

DAILY ENGLISH READING

2 September 2026 - 30-minute active reading pack

TODAY'S QUESTION

What changes when an endpoint becomes a continuous data stream?

Difficulty: C1 | digital endpoints | sensor data | FDA | CDISC | ADaM

WHY SELECTED

Sensor-derived endpoints begin as high-frequency data streams, not analysis variables. SP teams must define validity, wear time, missingness, windows and aggregation before an endpoint reaches ADaM. FDA discussed these statistical and data-standard issues on 27 August 2026, making the topic unusually current.

READING ORDER

0-3 min Preview: identify physiological, functional and performance measures.

3-14 min Main review: CGM, activity, sleep and implementation challenges.

14-20 min FDA: statistical methods, data standards and CGM specifications.

20-25 min CDISC: machine-readable, API-enabled standards automation.

25-30 min Output: design one digital-endpoint derivation pipeline.

SOURCES

Main: Sensor-based digital health technologies to capture endpoints - npj Digital Medicine

<https://www.nature.com/articles/s41746-026-02512-w>

Support: FDA workshop on digitally-derived endpoints - 27 Aug 2026

Support: CDISC TechniCon 2026 - 9 Sep 2026

BRIEF BACKGROUND

48 recent studies were included in the scoping review.

38 (79%) used sensor-based physiological data; 36 of those used CGM.

12 studies used sensor-derived outcomes such as activity or sleep.

Common derived endpoints include time in range, daily steps and total sleep time.

The algorithm from raw device data to endpoint is part of the statistical specification.

Architecture: raw stream -> validity -> aggregation -> analysis window -> ADaM -> TFL.

KEY VOCABULARY

digitally-derived endpoint	数字化派生终点	endpoint computed from digital data
digital health technology	数字健康技术	sensor software or connected device
continuous glucose monitoring	持续葡萄糖监测	continuous interstitial glucose data
sensor-based functional outcome	传感器功能结局	passively derived functional measure
performance outcome	表现性结局	standardized task-based measure
high-frequency data	高频数据	many observations per unit time
time in range	目标范围内时间	proportion within a target interval
time above range	高于目标范围时间	proportion above a threshold
time below range	低于目标范围时间	proportion below a threshold
data reduction	数据降维 / 汇总	convert dense data to summaries
wear-time rule	佩戴时长规则	minimum valid device-use rule
missingness pattern	缺失模式	structure of unavailable data
fit-for-purpose	适用于既定目的	suitable for intended use
machine-readable pipeline	机器可读流程	structured software-processable workflow
endpoint derivation provenance	终点派生谱系	trace from raw data to endpoint

USEFUL PHRASES

1. turn a dense sensor stream into an analysis-ready endpoint
2. define valid wear time before deriving the endpoint
3. separate raw acquisition from analysis derivation
4. preserve the lineage from device data to the final TFL
5. apply prespecified rules for missing sensor periods
6. summarize high-frequency measurements into clinically meaningful metrics
7. validate device-specific transformations independently
8. treat the endpoint algorithm as part of the statistical specification
9. design metadata for machine-readable reuse
10. make implementation choices visible to reviewers

COMPREHENSION QUESTIONS

1. Why are continuous sensors different from visit-based measurements?
2. What does heavy CGM use tell us about digital-endpoint maturity?
3. Why define wear-time and missing-data rules before derivation?
4. Why is FDA linking statistical methods with data standards?
5. How could machine-readable metadata improve validation and reuse?

RETELLING PROMPTS

30 sec: define a digitally-derived endpoint and give two examples.

45 sec: raw sensor -> validity -> aggregation -> endpoint -> ADaM -> TFL.

60 sec: explain why the endpoint algorithm belongs in the statistical spec.

5-MINUTE SPEAKING / OUTPUT TASK

Minute 1: choose glucose range, steps, activity, sleep or AF burden.

Minutes 2-3: define frequency, wear-time, invalid readings, aggregation and ADaM.

Minute 4: add device, algorithm, data version, QC and missingness provenance.

Minute 5: explain how the endpoint can be reproduced independently.

ONE SENTENCE TO KEEP

With continuous sensors, statistical programming begins before the final ADaM variable:

validity rules, time windows, aggregation algorithms and provenance are part of the analysis.