

# Patient-Reported Outcomes

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# Outline

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- Review outcome domains and measures recommended in chronic pain clinical trials
- Highlight innovations in patient-reported outcome assessment that could be applied to pancreatic pain
  - sensors, electronic diaries, ecological momentary assessment

# Patient Reported Outcomes (PROs)

- PROs provide unique information on the impact of a medical condition and its treatment from the patient's perspective
- Assessment of disease symptoms or treatment side effects, such as pain, fatigue, or anxiety
- Assessment of functional outcomes such as physical, social, role, emotional, or cognitive functioning
- Can include multidimensional constructs such as health-related quality of life (HRQOL) or health utility

# IMMPACT Recommendations: Chronic Pain

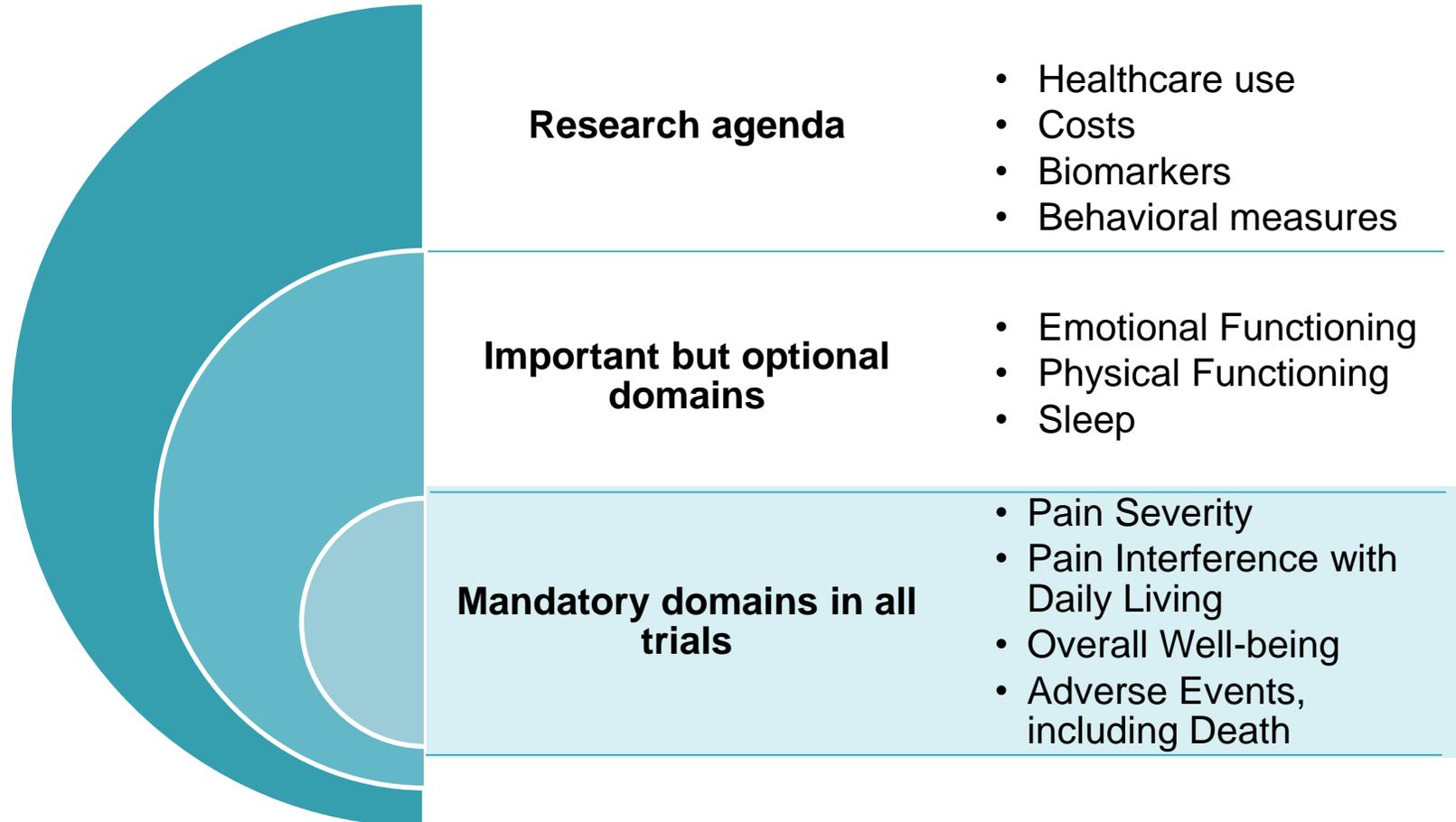
## Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT)

(2003 adult,  
2008 pediatric),  
consensus  
based

### IMMPACT domains:

- pain intensity
- physical functioning
- emotional functioning
- participant ratings of improvement and satisfaction with treatment
- symptoms and adverse events
- participant disposition (e.g. adherence to the treatment regimen and reasons for premature withdrawal from the trial)

# Pediatric Core Outcome Set for Chronic Pain Trials



Palermo, et al., 2021, PAIN

# NIH HEAL Pain ERN (Effectiveness Research Network) Common Data Elements

- Adult Chronic Pain (Number of total CDE Questions - 30 questions)\*

Pain Intensity	Pain Interference	Physical Functioning/ QOL	Sleep	Pain Catastrophizing	Depression	Anxiety	Global Satisfaction with Treatment	Substance Use Screener
PEG (Pain, Enjoyment, General Activity)		PROMIS Physical Functioning Short Form 6b	PROMIS Sleep Disturbance 6a + Sleep Duration Question	Pain Catastrophizing Scale – Short Form 6	PHQ-2	GAD-2	PGIC	TAPS 1
3		6	6	6	2	2	1	4

\*monitor opioids (including dosage) by appropriate PRO, EHR, or other measure.

# Pancreatitis Pain

- Disease specific measures
  - Pain measures (COMPAT)
  - Health related quality of life (PANQOLI)
- General measures
  - PROMIS measures
  - Legacy pain measures
- Remain gaps in measurement of some domains and overreliance on pain as single retrospective measure

# Innovations in Measurement

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- Objective measures/sensors
  - Actigraphy
- Daily diaries
- Ecological momentary assessment

# Electronic Capture of Medication Use

- Real time capture of medication use by vial opening
- Passive recording of time/date
- Can be used to examine temporal patterns or to convert to percent adherence as an overall adherence measure

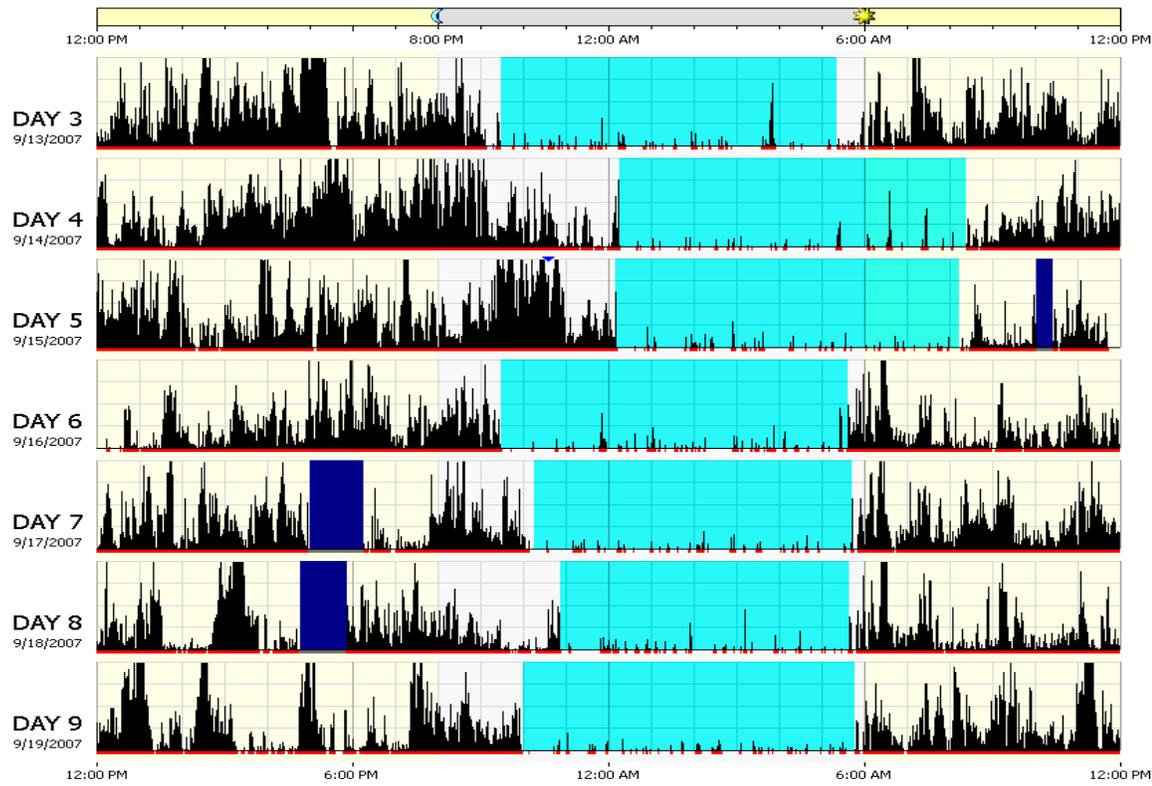


# Objective Assessment Tools

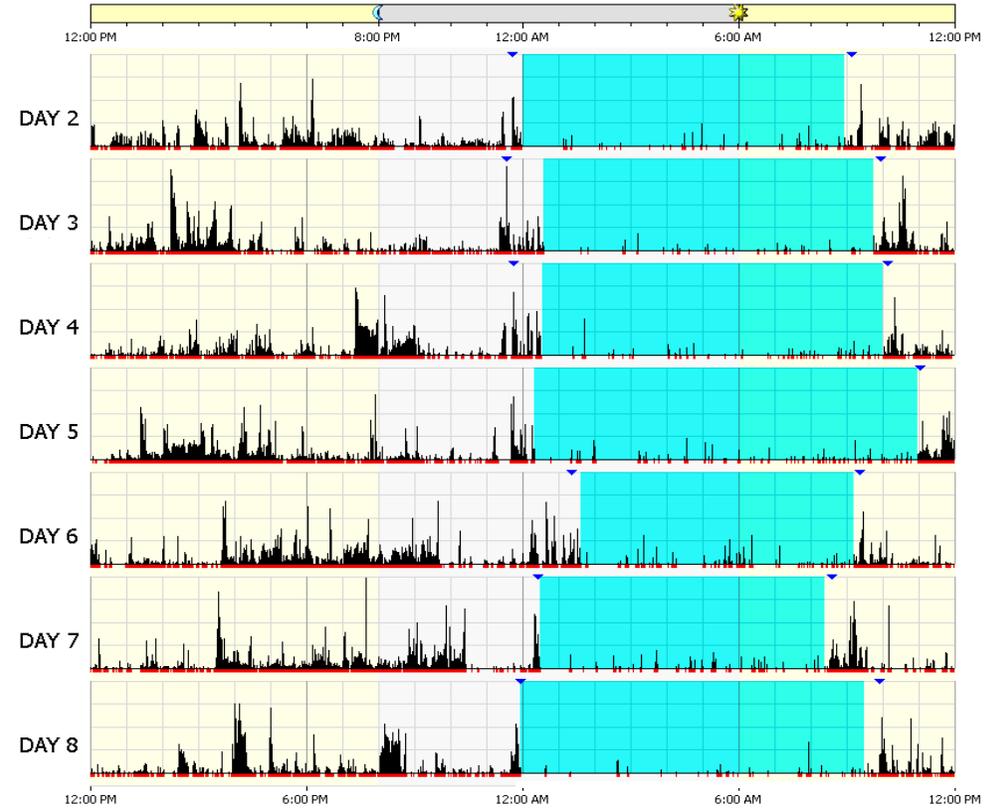


- Ambulatory actigraphy can be used to assess sleep and activity patterns
- Research vs commercial grade (Fitbit, etc)?
- Relatively unobtrusive, embedded in day-to-day life
- Minute by minute (or more frequent) time stamped data

# High physical activity

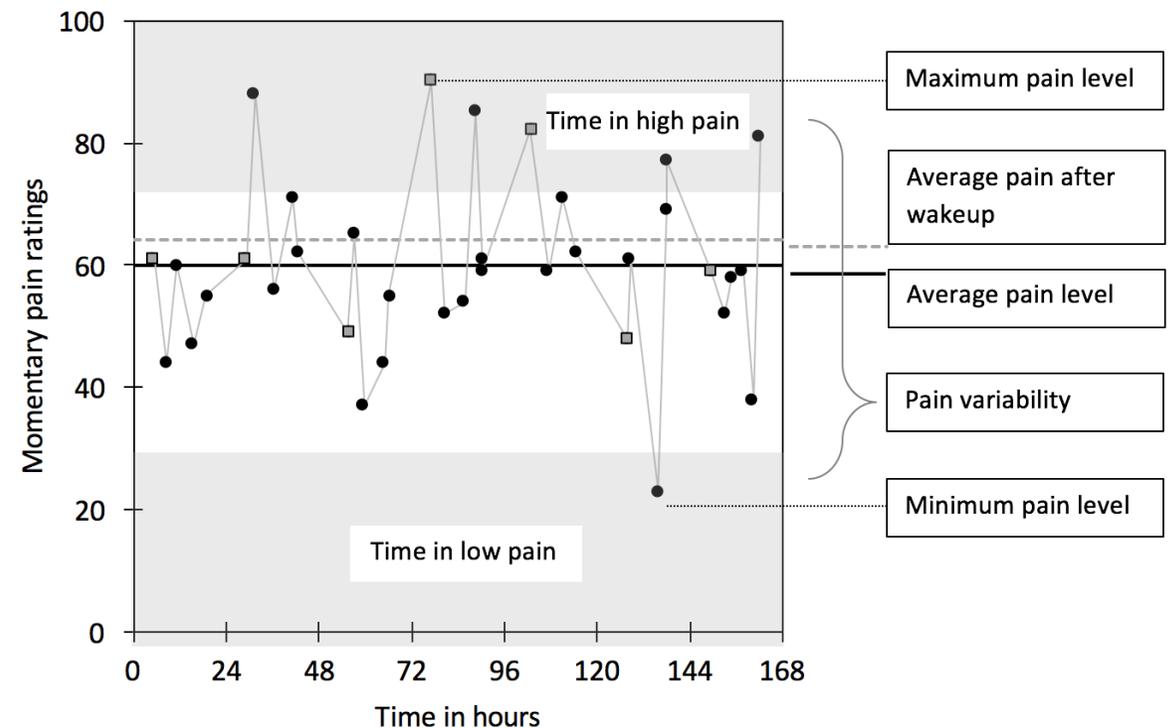


# Low physical activity



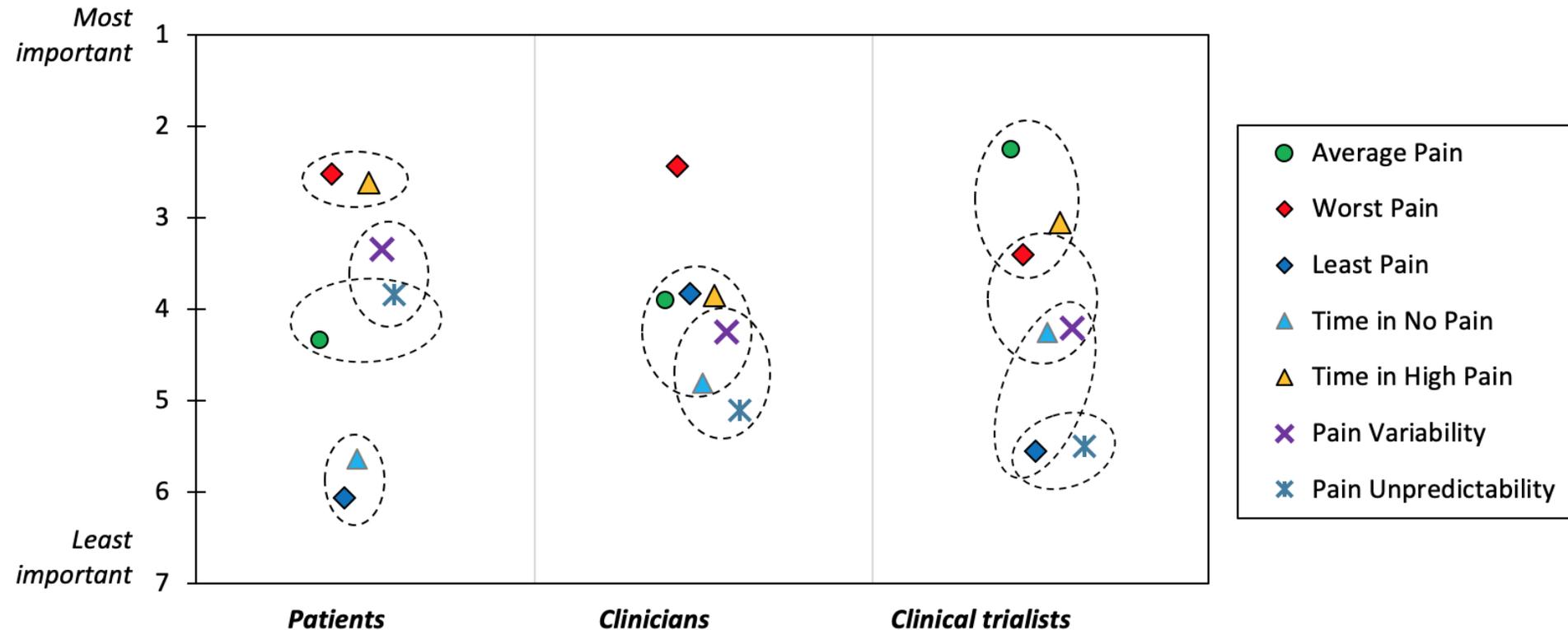
# Patient-Reported Outcome Diaries

- Prospective daily diary can provide information on patterns over time
- Real time assessment
- Reduces recall bias, ability to determine dynamic changes in domains of interest
- Can examine group-based or individual trajectories



See series of papers in J Pain 2021 April: [Stefan Schneider](#),<sup>1</sup> [Doerte U. Junghaenel](#),<sup>1</sup> [Masakatsu Ono](#),<sup>1</sup> [Joan E. Broderick](#),<sup>1</sup> and [Arthur A. Stone](#)<sup>1,2</sup>

# Importance Ratings by Stakeholders



# E-diaries in Clinical Trials: REDCap and Customized

End of day diary

Pain characteristics

Activity limitations (e.g., school, sports, social activities)

Can get very high compliance in protocols from 7-30 days long

**WebMAP**

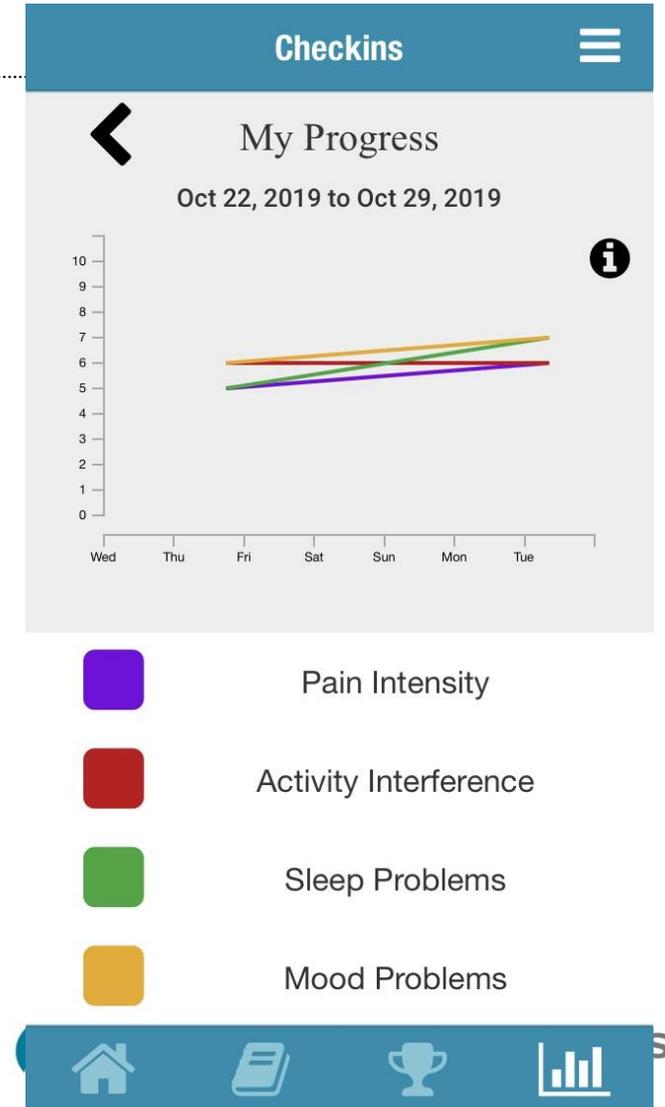
**Check-in**

What was your level of pain today?  
0 [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] 10  
no pain worst pain

How difficult was schoolwork  
0 [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] 10  
Not very Somewhat Extremely

How difficult was it to fall or stay asleep last night?  
0 [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] 10  
Not very Somewhat Extremely

Did you feel down, depressed, or hopeless today?  
0 [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] 10  
Not very Somewhat Extremely



# Summary and Conclusions

- Outcome assessment is a critically important component of identifying effective treatments
- There are some gaps in measurement of pancreatitis pain in certain domains and in prospective measurement of pain
- Innovations in use of sensors/devices and daily measurements using electronic methods may enhance symptom capture in pancreatitis studies



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