

Koneksa Platform Timed Walk Assessment

The Koneksa Platform is an end-to-end SaaS platform that can be configured to satisfy a variety of clinical study remote data collection requirements. When combined with Koneksa's study professional services and device/logistics services, a full lifecycle of a clinical study can be managed efficiently with high compliance.

Study participants can remotely perform the Timed Walk Assessment using the [Koneksa Mobile App](#). This assessment can be configured to digital equivalents of the Six-Minute Walk Test (6MWT), Two-Minute Walk Test (2MWT), and 20-Second Walk Test for both a straight path or U-Turn walking direction. Derived gait and balance measures are available as output, such as step count, average walking speed, distance walked, and actual duration.

How does it work?

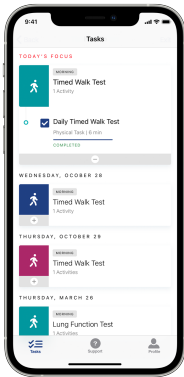
The Timed Walk Assessment is completed by study participants using the Koneksa Mobile App. When a study participant performs this assessment, they carry the phone close to their body (in a pocket, belt clip, or shoulder bag) while walking for the defined period of time.

The Koneksa Mobile App gives clear written instructions to the participant to start and stop the assessment. Audio encouragement is also given throughout the assessment. The following components of the Timed Walk Assessment are configured to suit specific study needs:

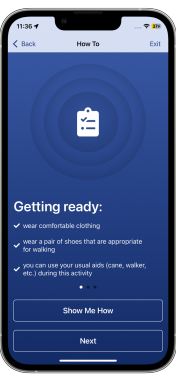
- Walk type (Straight Path vs. U-Turn)
- Duration (6 minutes, 2 minutes, or 20 seconds)
- Optional 10 minute rest period for the 6MWT
- Instructional text
- Assessment display name

Additionally, the Koneksa Mobile App can be configured to capture a participant's blood oxygen saturation through a Bluetooth-enabled external pulse oximeter before and/or after the walking assessment.

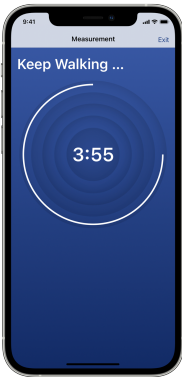
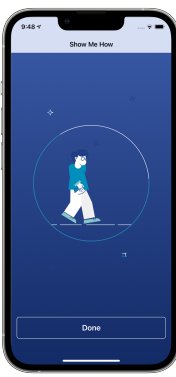
Out of the box, the straight path Koneksa 6MWT is configured to follow the American Thoracic Society 6MWT guidelines.



At-a-glance
Tasklist shows
participants the
expected study
activities



Tutorial gives straightforward
written and animated
instructions to participants



Participants are prompted
with audio cues during the
assessment.

Phone sensors record all data
as the participant completes
the activity.

At the end of the assessment, the raw sensor data collected from the study iPhone transmits securely to the Koneksa Platform via the Koneksa Mobile App. There, the data is processed through our validated algorithms.

Devices

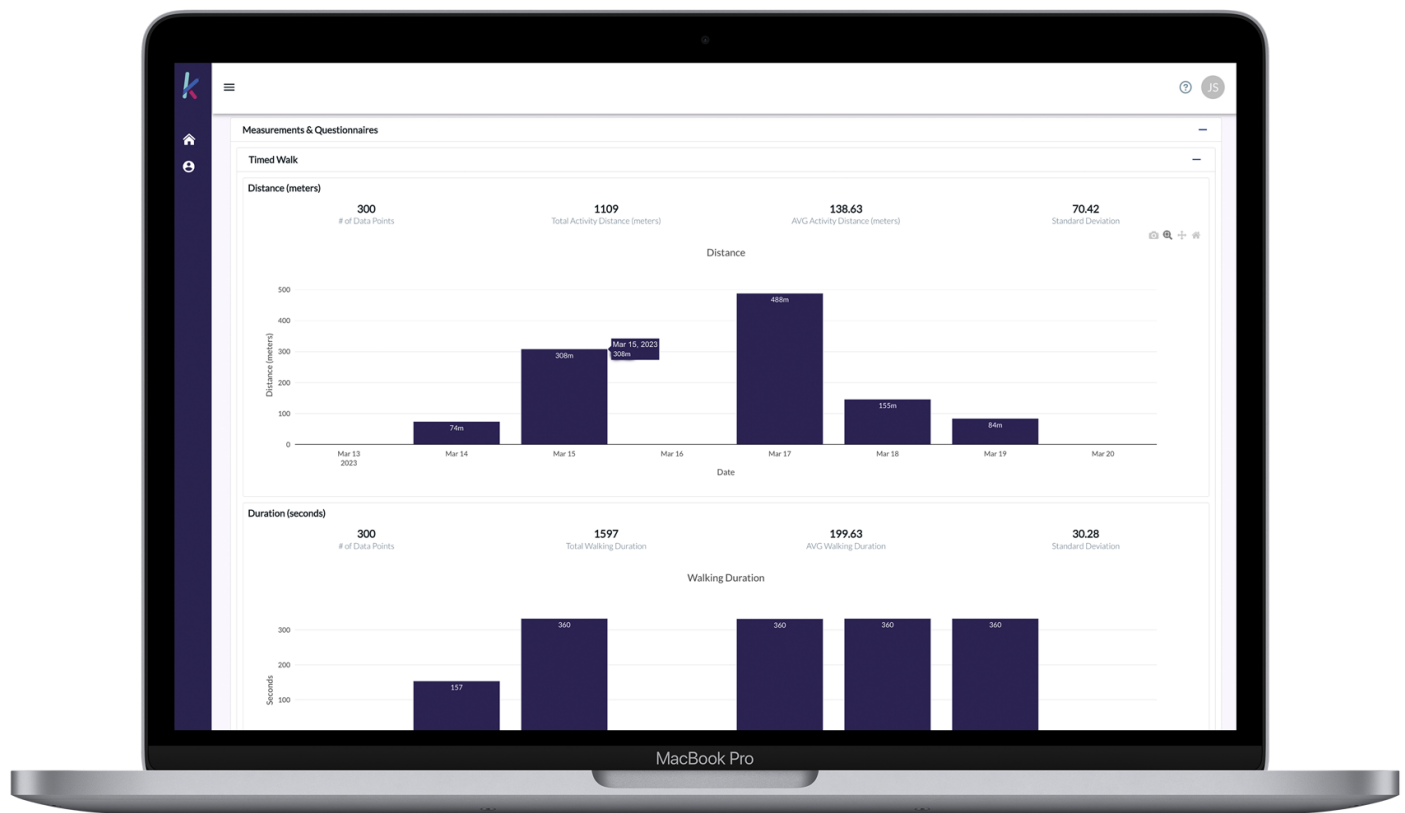
Devices deployed for Koneksa studies are provisioned and managed. Study participants do not have the ability to install or uninstall apps from the study iPhones, or to share their study data with organizations not commissioned by the study. The Timed Walk Assessment deploys on an Apple iPhone (see [Device Specifications](#) for more details):

Device	Apple iPhone XR/11/12
Image	
Certifications	CE Mark: (XR) link , (11) link , (12) link 510K: No
Battery life	25 hours
Storage	64 GB
Data Transfer	Via data upload to Koneksa Platform (wifi or cellular)

Data Collection & Visualization

The Koneksa Mobile App captures raw accelerometer data at a default sampling rate of 100 Hz; data is transmitted in near real-time. Koneksa applies algorithms to extract measures from sensor data and does NOT send data to Apple.

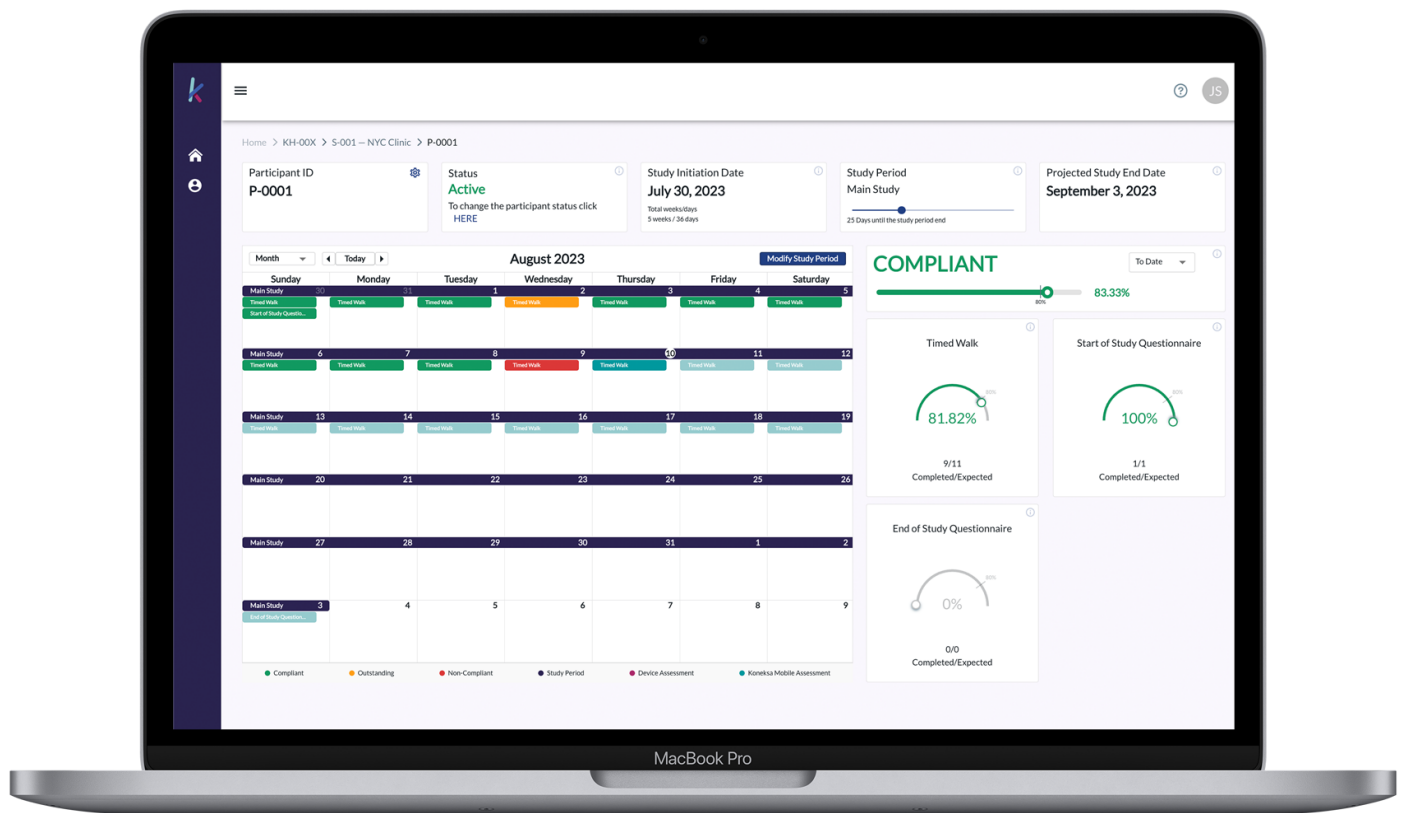
The derived Step Count, Distance, and Duration the participant walks for the standard assessment can be visualized on the Koneksa Platform web application, which is available to site and sponsor users for the study.



Derived measures are calculated from raw sensor acceleration data collected on the study iPhone. The following measures are provided to the sponsor in a SDTM export (see [Standard Measures & Export Format](#) for more details). See [Koneksa Algorithm Library](#) for algorithm details.

Concept	Measure	Units	Basis
Gait	Assessment start time	timestamp	Assessment
	Assessment end time	timestamp	Assessment
	Distance	meters	Walking period
	Duration	seconds	Assessment
	Gait speed	meters/second	Walking period
	Number of steps	N/A	Walking period
	Step length	meters	Walking period
	Step period	seconds	Walking period
	Steps per minute (Cadence)	steps/minute	Walking period
	Step time discrepancy	N/A	Walking period
	Stride length	meters	Walking period
	Stride period	seconds	Walking period
	Stride similarity	N/A	Walking period
	Walk period start time	timestamp	Walking period
	Walk period end time	timestamp	Walking period
Balance	X variability	g	Walking period
	Y variability	g	Walking period
	Z variability	g	Walking period
	X-Y variability	g	Walking period
	Freezing index	N/A	Walking period
Turning	Duration	seconds	Turn
	Angle of turn	radians	Turn
	Rotation rate	radians/second	Turn
	Maximum rotation rate	radians/second	Walking period

The assessment completion compliance rate may also be tracked on the Koneksa Platform web application, which is available to site and sponsor users for the study. The Participant Dashboard provides a visualized assessment schedule for a single participant, which clearly indicates when assessments are expected to be completed throughout the course of the study; color coding is also employed in the calendar to clearly differentiate between **Compliant**, **Outstanding**, and **Non-Compliant** assessments.



Compliance Monitoring

- Configurable notifications available to remind participants to perform study tasks
- Participants' task completion metrics are provided on various dashboards on the Koneksa Platform web application for study site coordinator users.
- Key metric reports available to view and download for further understanding of compliance and study progress.

Experience Highlights

- All data is anonymized.
- Configurable platform brings a tailored study Mobile App experience to participants: study schedule of assessments and study assessment reminders are all configurable.
- The following measures can also be enabled on the Mobile App on the same study iPhone for additional data collection:

- Vital Signs data from a variety of devices
 - Questionnaires (i.e. ePROs)
 - Spirometry measurements
 - Various Neuroscience assessments
- Participants experience the Mobile App in their native language; for a complete list of supported languages, see [Language Support](#).
- Standard SDTM exports available