Patient States:
Artificial Intelligence-Driven Metric Providing Comprehensive Yet Straightforward Understanding of Chronic Pain Patients

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Disclosures

Louis Raso, MD

- Boston Scientific: Speakers Bureau
- Aurora Spine: Speakers Bureau and Stockholder
- Surgentec: Speakers Bureau, and Royalties
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Pain Patient Health is Multidimensional

Pain Scores
Sources of Bias & Confound Factors

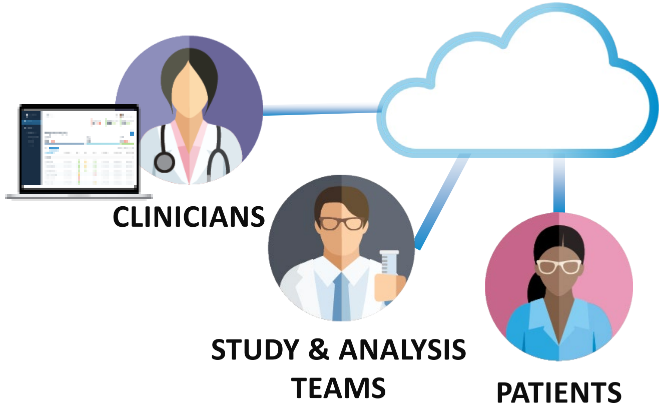
- Response bias[1]
- Memory bias/accuracy[2,3]
- Patient comprehension
- Psychosocial and behavioral factors[1]
- Methodological issues

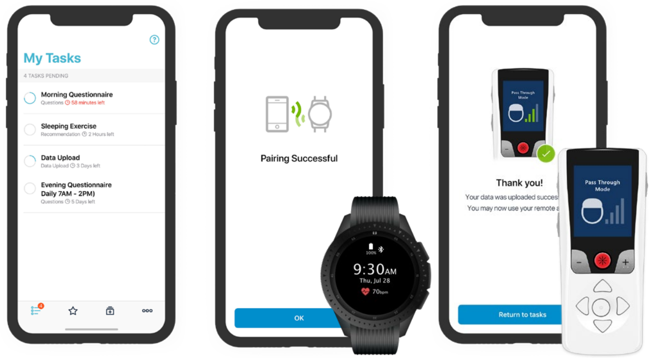
Broad Outcomes
IMMPACT Recommended domains[4]

- PAIN
- PHYSICAL FUNCTION
- EMOTIONAL FUNCTION
- PT RATING OF IMPROVEMENT / SATISFACTION
- SYMPTOMS / ADVERSE EVENTS
- PARTICIPANT DISPOSITION

The Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials

New Tools
Digital and continuous





Questionnaires, Text Responses, & Voice Recordings | Wearables | Stimulator Data

1) Robinson, et al. 1997
2) Redelmeier and Kahneman, 1996
3) Schneider, et al. 2011
4) Turk et al, 2002

Study Methods

Study Design	Two ongoing, multi-center, prospective Boston Scientific-sponsored SCS studies (NAVITAS and ENVISION), NCT03240588
Key Study Methods	• Ongoing Digital Health Study • Advanced data analytic techniques and novel patient measures
Analysis Cohort	n = 116/182 patients with chronic pain treated with or candidates for SCS met the analysis inclusion criteria: • Subjects wore the smartwatch >10 days with overlapping daily questionnaires answered via custom-designed clinical study version of a digital health ecosystem (Boston Scientific, Valencia, CA)
In Clinic Assessments used in this Analysis	ODI Total EQ5D: Pain, Activities, Health VAS, Normed Score

Daily Questionnaires from Patient Phone Application used in this Analysis	Average Pain
	Medication
	Activities of Daily Living
	Mood
	Sleep
	Alertness
Smartwatch	Effective Mobility (Derived from accelerometer)

IBM AI analysis discovery:
Patients move between different “States” each day

Factors contributing to Patient States

Average Pain

Medication

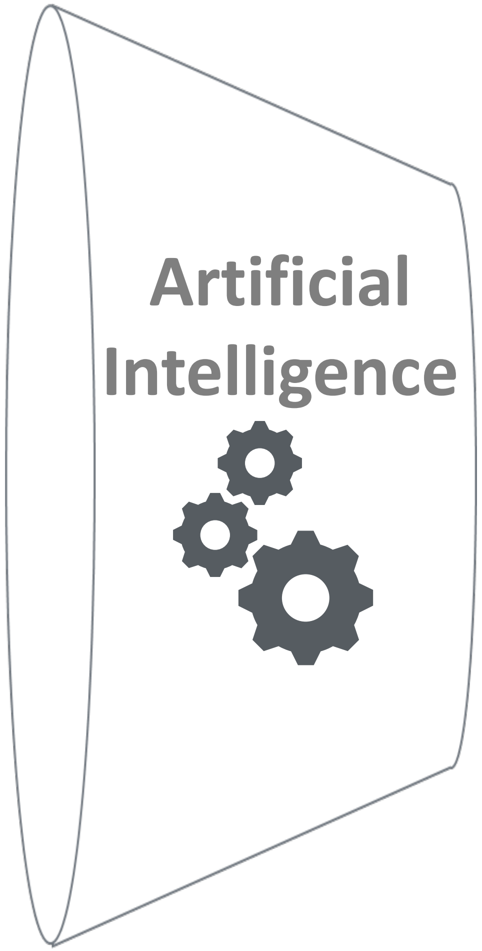
Activities of Daily Living

Mood

Sleep

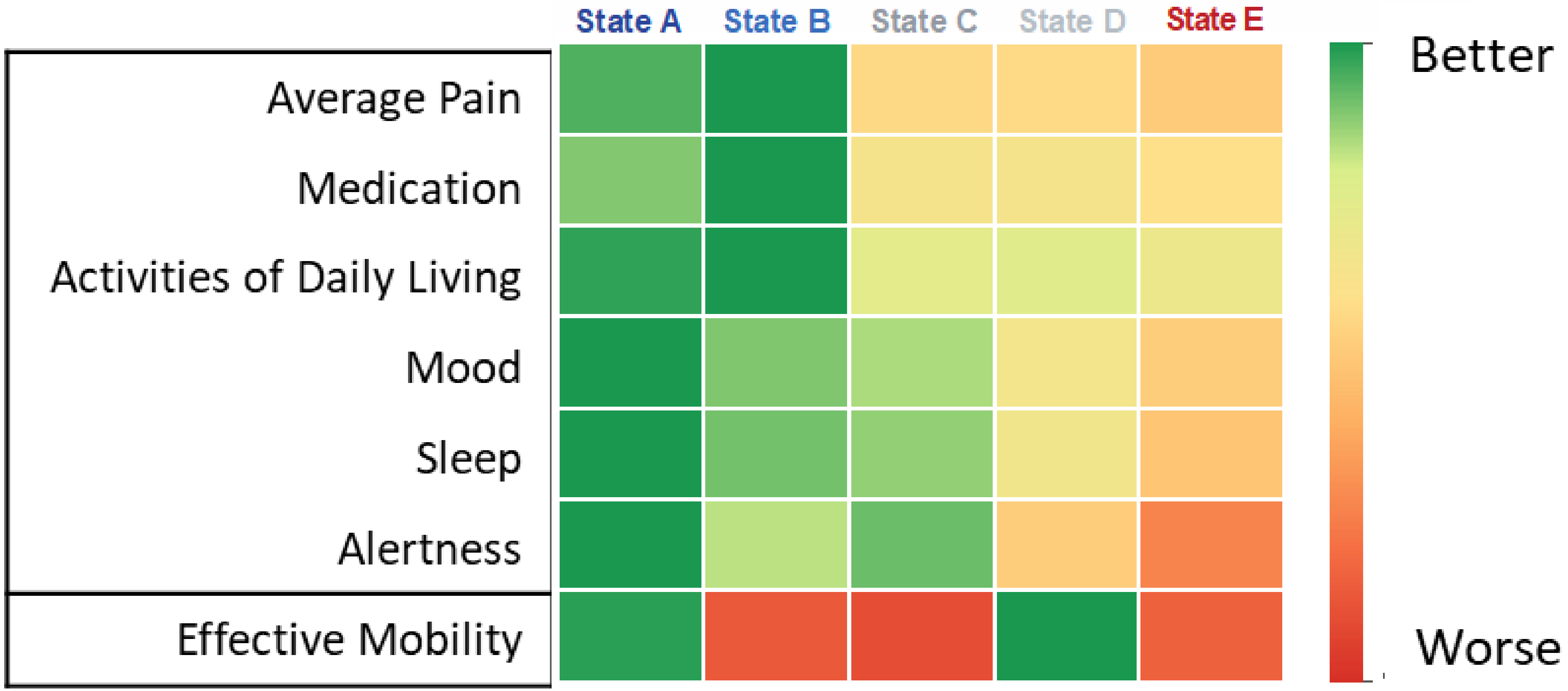
Alertness

Effective Mobility



States are Characterized by Differences in the Cluster Centroid Values

Factors contributing to Patient States

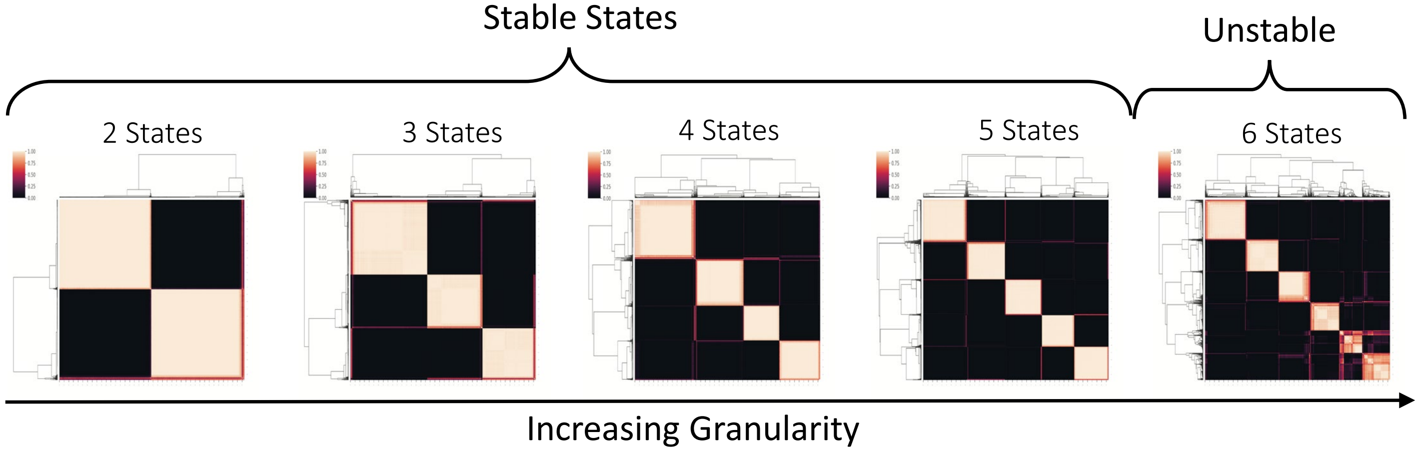


Normalized value for the centroid of each state color mapped from best to worst clinical outcome per dimension

Advanced Analytics with Patient States

1 5 Stable Clusters Exist.

Stable Clusters Identified with Unsupervised Consensus Clustering methods using k-means



Consensus Cluster assignments are based on 1000 sub-sampled iterations.
Strong consensus of cluster assignments indicated stability of ≤5 clusters.

2 States correlate with Validated In-Clinic metrics.

Correlations suggest an order from A-E.

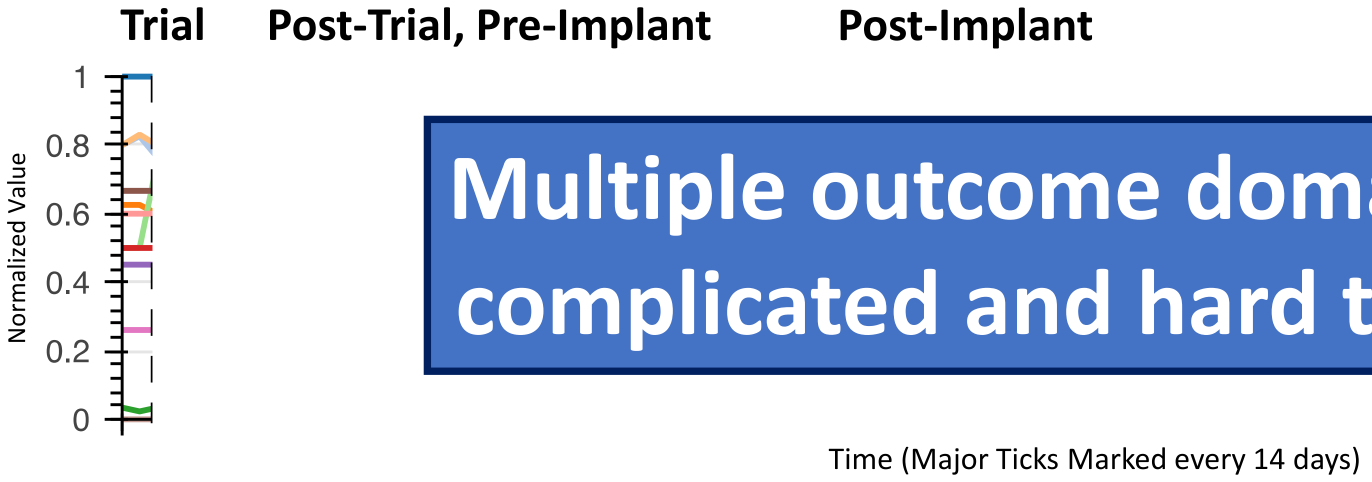
In Clinic Metric		Patients (samples)	State A	State B	State C	State D	State E
ODI Total		96 (1005)	r = 0.46**	r = 0.41**	r = -0.06*	r = -0.31**	r = -0.46**
EQ5D	Activities	96 (1006)	r = 0.28**	r = 0.26**	r = -0.09**	r = -0.25**	r = -0.32**
	Pain		r = 0.42**	r = 0.41**	r = -0.09**	r = -0.24**	r = -0.35**
	Health VAS		r = -0.18**	r = -0.13**	r = 0.04 ns	r = 0.19**	r = 0.23**
	Normed Score		r = 0.4**	r = 0.32**	r = -0.12**	r = -0.2**	r = -0.37**

Pearson Correlation comparing:
Distance from a State centroid to In-Clinic metrics.

R-values, app data w/in ±7days of clinic visit

***p < 0.01; *p < 0.05; ns = not significant*

Patient A:
Monitoring Individual Domains

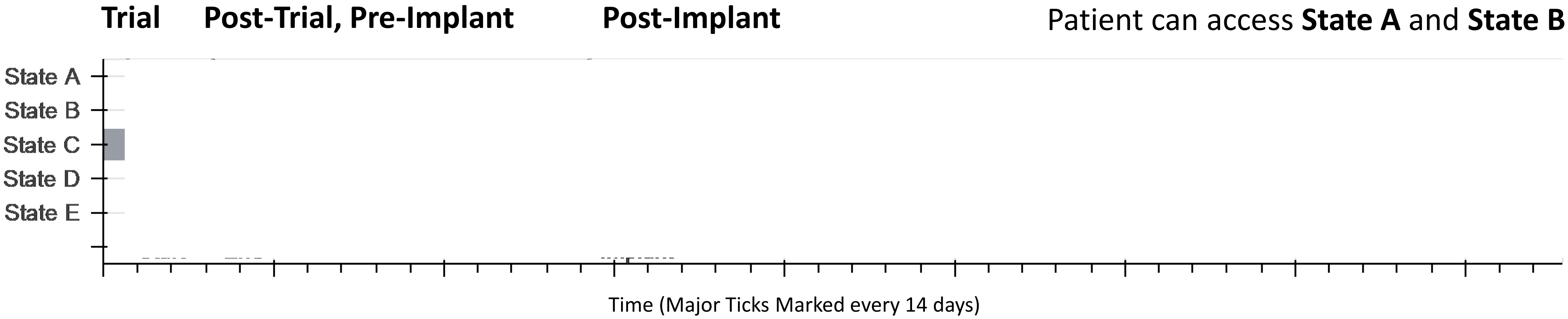


Multiple outcome domains can be complicated and hard to interpret

Domains Displayed: Pain, Sleep, Activities, Pain Interference, Medications, Alertness, Mood, Effective Mobility

Patient A:
Simplified Monitoring Using Patient States

With therapy,
Patient can access **State A** and **State B**

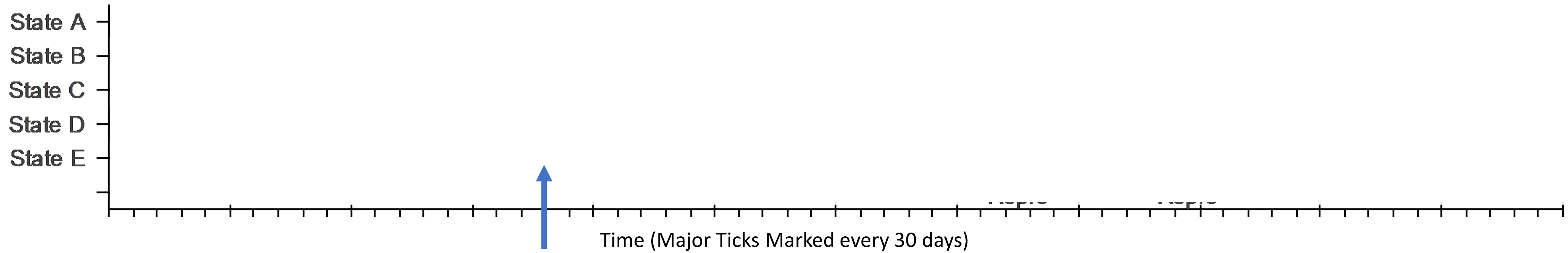


Patient States →
Comprehensive Yet Straightforward
Understanding of the Patient

Patient B:
Patient States Can Empower Clinicians

SCS patient implanted 2 years prior

After Reprogramming

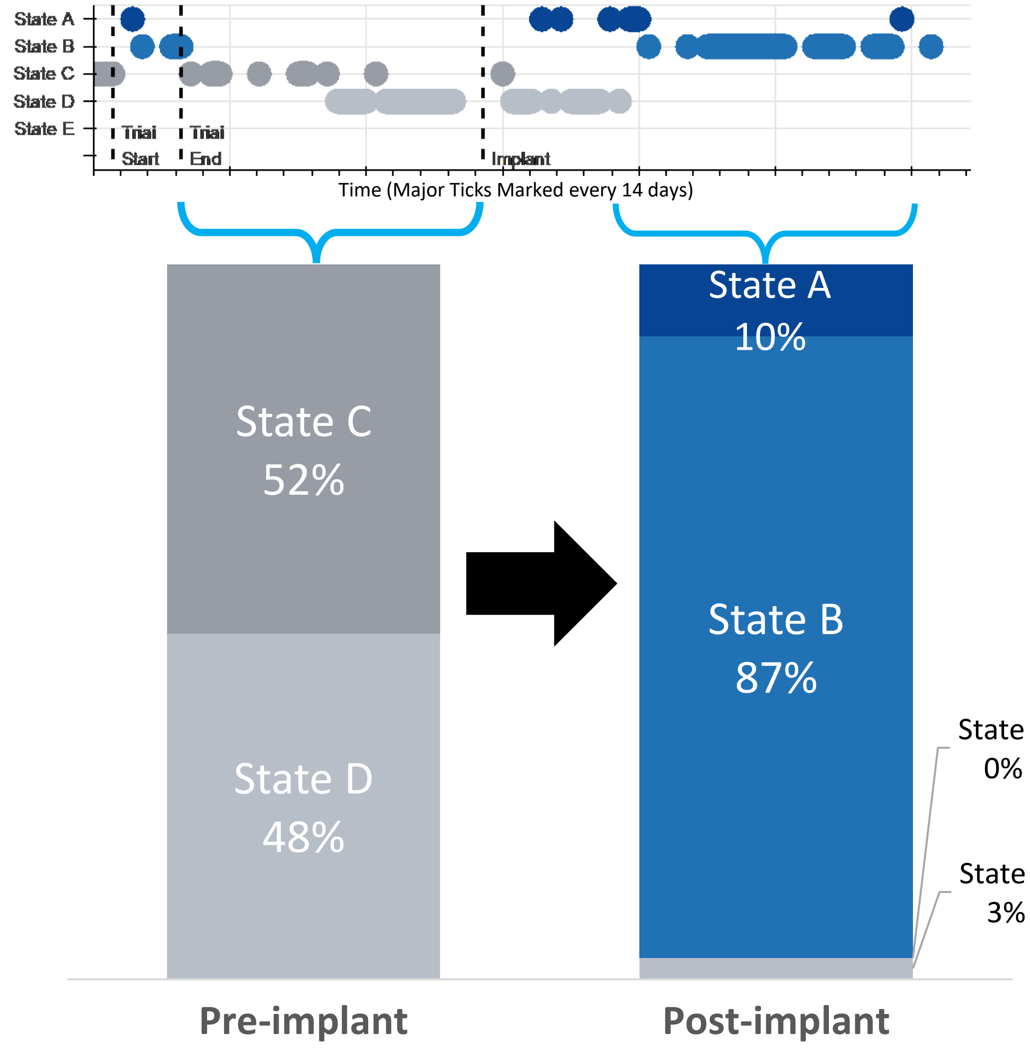


Patient Needing Intervention

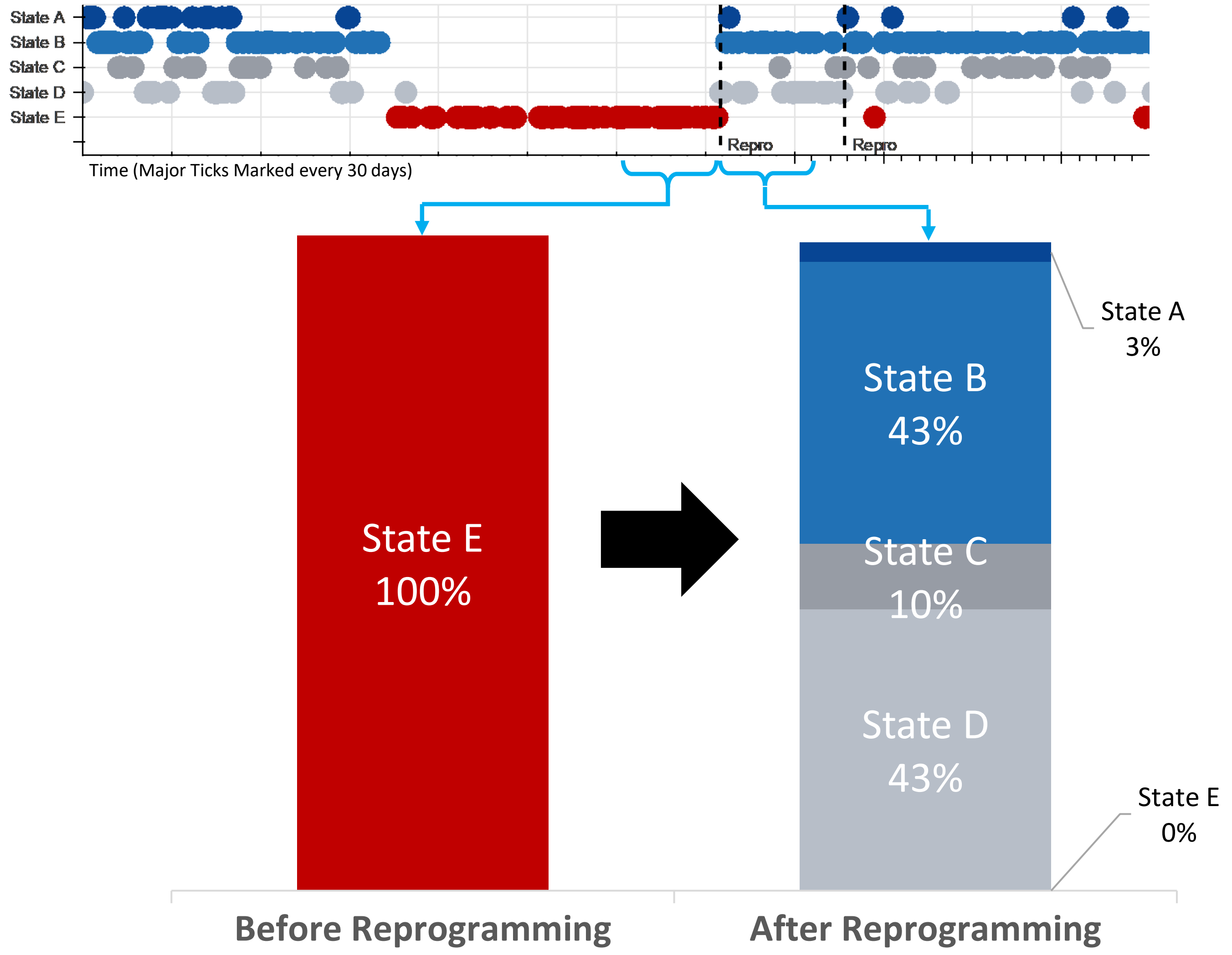
Patient States holds promise to allow timely intervention

Patient State Dwell Time: Simplified Comparisons

Patient A



Patient B



Conclusions

Patient States…

Harness artificial intelligence to provide novel understanding chronic pain patients in a simple and easy manner

Could enable clinicians to prioritize and deliver timely interventions to improve patient outcomes

Holds promise for the efficient management of care for large groups of chronic pain patients