evidation

Characterizing life events through self-report and wearable data

Traditional RWE leaves gaps in individuals' health journeys

As the life sciences industry becomes more competitive and personalized, asset differentiation and market success often depend on identifying the factors impacting health beyond the confines of clinical settings. Real-world evidence (RWE) plays an important role in providing a holistic view of individual experiences, and healthcare industry stakeholders are increasingly requiring RWE of an intervention's impact on health and quality of life to make approval, reimbursement, and prescribing decisions.
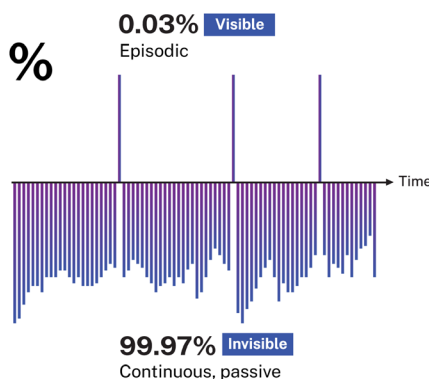
To meet these expectations, many life science companies rely on data from a snapshot in time such as electronic health records (EHRs) or infrequently collected patient-reported outcomes.

This information lacks the ability to show:

- A comprehensive picture of an individual's health journey
- Effects of life events on health
- Social determinants of health (SDOH) that impact health
- Individuals' knowledge about their health and available treatments
- Individual preferences for health care and treatments
- The hidden challenges and barriers to achieving the best health possible
- Quantitative measures of quality of life and health outcomes

99.97% of the information you've been missing can be unlocked with **longitudinal, direct-from patient data**

0.03% Visible
Episodic

Time

99.97% Invisible
Continuous, passive

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Filling gaps with more complete, continuous data

Compelling RWE that more deeply captures what is happening in a person's life can be achieved by integrating conventional real-world data (RWD) sources (e.g., EHR, prescription records, claims) with data collected directly from people in their everyday lives, such as:

- Self-report surveys about symptoms, quality of life, and lifestyle
- Digital measures from wearables and devices (e.g., sleep, activity, heart rate) that can provide an objective, longitudinal view of living with a disease
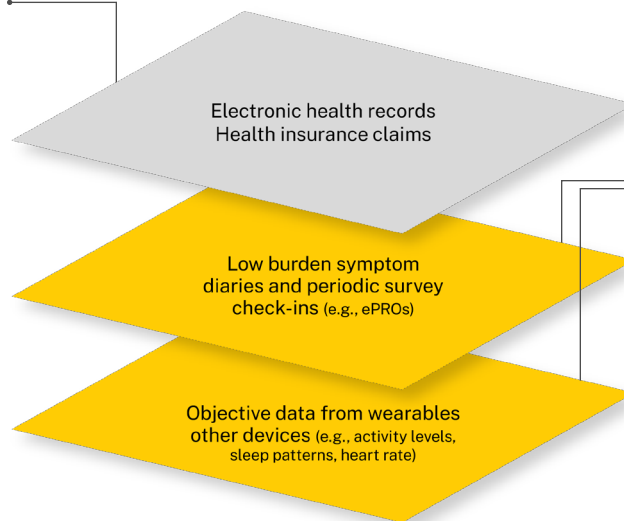
Traditional RWD paired with direct from patient data builds a more complete health journey

Traditional RWD Sources

Snapshots in time

Captures:

- Clinical measures, medication usage, and healthcare utilization
- Point-in-time or infrequent views into individuals' experiences with health and disease

Electronic health records
Health insurance claims

Low burden symptom diaries and periodic survey check-ins (e.g., ePROs)

Objective data from wearables other devices (e.g., activity levels, sleep patterns, heart rate)

Direct From Patient Data

Everyday life, over time

Captures:

- Insights into how life events and contextual factors influence health behaviors and access to care
- Daily changes in activity and other health measures close in time to when health events occur
- Day-to-day symptom burden, productivity, and other measures that are not easily observed

More comprehensive data collected directly from individuals, complemented by snapshot-in-time information, can inform evidence-based discussions around:

- Health in everyday life
- The burden of illness
- Solutions that improve physical and mental well-being

Pairing wearable data with surveys and PROs, for example, can uncover the effects of injury, disease, or stressful events on daily life that may not be evident even to the person itself.

Differences between self-reported sleep quality and wearable-reported sleep quality

Using an asthma survey paired with wearable sleep data from members on the Evidation platform, we detected discrepancies between the perceived effects and actual effects of asthma on sleep.

**Survey:** *In the past 4 weeks how often did you wake up at night due to your asthma symptoms?*
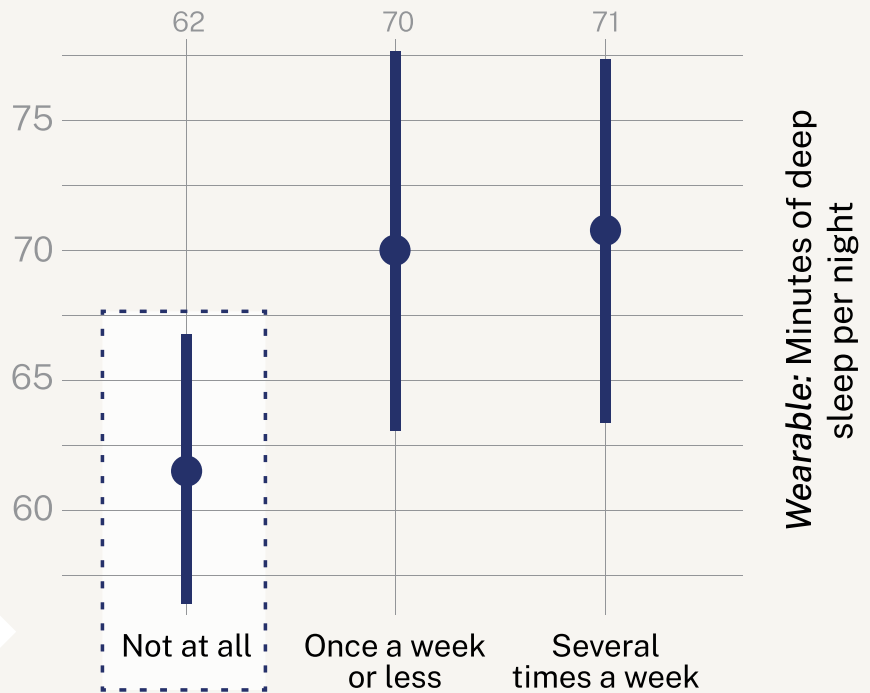
The respondents who reported they did not wake up at all due to asthma symptoms actually had the least amount of deep sleep.

Wearable: Minutes of deep sleep per night

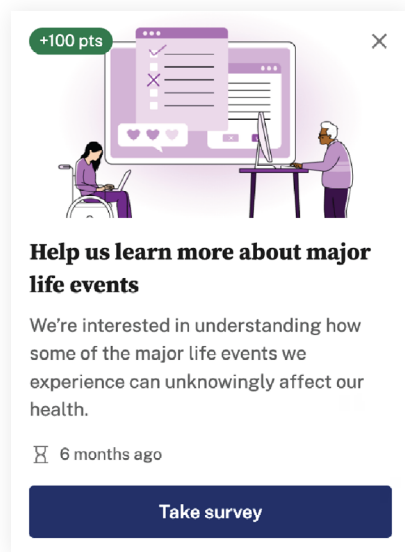|	Not at all	Once a week or less	Several times a week
	62	70	71

This is a powerful example of how passively collected wearable data can supplement actively collected, self-reported feedback to:

- Identify unmet needs that could be addressed by better treatment adherence or patient support programs
- Predict who would benefit from interventions for side effects
- Track the impact of treatments over time
- Provide education to physicians about symptoms that might go unnoticed by patients

In the following sections, we present examples of active and passive data collection from individuals that provides a more complete understanding of their health journeys.
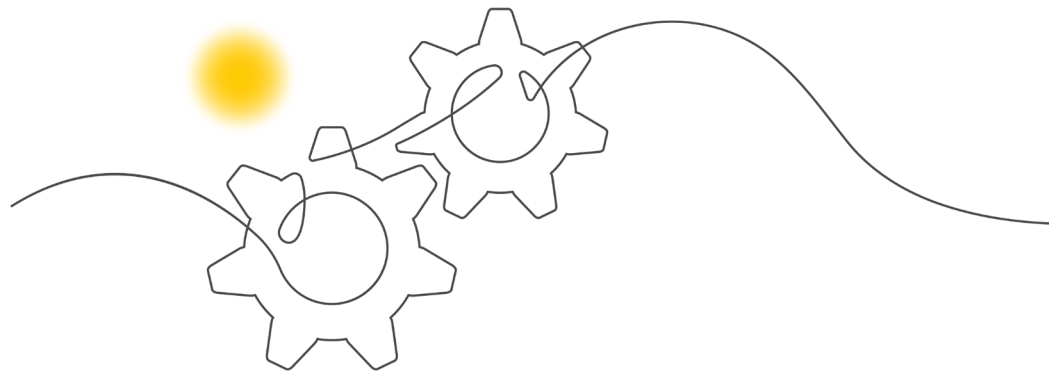
Quantifying the impact of major life events on health and outcomes

Help us learn more about major life events

We're interested in understanding how some of the major life events we experience can unknowingly affect our health.

⏳ 6 months ago

Take survey

Between June 10, 2023 and July 24, 2023, we offered Evidation Members the opportunity to complete a survey about major life events that had occurred over the previous five years. When members indicated they had experienced one of the events, we asked them to provide the date it occurred.

Survey information:

142,759
MEMBERS

Wearable data
(steps, sleep, and heart rate):

109,554
OF THOSE MEMBERS

We explored 5-year trends in the occurrence of major life events for the entire sample to illustrate their prevalence. For those who experienced an event and had wearable data, we also compared the health activity metrics before and after each event to quantify the event's impact.

Combination of data from the Evidation platform for this analysis:

📋 Life event survey

⌚ Wearable data
- Sleep
- Activity (steps)
- Heart rate

Aggregated data from a large population such as this can be used not only to understand what events are happening in everyday life but also to establish a "normal" pattern, response to a treatment, or recovery from an illness or injury. Individual data can then be compared against the "normal" pattern to detect atypical responses that might benefit from additional support.

Examples of major life events from the survey and their impact on activity:

1. Major illness or injury following hospitalization
2. Being laid off or fired from a job

Mapping recovery after a major illness or injury requiring hospitalization

Challenge

Characterizing both collective and individual recovery journeys, including factors predictive of positive outcomes.

Commercial implication

Wearable data, combined with periodic self-reported information, provide an indication of a "normal" recovery and the ability to identify individual outliers.

Setting the scene

The trend analysis of the survey responses showed that the number of hospitalizations experienced by Evidation Members steadily increased from 2018 to 2022, which could have included COVID-19-related admissions.
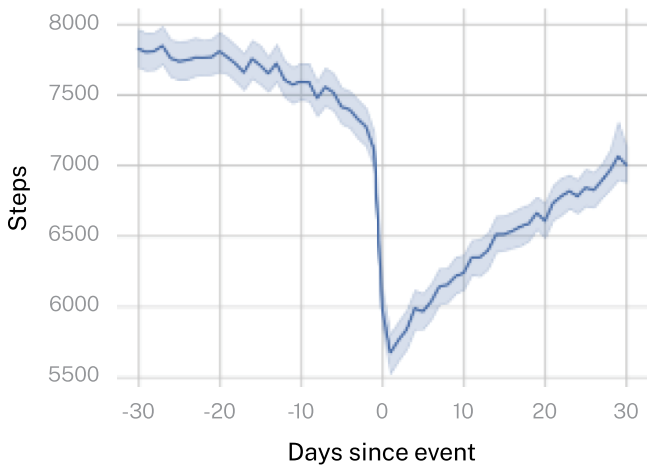
Individuals who experienced a hospitalization
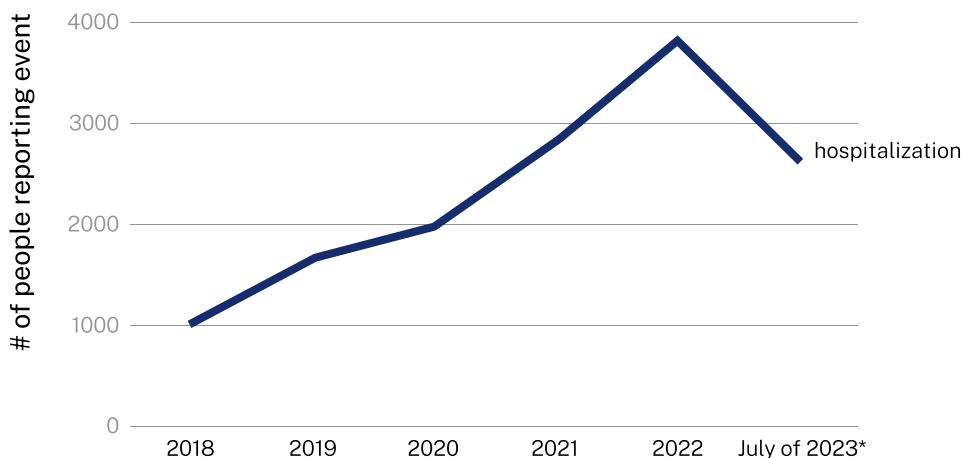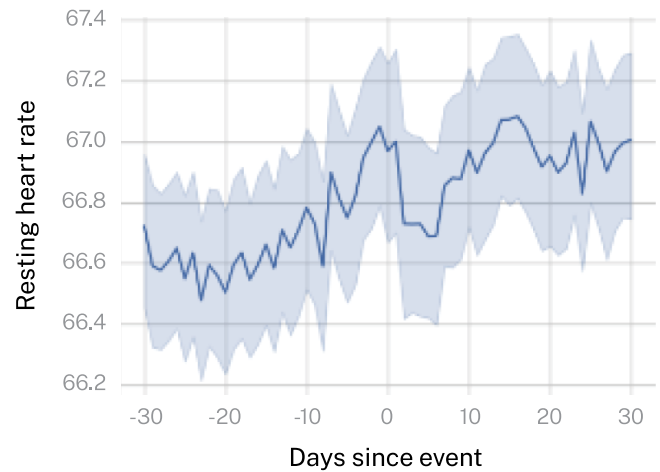

2023 only includes ~6 months of data

Insights from the wearable data

The wearable data show the changes in activity (steps), heart rate, and sleep duration before and after hospitalization (indicated by Day 0 on the x axis).
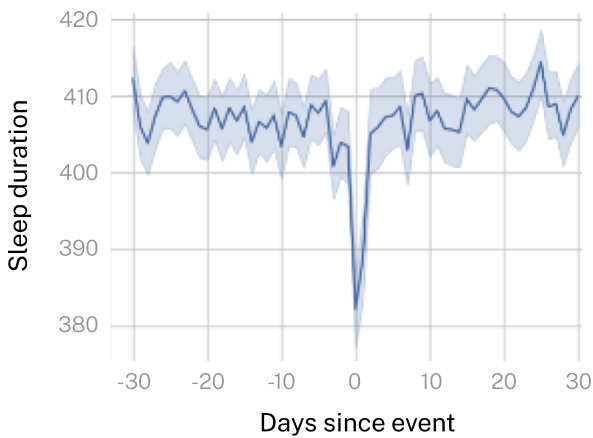
The number of steps gradually recovered post-hospitalization.

Resting heart rate was higher post-hospitalization.

Sleep duration rapidly returned to pre-event levels.

The post-hospitalization data provide insights into physiological responses and the time to resume baseline activity during recovery.

Other potential data sources that can be integrated in the Evidation platform for greater insights:

- Self-reported treatment adherence

- Self-reported pain levels

- PROs measuring pain, mobility, and activity levels

- Surveys regarding recovery-related challenges

- Physical, occupational, and other ambulatory visits or home-based care

- Previous prescription and OTC drug use

- Newly prescribed medications related to the injury or illness

- Subsequent hospitalizations for the same injury or illness

How these data could be used:

- Characterize the "typical" recovery activity pattern for the target population

- Identify barriers to recovery such as treatment adherence

- Explore factors predictive of positive outcomes, such as a good recovery (both personally and clinically evaluated), no longer needing medication (including pain meds), the time required for a full recovery (e.g., full mobility)

- Explore factors related with poorer outcomes, such as needing to access post-event care and subsequent hospitalizations

Real-world example of predicting post-surgical recovery using wearable data

Population:
1,324 individuals who underwent lower limb surgery

Challenge:
Lack of long-term individual baseline data for an accurate and objective assessment of functional post-surgical recovery

Approach:

- Collection of Fitbit device data (steps, heart rate, and sleep) 26 weeks before and after the self-reported surgery date

- Subgroup identification based on self-reported surgery type

- Development of a method to predict the self-reported recovery time

Results

- 12-week pre-surgery and 26-week post-surgery trajectories of daily measurements captured changes from baseline.

- Trajectories differed across surgery types.

- Long-term individual recovery could be accurately predicted only 1 month after surgery.

- The predictions were most accurate when long-term, individual baseline data were available.

*For more information, read the **publication.***

Identifying the health-related effects of losing one's job

Challenge

Identifying individuals experiencing changes in SDOH, including income and access to healthcare, that could influence their health outcomes.

Commercial implication

Detecting changes to an individual's social, behavioral, and environmental context facilitates help us understand what places someone at risk for treatment non-adherence and other barriers to positive outcomes.

Setting the scene

The trend analysis of the survey responses showed that a higher number of respondents reported being laid off or fired from their job in 2020. This could be related to the drastic effects of COVID-19 on both temporary and permanent business closures and the subsequent effects on the labor market.
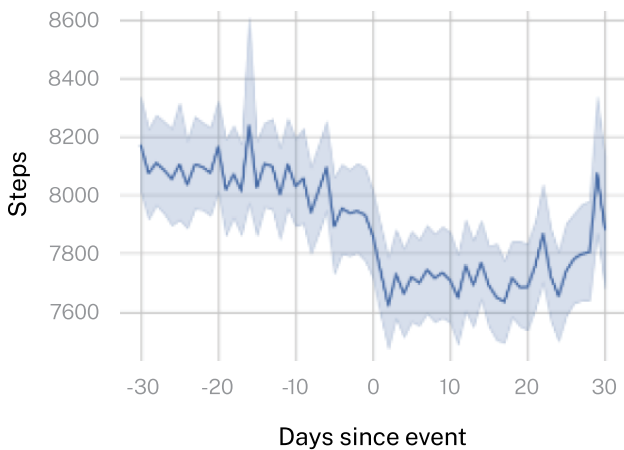
Individuals who experienced a job loss
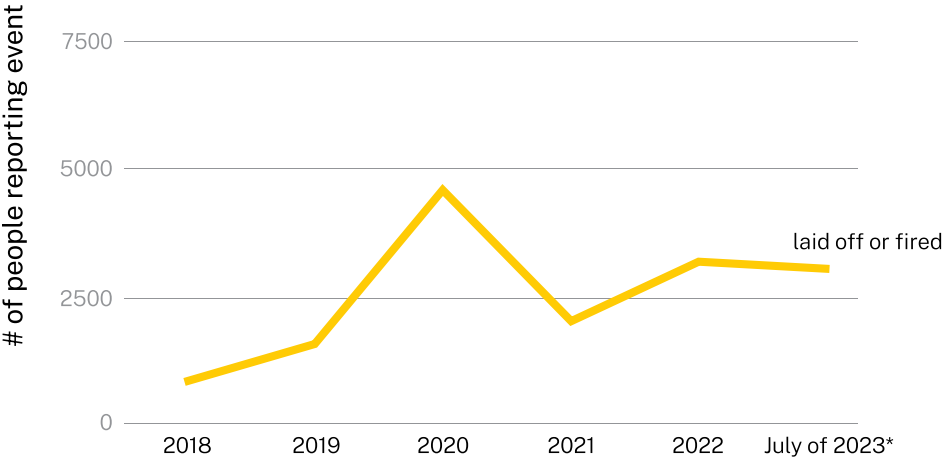

2023 only includes ~6 months of data

Insights from the wearable data

The wearable data show the changes in activity (steps), heart rate, and sleep duration before and after being fired or laid off (indicated by Day 0 on the x axis).
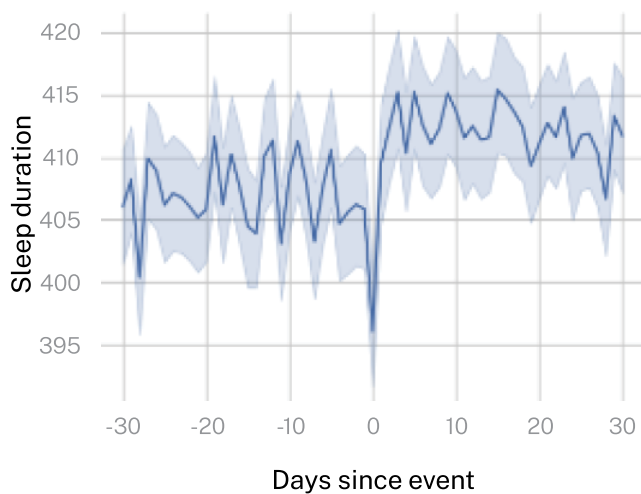
Activity (steps) decreased considerably for several weeks.

Days since event

After a spike in resting heart rate, it decreased to below pre-event levels.

Days since event
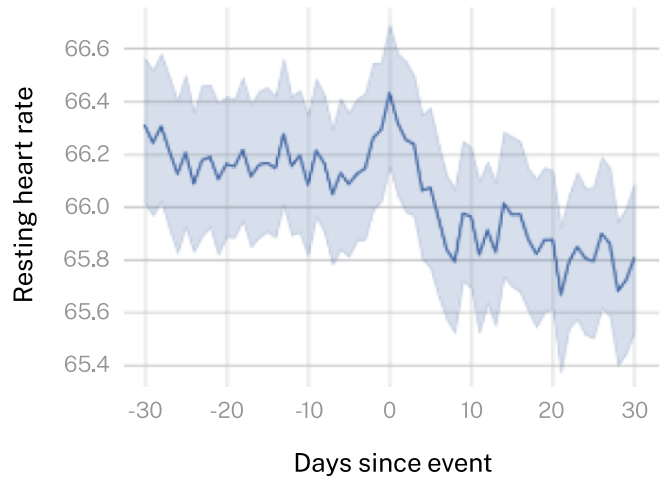
Sleep duration increased for at least a month.

Days since event

In addition to introducing chronic stress and disrupting health-promoting behaviors, losing one's job could disrupt regular healthcare by impacting both income stability and availability of insurance benefits.

The impacts could be:

- Deferred care for acute and chronic conditions, as well as preventive care
- Gaps in medication use for entire families, which could result in otherwise preventable emergency room visits

Other potential data sources that can be integrated in the Evidation platform for greater insights:

- Claims data
- Prescription data
- Survey on healthcare utilization

How these data could be used:

- Identify who might be at risk of decreased access to care
- Predict who might need additional care or medication support
- Design supportive solutions for mental health and treatment access that could help fill the gaps
- Determine when varying activity levels are due to changes in SDOH or health-related events

Gaining insights into health outside of clinic walls

Complementing traditional RWD sources, such as claims, EHRs, and patient registries, with objective wearable data, self-reported symptoms, and quality of life measures provides a novel view into individuals' health outside of clinic walls. Coupling data continuously across the health journey (e.g., before a diagnosis, during an illness, post-treatment) with knowledge of major life events helps:

- Contextualize changes in behaviors and health
- Establish a baseline against which to measure post-event changes
- Document individuals' priorities and preferences in the face of a life-changing event or illness
- Identify the need for additional support to optimize health
- Determine the most effective support mechanisms

To discover how the Evidation platform can assist you in collecting data from wearables and individuals – including symptoms and significant life events – **get in touch** with us today.

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