

Koneksa Platform Tremor 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.

Tremor is a neurological indicator for participants, and can manifest in several ways; it is often assessed by clinicians utilizing standard, observational exams. During these exams, the participant is instructed to perform specific motions with their arms while the clinician makes subjective conclusions related to the amount of observed tremor.

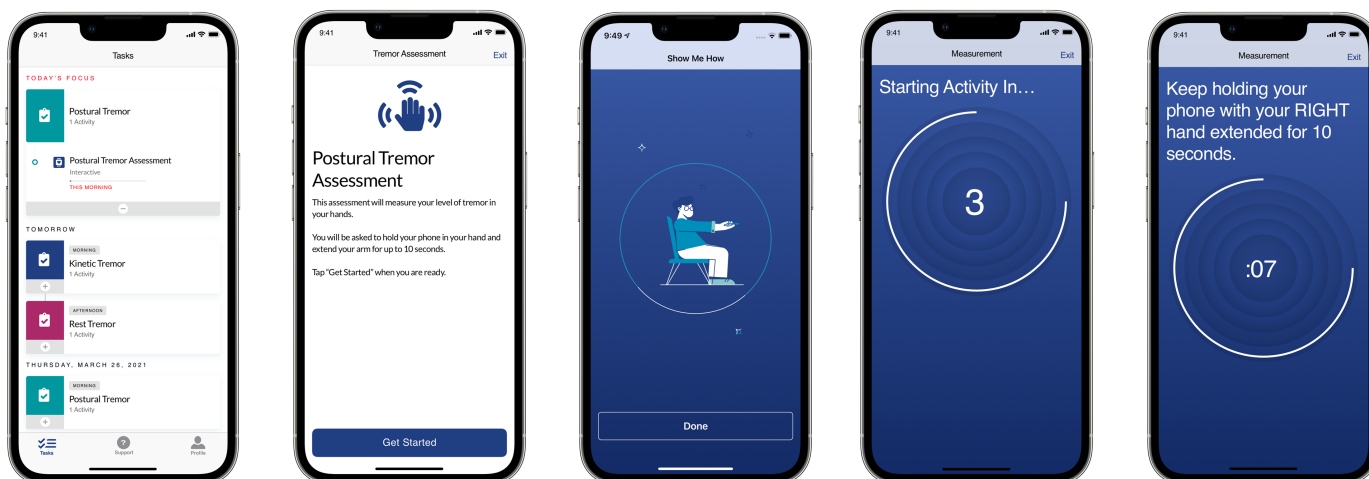
The Koneksa Platform's Tremor Assessment is a digital and quantitative means of performing a Postural, Rest, or Kinetic Tremor exam. This assessment eliminates human error by providing a more accurate and objective measurement, which captures subtle changes the human eye is not always capable of noticing. Study participants can remotely perform this activity using the Koneksa Mobile App. Derived tremor measures are available as output, such as tremor amplitude and frequency.

How does it work?

The Tremor Assessment is completed by study participants using the [Koneksa Mobile App](#), which gives clear written, audible, and visual instructions. During a Tremor Assessment, the participant must sit while holding the study iPhone. Depending on the type of tremor, the participant is given different instructions for how to move or not move their arm for a set period of time.

The following components of the Tremor Assessment are configured to suit specific study needs:

- Type of tremor being measured (postural, rest, or kinetic)
- Use of left vs. right hand
- Instructional text
- Assessment display name



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 movement data as the activity is completed.

At the end of the assessment, the iPhone's raw sensor data transmits securely to the Koneksa Platform via the Koneksa Mobile App. There, data is processed by our data analytics 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 Tremor 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)

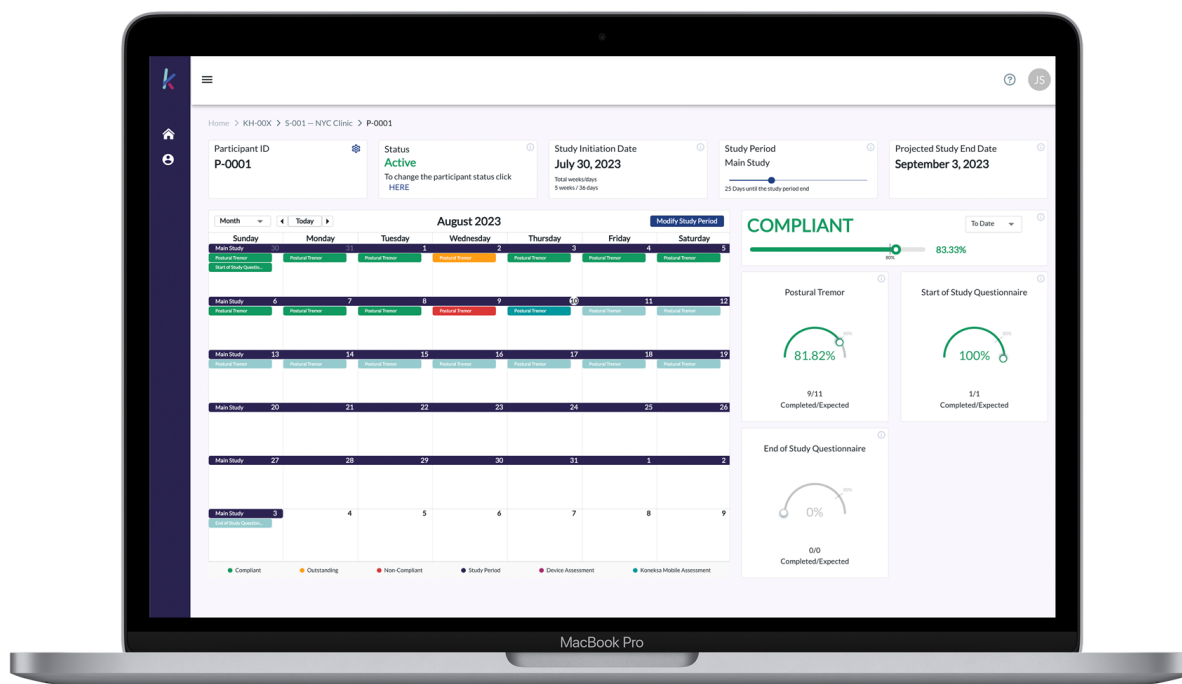
Data Collection & Visualization

The Koneksa Mobile App captures raw accelerometer and gyroscope data and transmits the collected data to the Koneksa platform as soon as the participant completes the assessment. Koneksa utilizes an algorithm to extract measures from sensor data and does NOT send data to Apple. See [Koneksa Algorithm Library](#) for algorithm details.

The following measures are provided to the sponsor in a SDTM export (see [Standard Measures & Export Format](#) for more details):

Concept	Measure	Description	Units
Tremor (Postural, Rest, and Kinetic)	Tremor RMS Acceleration	Root-mean-square acceleration in the tremor frequency band	g
	Tremor Peak Frequency Acceleration	The strongest frequency of acceleration within the tremor frequency range	Hz
	Tremor RMS Displacement	Root-mean-square displacement in the tremor frequency band	m
	TremorPeak Frequency Displacement	The strongest frequency of displacement within the tremor frequency range	Hz

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