

Koneksa Platform Pronation / Supination 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.

The Pronation / Supination exam is widely used by clinicians as a neurological indicator for participants. The participant must hold one arm straight out in front of themselves while rotating the arm palm up then palm down. It is the clinician's responsibility to make subjective observations related to a reduction of rotation amplitude and speed.

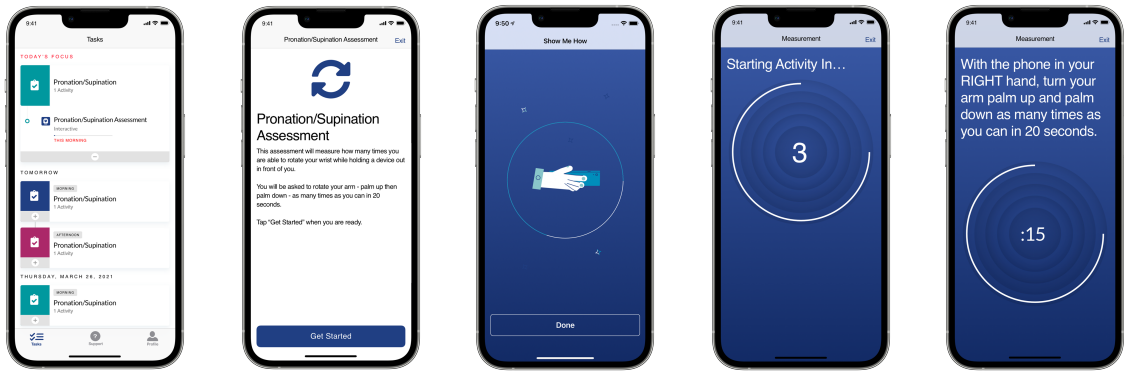
The Koneksa Platform's Pronation / Supination Assessment is a digital and quantitative means of performing this exam. This assessment eliminates human error by providing a more accurate and objective measurement, which captures subtle changes the human eye is not always capable of noticing. Study participants can remotely perform this activity using the Koneksa Mobile App, which can be configured for participants to use their left or right hand. Derived pronation / supination measures are available as output, such as number of turns, turn rate, rotation rate, and axial variability.

How does it work?

The Pronation / Supination Assessment is completed by study participants using the [Koneksa Mobile App](#). The study participant performs this assessment in a seated position. They must extend their arm out in front of themselves while holding the study iPhone with the screen facing away from their palm. After a starting countdown, the participant rotates their arm (i.e palm up then palm down) as many times as they can for 20 seconds.

The Koneksa Mobile App gives clear written, audible, and visual instructions on how to perform the Pronation / Supination Assessment. The following components of the Assessment are configured to suit specific study needs:

- Use left or right hand
- Instructional text and assessment 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 all data as the participant completes the activity.

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

Devices

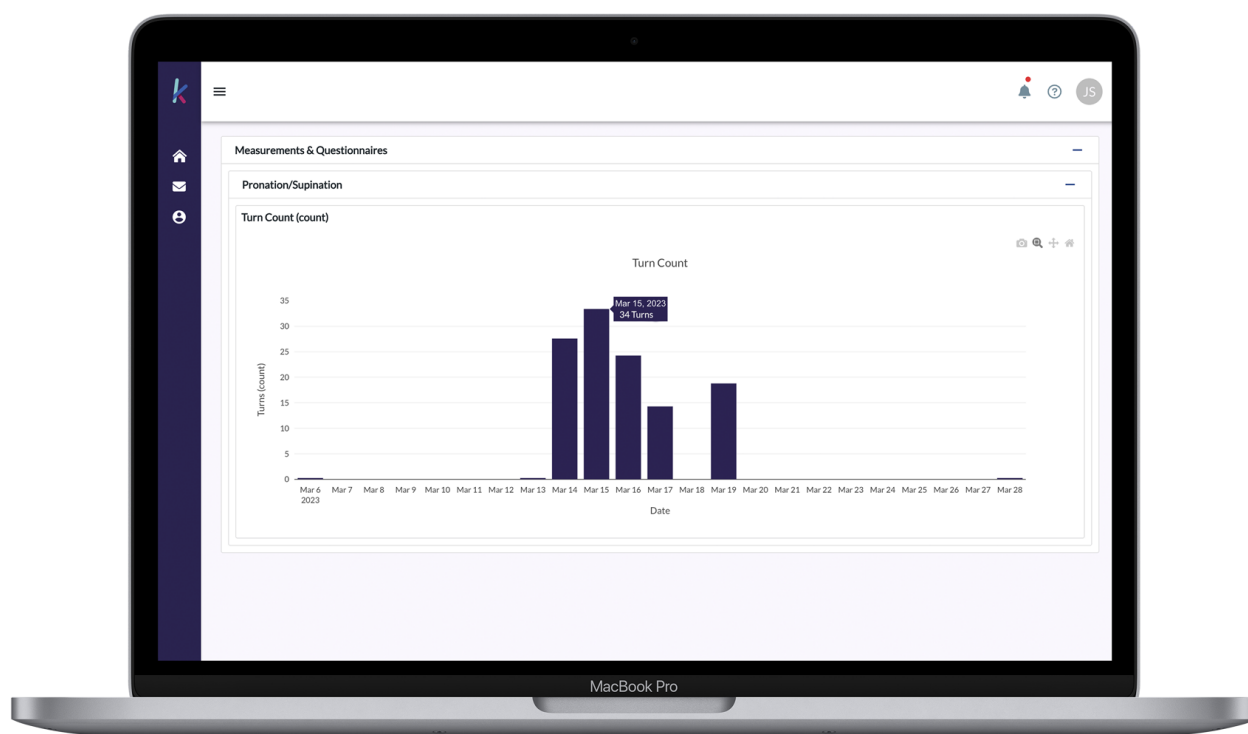
Devices deployed for Koneksa studies are provisioned and managed. Study participants do not have the ability to install or uninstall apps from the study iPhones, or to share their study data with organizations not commissioned by the study. The Pronation / Supination Assessment deploys on an Apple iPhone (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.

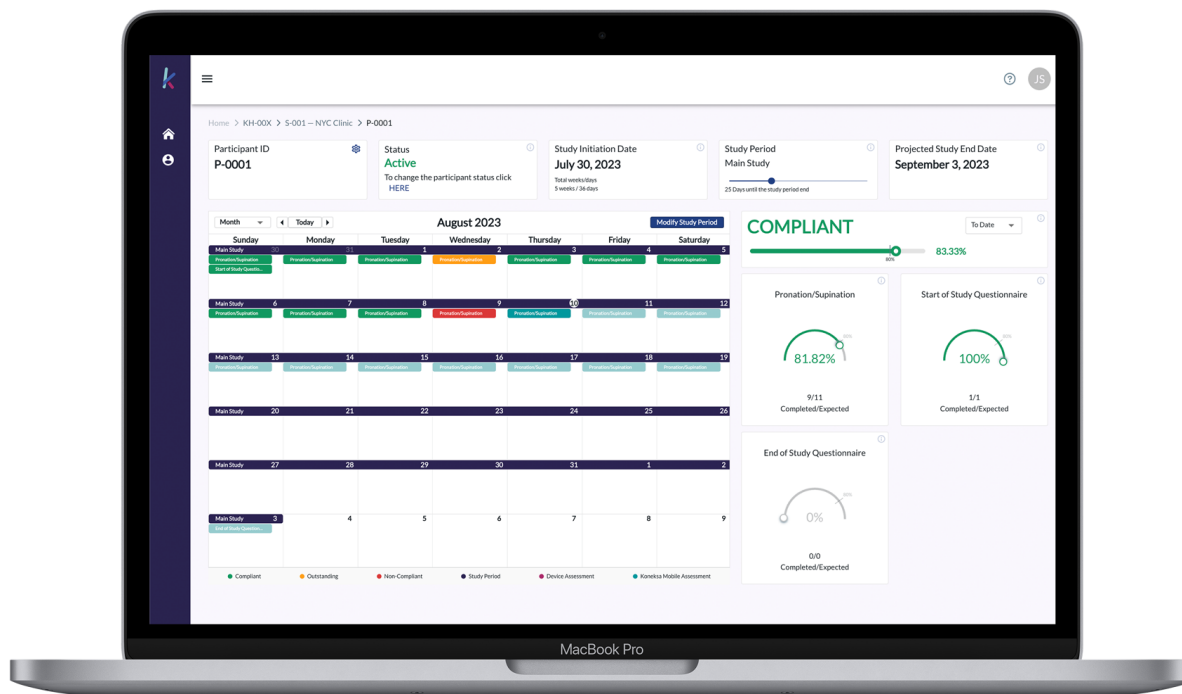
The derived Turn Count for each assessment can be visualized on the Koneksa Platform web application, which is available to site and sponsor users for the study.



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

Concept	Measure	Description	Units
Pronation / Supination	Number of turns	Number of pronation / supination maneuvers	N/A
	Turn rate	Average number of turns per second	turns/second
	Rotation rate	Average rotation rate	radians/second
	Axial variability	The proportion of the rotation about axes other than the principal rotation axis	ratio

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