Emerging Digital Technologies in Chronic Pain Measurement and Management

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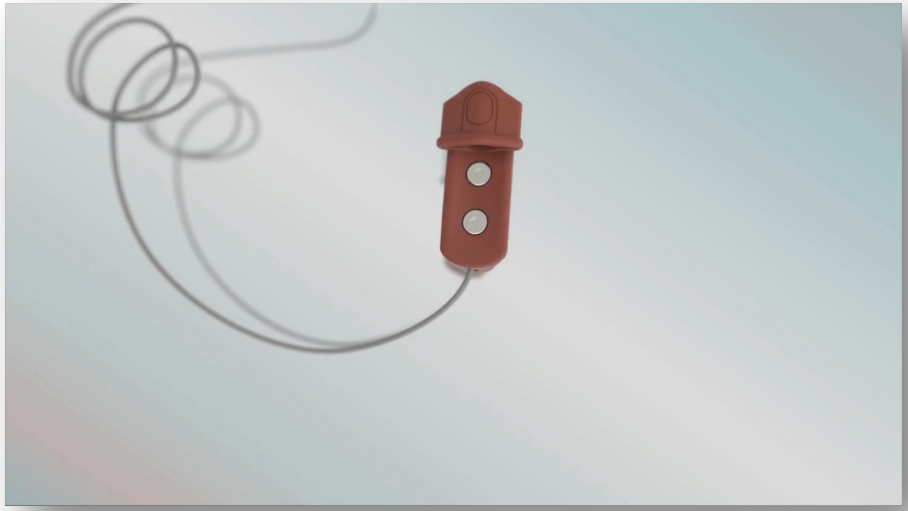
Disclosures

- None

Objective pain biomarkers

FDA-approved objective composite pain biomarker

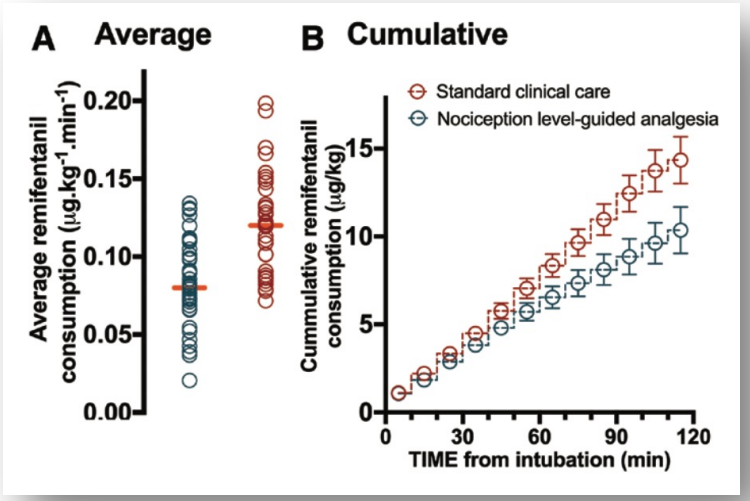
- Medasense PMD-200
- First FDA-approved device for quantitative assessment of nociception during surgery Finger probe integrating temperature, heart rate, movement, and skin moisture
- Outputs a pain score **NoL** calibrated to each patient, between 0 to 100

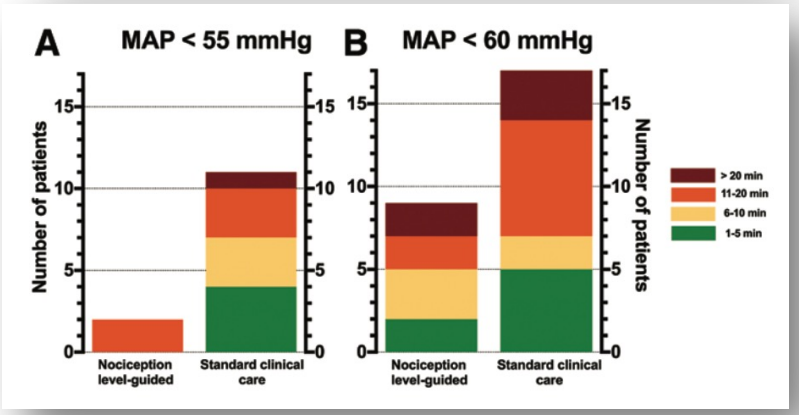


https://medasense.com/pmd-200/

Continuous objective nociception tracking improves quality of anesthesia

- RCT: 80 subjects undergoing elective major surgeries
- Routine anesthesia with remifentanil vs addition of nociception level NOL
- NOL group
  - 30% less remifentanil
  - Fewer episodes of low blood pressure
  - Required less medications to raise blood pressure





Meijer et al 2019. *Nociception-guided vs Standard Care during…* Anesthesiology

A milestone in pain management

- Approved in 2023 as a Class II medical device via the De Novo classification
- May serve as the predicate device for future devices with substantial equivalence (use of composite pain biomarkers to guide anesthesia) to seek approval via the 510(k) pathway

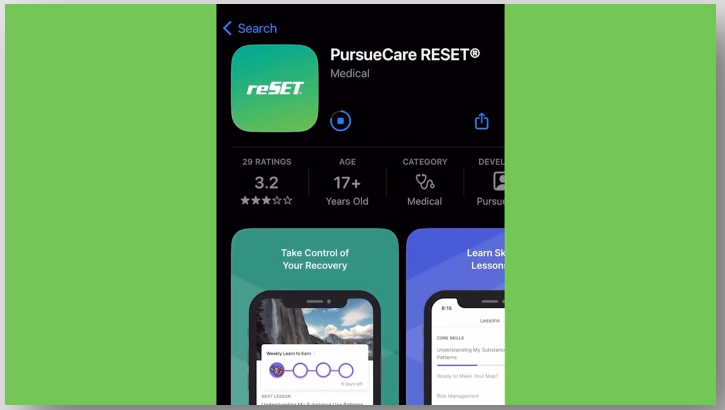
FDA Approval Document: https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN210022.pdf

Digital mental health treatments (DMHTs)

Medicare now covers Digital Mental Health Treatments (DMHTs)

- Digital Therapeutics (DTx) defined by ISO as "health software that delivers an evidence-backed medical intervention for a disease or disorder"
  - Prescription Digital Therapeutics (PDTs)
  - DMHTs are a type of DTx
- FDA guidance for "Software as Medical Device" (SaMD)
- As of 2025, Medicare reimburses for 3 CPT codes for the 7 DMHTs that have been FDA cleared as SaMD

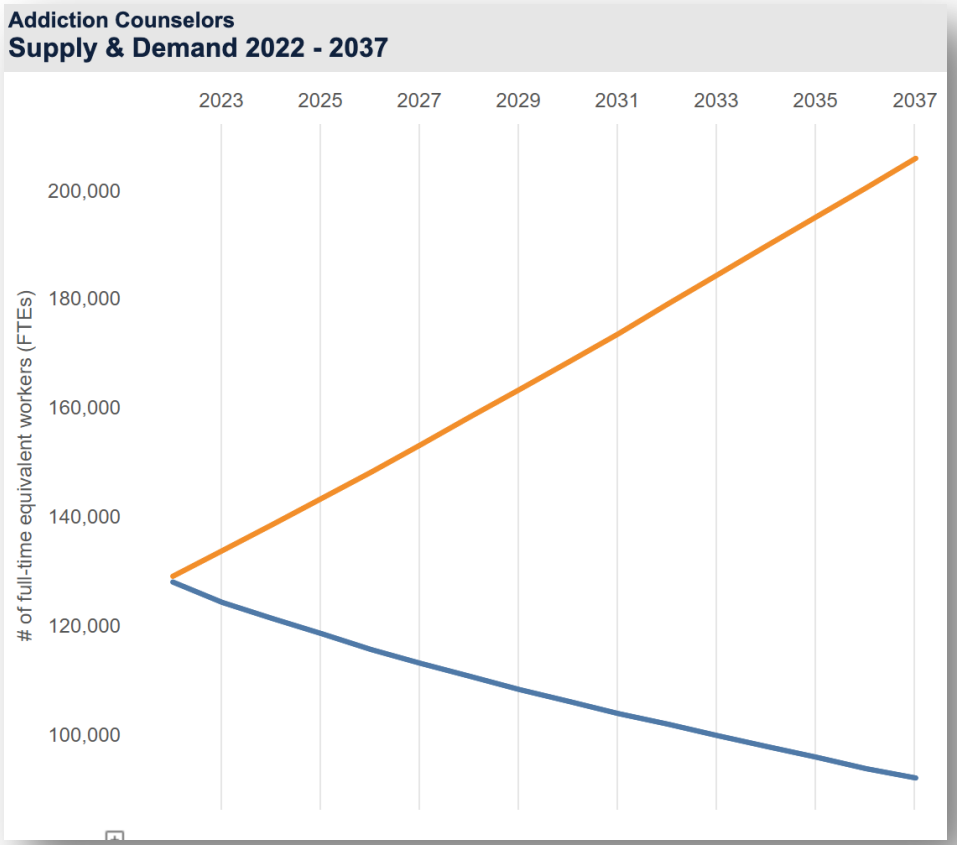
App	Company	Disease	FDA pathway
SleepioRx	Big Health	Insomnia	510(k)
Daylight	Big Health	Anxiety	De Novo
Rejoyn	Otsuka, Click Therapeutics	Depression	510(k)
reSET	PursueCare	SUD	De Novo
reSET-O	PursueCare	OUD	510(k)
Somryst	Nox Health	Insomnia	510(k)
MamaLift Plus	Curio	Maternal Mental Health	510(k)



https://www.iso.org/obp/ui/#iso:std:iso:tr:11147:ed-1:v1:en

DMHTs will help with improve access: Worsening healthcare worker shortage in the next decade

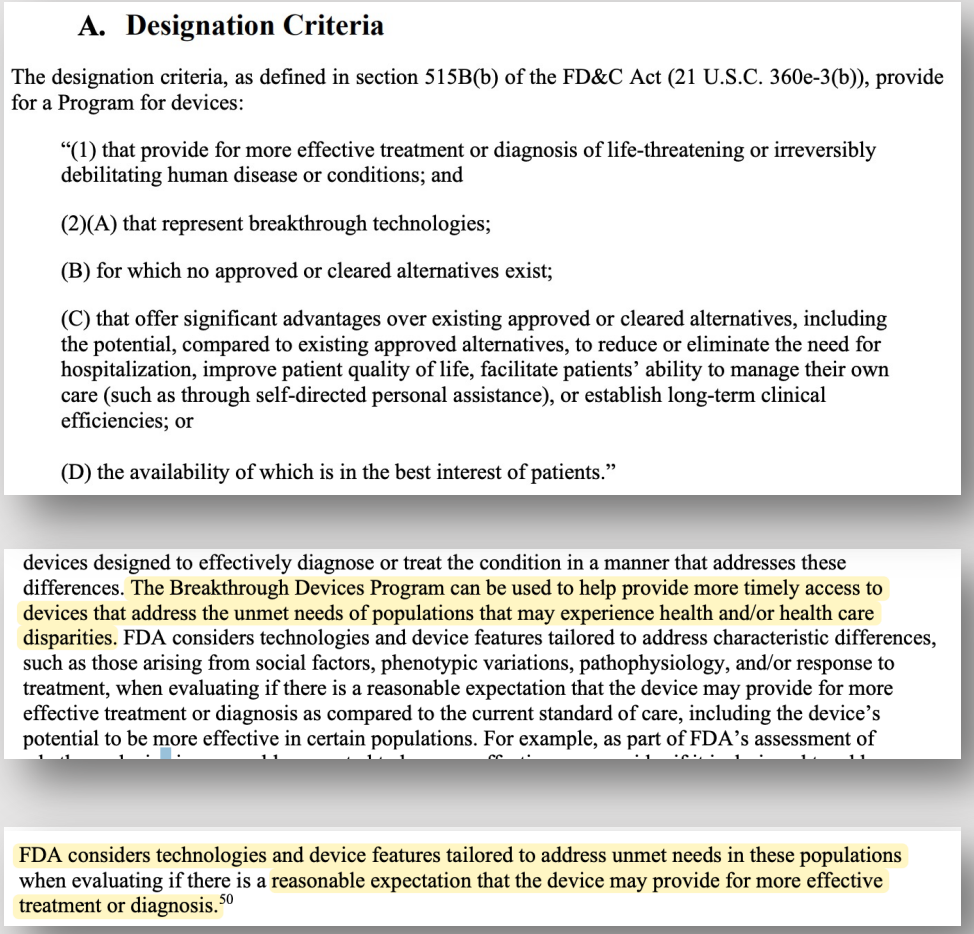
- Addiction counselors
  - Expected supply of 92,160 with a shortfall of 113,939 by 2037 (HRSA)
- Physical Therapists
  - Current shortfall of 12,070 PTs continuing into 2037 without intervention (APTA)
- Psychologists
  - Shortfall of 68,170 psychologists by 2035 (HRSA), 45% of the expected demand
- Home Health Aids
  - Demand for 539,560 HHAs by 2035
- Social workers
  - More than 2x by 2035



https://data.hrsa.gov/topics/health-workforce/workforce-projections

Disability-focused SaMD are excluded by Breakthrough Device Program

- FDA's **Breakthrough Device Program (21st Century Cures Act 2016)**
  - Disability-focused devices do not meet "life-threatening" criteria. The "additional considerations" section addresses health equity and access but does not supersede this requirement
- **Broaden Eligibility?** Include SaMD that **"substantially improves quality of life or functional independence"** for disabled populations
- **Dedicated Disability Track?** For SaMD targeting underserved disabled populations



A. Designation Criteria

The designation criteria, as defined in section 515B(b) of the FD&C Act (21 U.S.C. 360e-3(b)), provide for a Program for devices:

"(1) that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions; and

(2)(A) that represent breakthrough technologies;

(B) for which no approved or cleared alternatives exist;

(C) that offer significant advantages over existing approved or cleared alternatives, including the potential, compared to existing approved alternatives, to reduce or eliminate the need for hospitalization, improve patient quality of life, facilitate patients' ability to manage their own care (such as through self-directed personal assistance), or establish long-term clinical efficiencies; or

(D) the availability of which is in the best interest of patients."

devices designed to effectively diagnose or treat the condition in a manner that addresses these differences. The Breakthrough Devices Program can be used to help provide more timely access to devices that address the unmet needs of populations that may experience health and/or health care disparities. FDA considers technologies and device features tailored to address characteristic differences, such as those arising from social factors, phenotypic variations, pathophysiology, and/or response to treatment, when evaluating if there is a reasonable expectation that the device may provide for more effective treatment or diagnosis as compared to the current standard of care, including the device's potential to be more effective in certain populations. For example, as part of FDA's assessment of

FDA considers technologies and device features tailored to address unmet needs in these populations when evaluating if there is a reasonable expectation that the device may provide for more effective treatment or diagnosis.[50]

https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program

Health digital therapeutics for rehabilitation

DTx for physical therapy

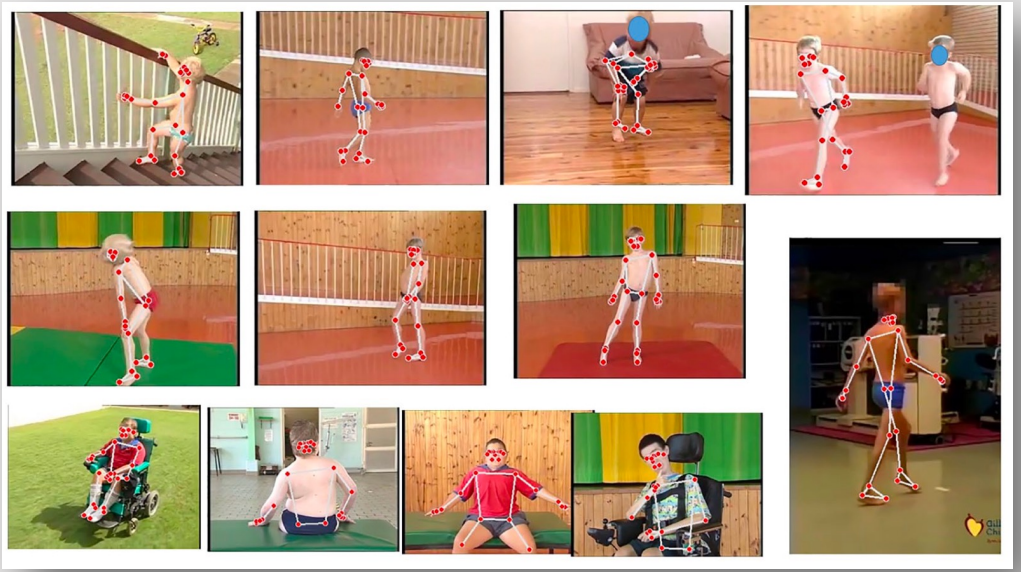
- RCT: 140 patients with low back pain randomized to 8-week DTx program *vs* conventional in-person PT
- Statistically significant improvements in **pain** and **pain interference** for both
- No statistically significant differences in **ODI, mood, activity impairment**
- Digital group had a significantly lower **dropout rate** (16% vs 34%)

- Technology:
  - X Activity trackers
  - ✓Vision-based pose estimation

Cui et al *Randomized-controlled trial assessing a digital care…* Nat Dig Med, 2023

Does video-based pose estimation work well for patients with disability?

- 0 of 8 commonly used algorithms trained on data with disabled persons. Key benchmarks do not contain data on disabled persons
- 1 study (Stenum 2024) found OpenPose can estimate gait pathologies in patients with stroke or Parkinson's disease
- 1 study (Ali 2024) used specialized dataset to train a new specialized gait analysis model
- No studies on exercise pose estimation

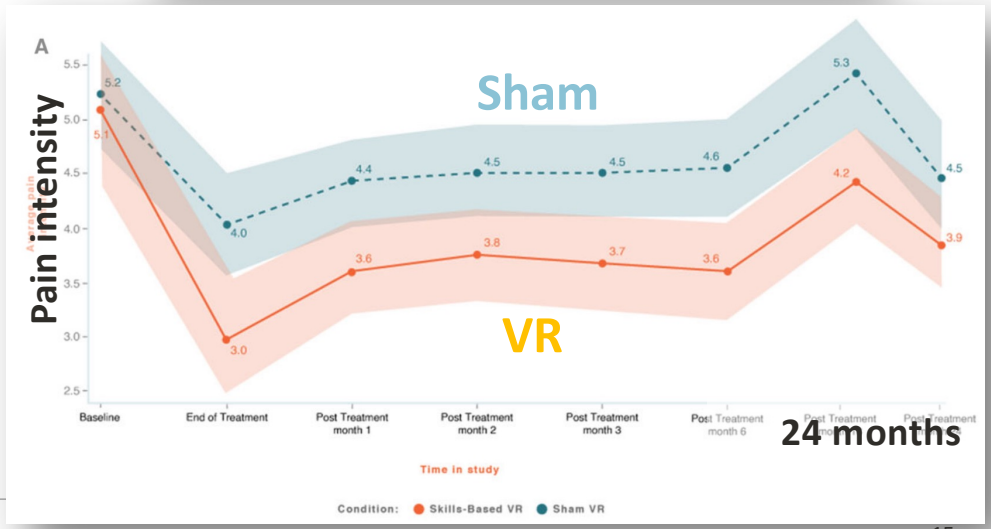


Pose estimation on patients with Duchenne muscular dystrophy (Ali et al 2024)

Virtual reality and augmented reality

8-week home-based VR program reduces chronic low back pain for up to 24 months

- RCT: 188 adults with low back pain, randomized into VR program vs sham
- VR Program (RelieVRx)
  - 56-day program
  - Daily sessions (2-16 minutes) in 8 weekly core themes across 5 content categories
    - Pain education
    - Relaxation and Interoception
    - Mindfulness escape
    - Pain Distraction Games
    - Dynamic Breathing
- VR group had significant and sustained reductions in pain intensity and pain interference



Maddox et al *Durable chronic low back pain reductions up to 24…* Pain Med, 2022

Accessibility considerations for PDTs with hardware components

- **Digital divide**: with unequal access to broadband internet, internet-enabled devices, and sufficient digital literacy
- **Cost barriers** includes potential data usage fees or the need for technical support
- Individuals with **disabilities or age-related limitations** may have difficulty using headsets or experience motion sickness with VR
- **Reimbursement pathways** are still evolving but Highmark of BCBS is covering RelieVRx

AI for medical chart summary

Large language models (LLMs) for medical chart summarization

Benefits

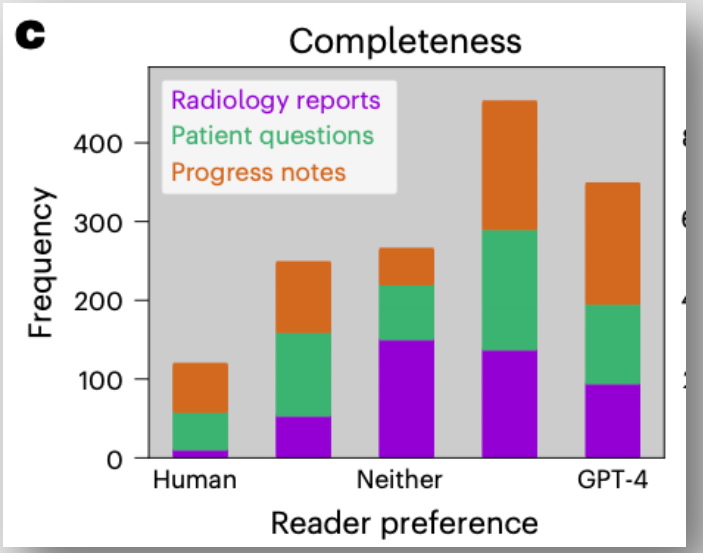
- ChatGPT 4.0 summarized radiology reports and patient notes with completeness, correctness, and conciseness

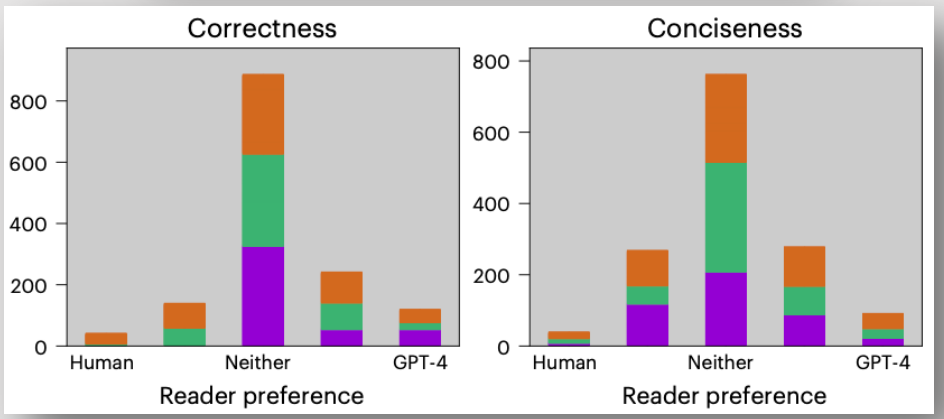
Risks

- ChatGPT 3 hallucinated, made incorrect inferences, and omitted subtle but important clinical details

Design principle for CHOIR

- Must be implemented with a **human-in-the-loop** for safety and accuracy



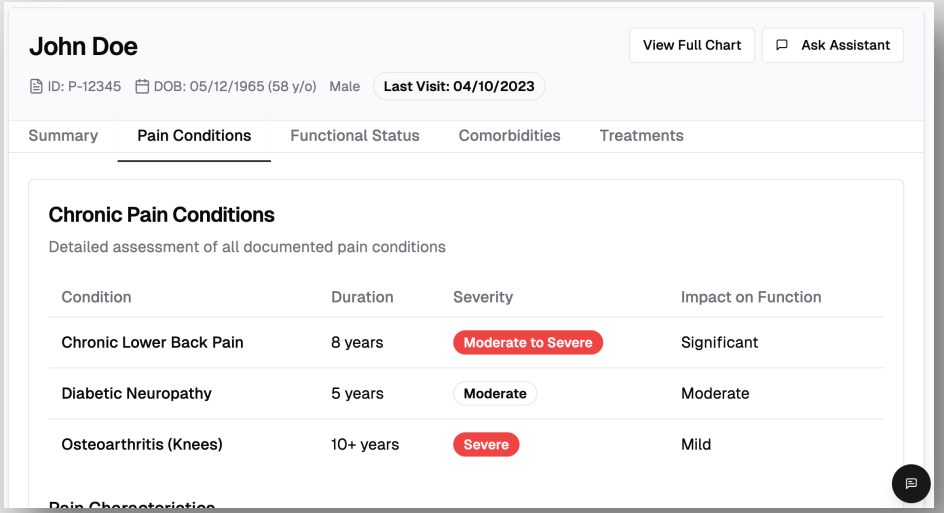


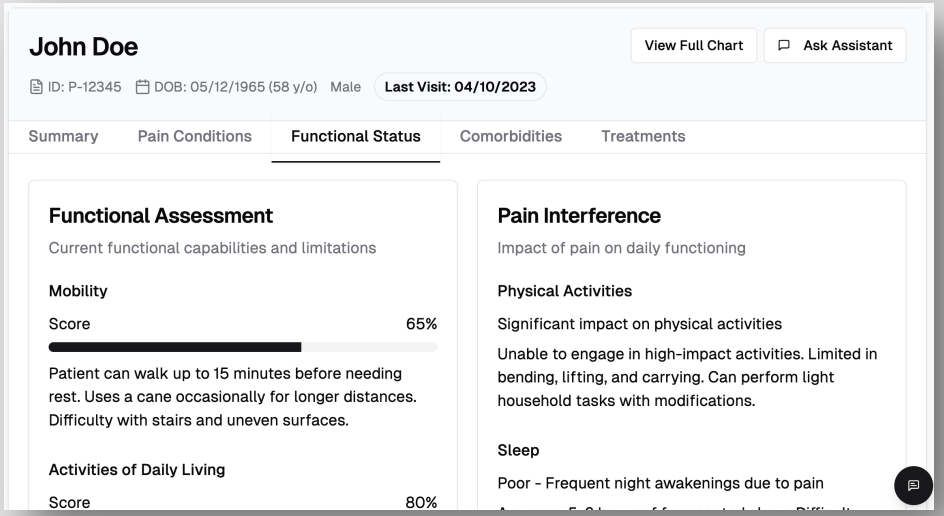
Van Veen et al 2024 Nat Med, Tang et al 2023 Nat Med

LLM complements natural language processing (NLP) systems

LLMs as an Evolution

- LLMs can complement NLP systems: better context, summarization, and decision support
- Seamless integration to enrich, not disrupt, current workflows





Integration and future readiness

Implementation Priorities

- Modular, scalable infrastructure to adapt with AI advancements
- Continuous monitoring to ensure fairness, accuracy, and transparency
- Retain adjudicator oversight for final decisions

Looking Ahead

- Open-source LLMs offer flexibility and long-term control
- Pilot programs can guide safe, iterative deployment

Key Performances	Benchmarks	Leading Commercial LLMs	Leading Open Source LLMs
Accuracy & Factuality	MedQA, PubMedQA, TruthfulQA	OpenAI o1, o3-mini, Med-Gemini	Qwen2.5, Meditron, Llama 3.1, JSL-MedLlama
Clinical Knowledge	MedQA, MMLU (clinical), MedJourney	OpenAI o1, o3-mini Med-Gemini	Qwen2.5, Meditron, Llama 3.1, JSL-MedLlama
Long Context Handling	Needle-in-Haystack, LooGLE, MMLongBench-Doc	Gemini 2.5 Pro (2M)	Llama 3.1 Nemotron (3M)
Summarization Fidelity	ROUGE, BERTScore, Domain datasets (MIMIC), Human Eval	GPT-4 variants (GPT-4o), Claude 3.7	Llama 3.1, Qwen2,5, Mistral Large,
Controllability	Instruction following tests, Human Eval	GPT-4 variants, Claude 3.7	Llama 3.1 Instruct, Qwen2.5 Instruct, Mistral Instruct
Multimodality	DocVQA, ChartQA, TextVQA, MMLongBench-Doc, OCR Eval, Human Eval	GPT-o4-mini-high, Gemini 2.5 Pro	LLaVA variants, Qwen-VL

Thank you