

# *Landscape for Clinical Outcome Assessments (COAs) for Pain*

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# Types of Outcome Measures

## Biomarkers

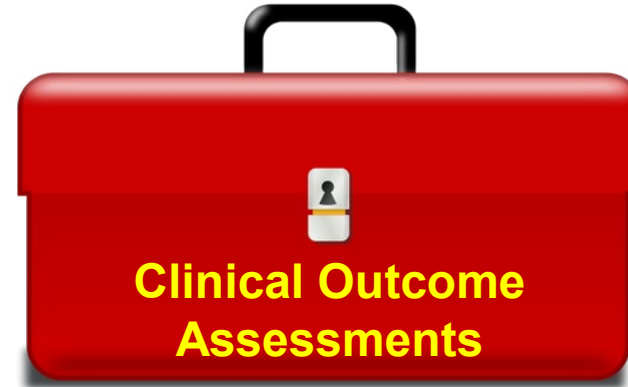


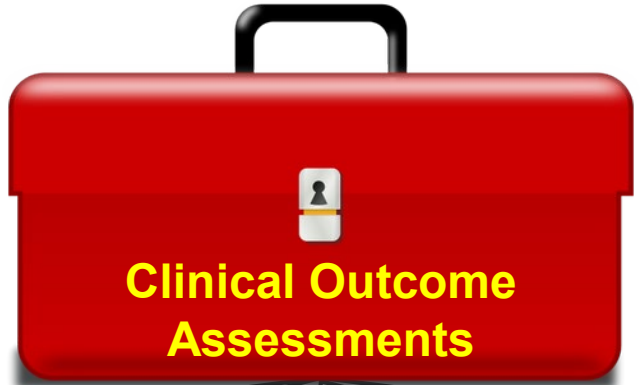
Example:

Salivary levels of cytokines,  
neuropeptides, and  
hormones.

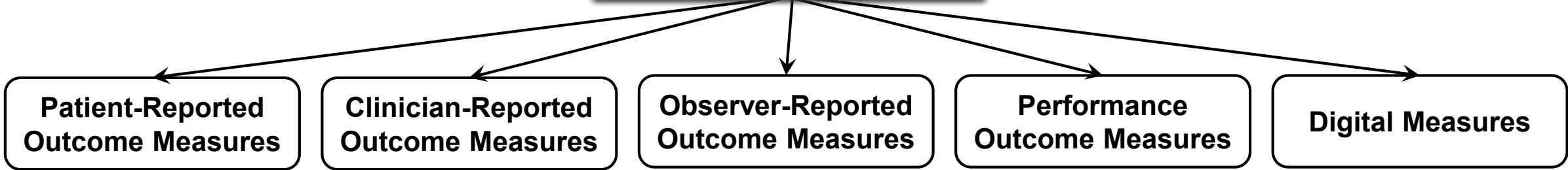
Presented by Dr. Petra  
Schweinhardt (University of Zurich)

## Clinical Outcome Assessments

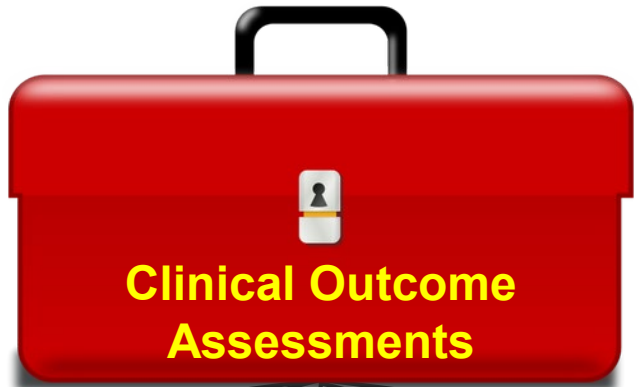




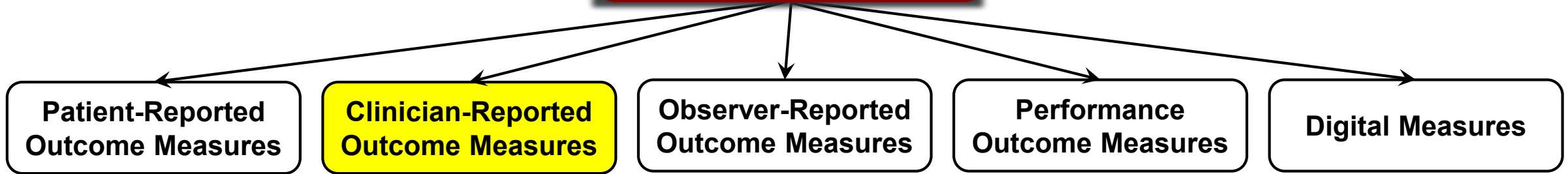
# Clinical Outcome Assessments





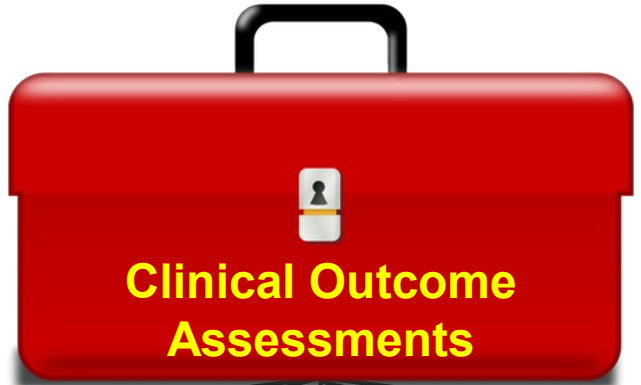


## Clinical Outcome Assessments

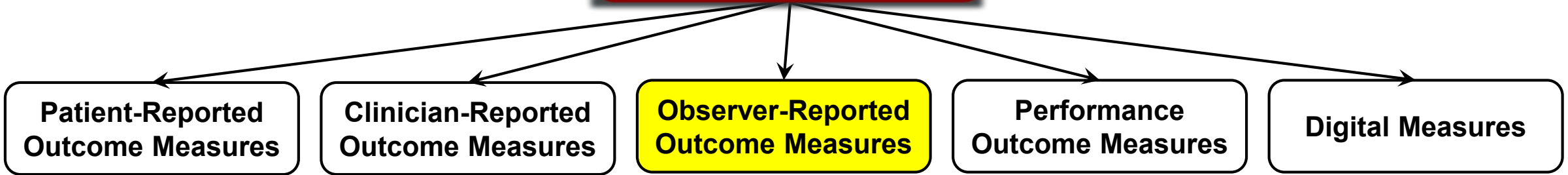


### Face, Legs, Activity, Cry, Consolability (FLACC) Scale

Criteria	Score 0	Score 1	Score 2
Face	No particular expression or smile	Occasional grimace or frown, withdrawn, uninterested	Frequent to constant quivering chin, clenched jaw
Legs	Normal position or relaxed	Uneasy, restless, tense	Kicking, or legs drawn up
Activity	Lying quietly, normal position, moves easily	Squirming, shifting back and forth, tense	Arched, rigid, or jerking
Cry	No cry (awake or asleep)	Moans or whimpers; occasional complaint	Crying steadily, screams or sobs, frequent complaints
Consolability	Content, relaxed	Reassured by occasional touching, hugging, or being talked to, distractible	Difficult to console or comfort



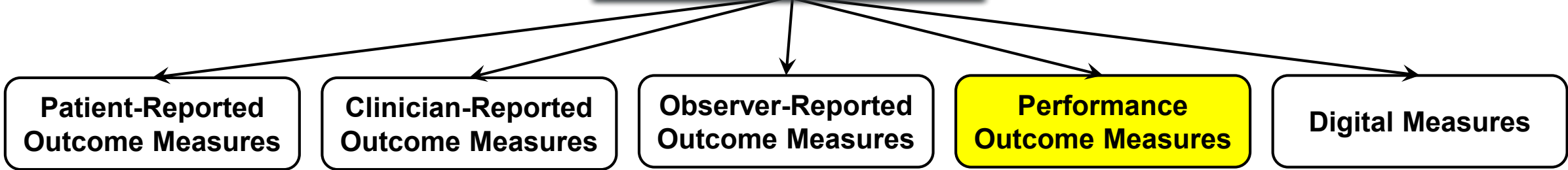
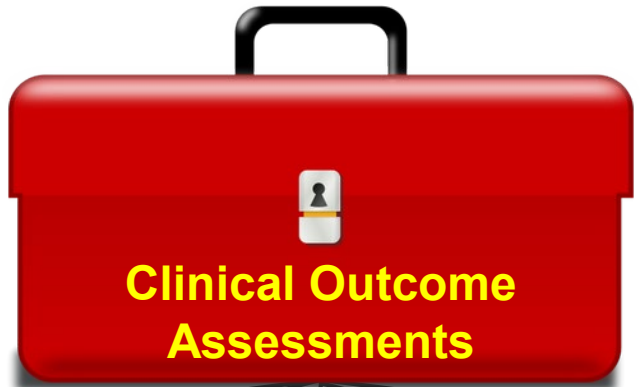
## Clinical Outcome Assessments



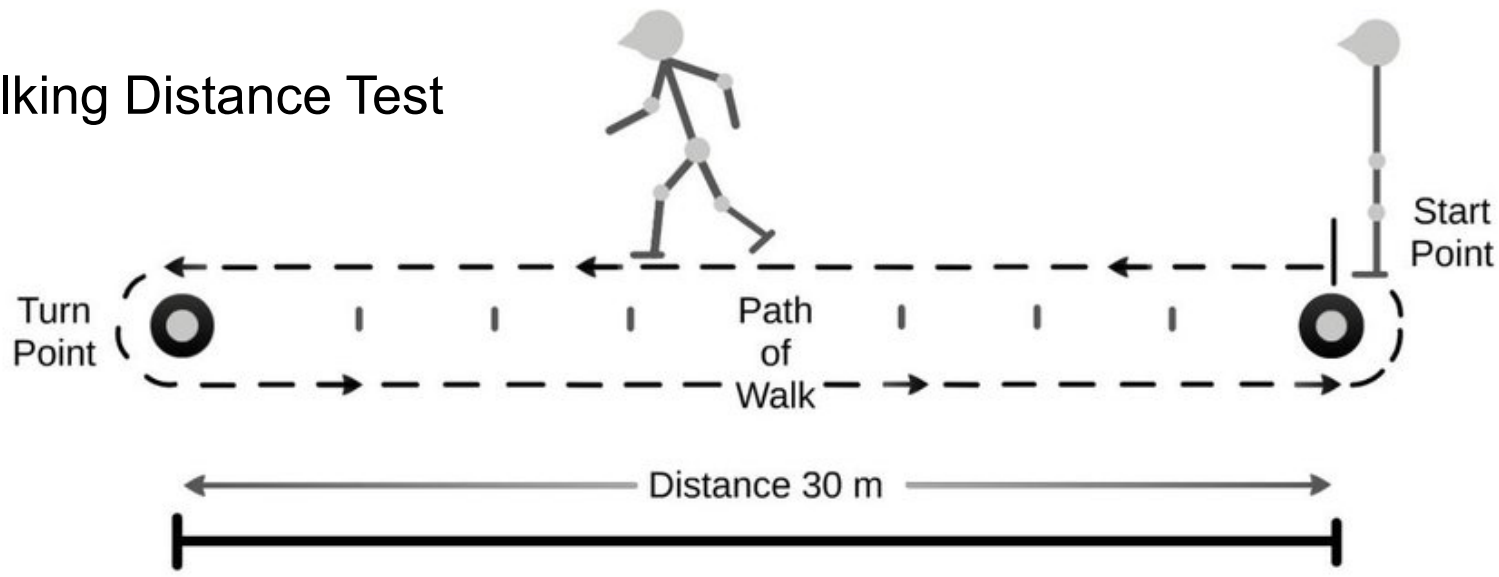
### PARENTS' POSTOPERATIVE PAIN MEASURE (PPPM)

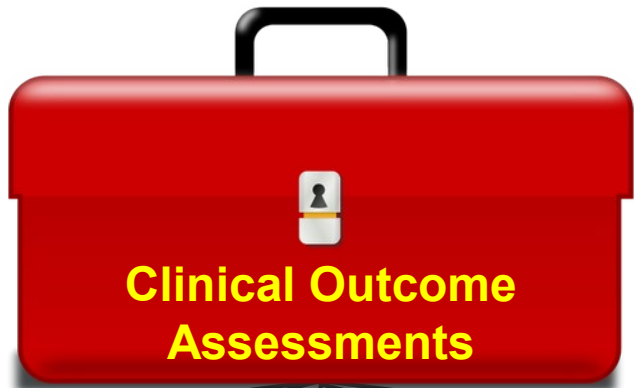
*When your child was recovering from surgery between \_\_\_\_\_ and \_\_\_\_\_ today, did s/he . . .*

1)	Whine or complain more than usual? .....	Yes	No
2)	Cry more easily than usual? .....	Yes	No
3)	Play less than usual? .....	Yes	No
4)	Not do the things s/he normally does? .....	Yes	No
5)	Act more worried than usual? .....	Yes	No
6)	Act more quiet than usual? .....	Yes	No
7)	Have less energy than usual? .....	Yes	No
8)	Refuse to eat? .....	Yes	No



6-minute Walking Distance Test





**Clinical Outcome Assessments**

**Patient-Reported Outcome Measures**

**Clinician-Reported Outcome Measures**

**Observer-Reported Outcome Measures**

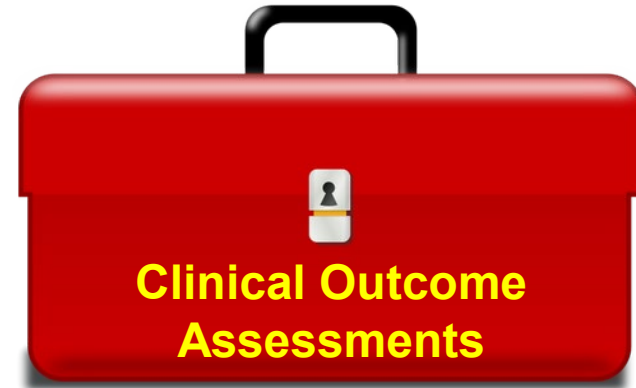
**Performance Outcome Measures**

**Digital Measures**





# Every measure has error.



*“What we observe is not nature in itself but nature exposed to our method of questioning.”*

-Werner Heisenberg, 1958

# Assessing Pain across the life span

**PAIN**

Intensity

Frequency

Interference

**Life  
Span**

**Baby Toddler**

**Child**

**Adolescent**

**Young Adult**

**Adult**

**Older Adult**

0

100+

**Data  
Sources**

Clinician-reported outcome (ClinRO) Measures

Observer-reported outcome (ObsRO) Measures

Performance outcome (PerfO) Measures

Patient-reported outcome (PRO) Measures

## Pain Interference



How is Pain Interference defined or conceptualized?

Does how we define or conceptualize Pain Interference vary across the lifespan?

Are there core features that are consistent across the lifespan to allow for a common metric?

**How does our definition of Pain Interference change based on a condition or disease?**

Life  
Span

**Baby Toddler**

**Child**

**Adolescent**

**Young Adult**

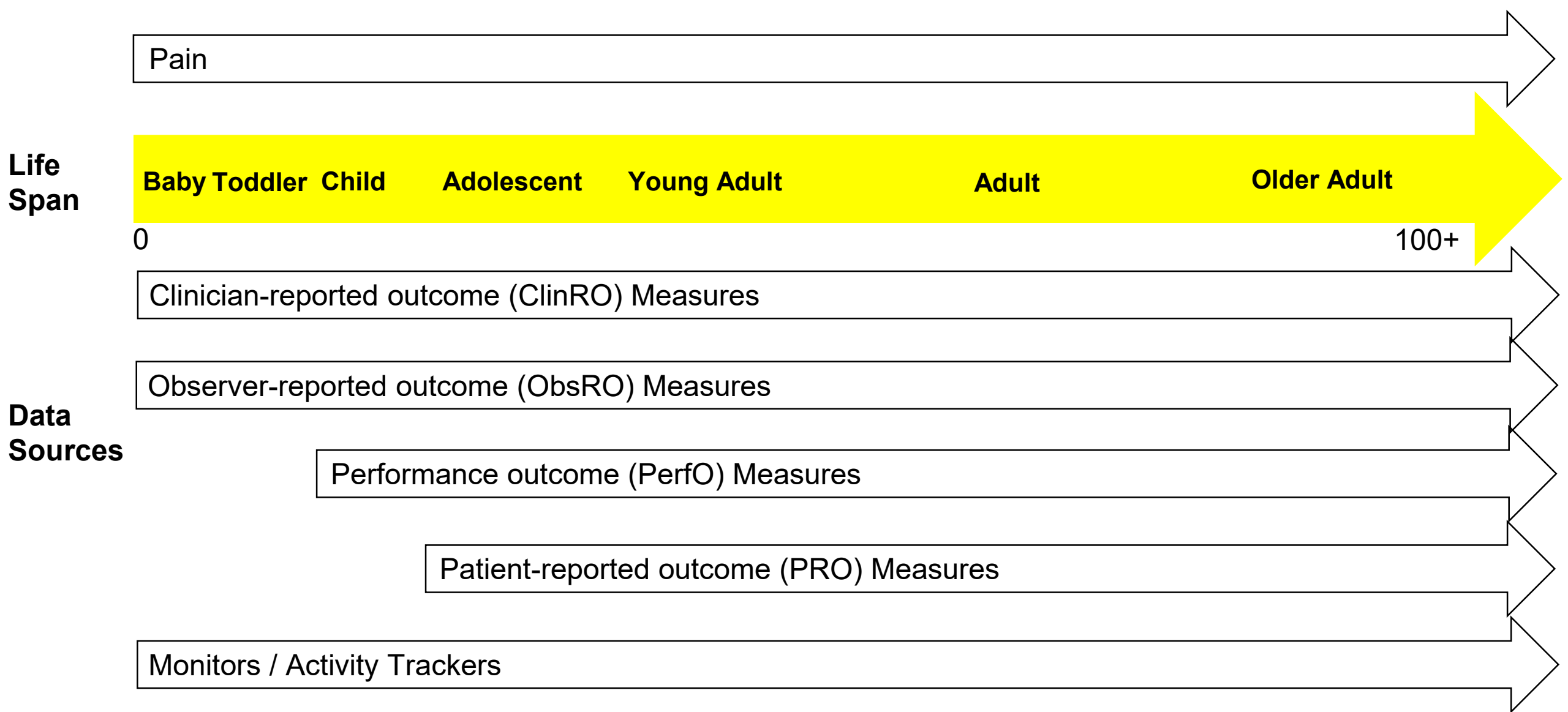
**Adult**

**Older Adult**

0

100+





Which measurement tools are more or less appropriate at different parts of the life span?

Can we create composites from different measurement tools?

**How does our measurement approach change based on a person's condition, disease, or setting?**

# The Field of Pain COAs Continues to Advance

1. Opportunities to enhance question stems and response options.
2. Move towards core COAs and endpoints
3. Opportunities to use digital COAs to get more frequent pain assessment.
4. Consider when to use different COAs to measure pain (and related constructs) or integrate multiple COAs together.
5. Include multiple stakeholders to make our research more patient-centered.
  - What are the most important aspects of pain? What is meaningful change?