely despondent

2

REPORTED SADNESS

0 = Occasional sadness in keeping with the circumstances

1

2 = Sad or low but brightens up without difficulty

3

4 = Pervasive feelings of sadness or gloominess. The mood is still influenced by external circumstances

5

3

INNER TENSION

0 = Placid. Only fleeting inner tension

1

2 = Occasional feelings of edginess and ill-defined discomfort

3

4 = Continuous feelings of inner tension or intermittent panic which the patient can only master with some difficulty

5

6 = Unrelenting dread or anguish. Overwhelming panic

4

REDUCED SLEEP

0 = Sleeps as usual

1

2 = Slight difficulty dropping off to sleep or slightly reduced, light or fitful sleep

3

4 = Sleep reduced or broken by at least 2 hours

5

6 = Less than 2 or 3 hours sleep

5

REDUCED APPETITE

0 = Normal or increased

1

2 = Slightly reduced appetite

3

4 = No appetite. Food is tasteless

5

6 = Needs persuasion to eat at all

6

CONCENTRATION DIFFICULTIES

0 = No difficulties in concentrating

1

2 = Occasional difficulties in collecting one's thoughts

3

4 = Difficulties in concentrating and sustaining thought which reduces ability to read or hold a conversation

5

6 = Unable to read or converse without great difficulty

The MADRS: Construct validity across cultures

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LASSITUDE

0 = Hardly any difficulties in getting started. No sluggishness

1

2 = Difficulties in starting activities

3

4 = Difficulties in starting simple routine activities, which are carried out with effort

5

6 = Complete lassitude. Unable to do anything without help

8

INABILITY TO FEEL

0 = Normal interest in the surroundings and in other people

1

2 = Reduced ability to enjoy usual interests

3

4 = Loss of interest in the surroundings. Loss of feelings for friends and acquaintances

5

6 = The experience of being emotionally paralysed; inability to feel anger, grief or pleasure and a complete or even painful failure to feel for close relatives and friends

9

PESSIMISTIC THOUGHTS

0 = No pessimistic thoughts

1

2 = Fluctuating ideas of failure, self-reproach or self-depreciation

3

4 = Persistent self-accusations, or definite but still rational ideas of guilt or sin. Increasingly pessimistic about the future

5

6 = Delusions of ruin, remorse or irredeemable sin. Self-accusations which are absurd and

10

SUICIDAL THOUGHTS

0 = Enjoys life or takes it as comes

1

2 = Weary of life. Only fleeting suicidal thoughts

3

4 = Probably better off dead. Suicidal thoughts are common, and suicide is considered as a possible solution but without specific plans or intention

5

6 = Explicit plans for suicide when there is an opportunity. Active preparations for suicide

Consequences of neglecting cultural issues in clinical trials

- Poor signal detection
 - Especially in multinational trials
- Short-term savings, long-term costs
- Poor ecological validity of the findings
- Marketing problems

