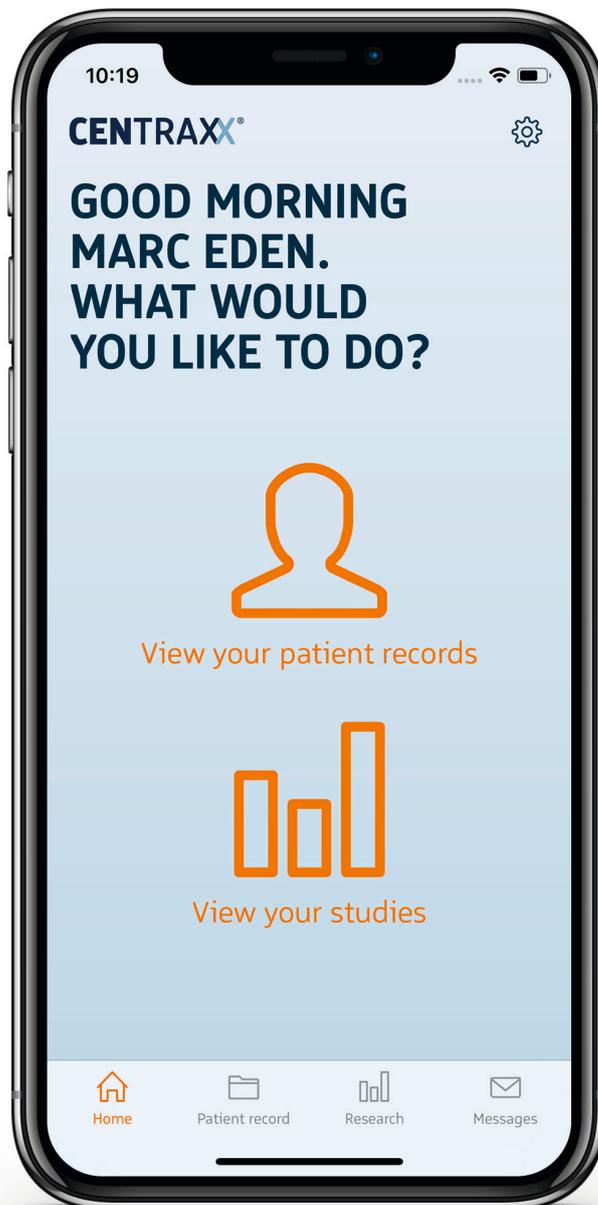


# ONE FOR ALL. THE CENTRAXX® PATIENT-APP





The CentraXX Patient App complements existing CentraXX products. Whereas our expert systems focus on treatment providers

and researchers, the app was developed with simplicity in mind for the patient to use him/herself.

# CENTRAXX® PATIENT-APP

The CentraXX Patient App is the technical platform for patients collecting and sharing their personal health data with healthcare and research professionals who work with CentraXX systems. Patients using the Patient App can directly submit their consents and self-assessments (patient reported outcomes). The app enables the patient to easily and immediately provide assessments and other information regarding their health status directly to the clinic. To this end, ICHOM standard sets can be used to structure the information that is transmitted. The International Consortium for Health Outcomes Measurement (ICHOM) in Boston is an independent Non-Profit-Institute, which together with patients, doctors, and quality experts have developed standard sets (STS) for medical outcome measurement. This IT tool also improves study recruitment when combined with suitable research IT system solutions like CentraXX Trial. With regards to recruiting study subjects for clinical studies, use of the CentraXX Patient App can lead to real win-win situations: On the one hand, the clinic can use the app to directly contact suitable patients that were detected through its research IT to inform them about the possibility of participating in a study. On the other hand, the patient can benefit from the app by staying up to date about studies they are interested in and may qualify for.

These recruitment opportunities improve the chances for carrying out meaningful studies with larger cohorts. The app thus has the potential of becoming the matching platform - the interface between the patient and clinical research, or the patient and the pharmaceutical industry.

**Would you like to find out more about the CentraXX PATIENT-APP? Or are you already a CentraXX user and would like to integrate this module into your existing CentraXX architecture?**

**Then please contact KAIROS >[info@kairos.us](mailto:info@kairos.us)**

**NOW IS THE TIME.**

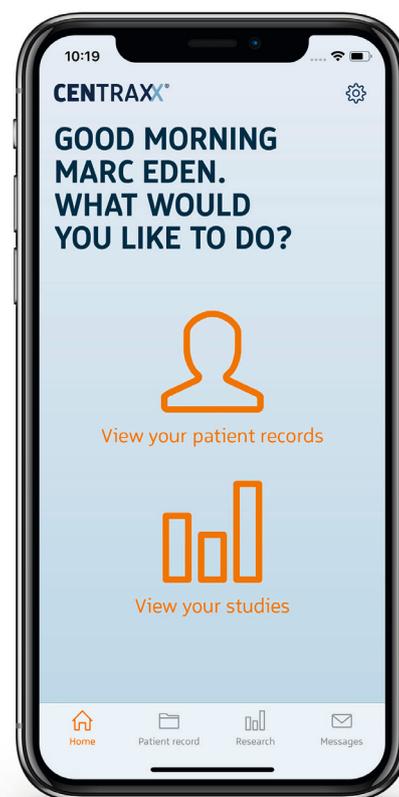
**> [kairos.us](http://kairos.us)**

## FUNCTIONAL CONCEPTION OF THE CENTRAXX®-PATIENT-APP

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The Patient App enables better communication between doctor and patient and offers the possibility to view the full scope of data records according to §630g BGB (inspection of the patient file) and Article 20 GDPR (right to data transferability). In addition, the CentraXX Patient App can be a central component for Patient Reported Outcomes (PRO), when the patient provides personal assessments about his/her health and experiences regarding the treatment. The information obtained not only serves to immediately improve the quality of the therapy, but also aids in the execution of studies according to ICHOM standards. The Patient App can be used anywhere at any time in order to transmit and receive data right to and from the user's personal mobile device. These features provide the physician with important data - that is, additional decision-support which further empowers the patient.

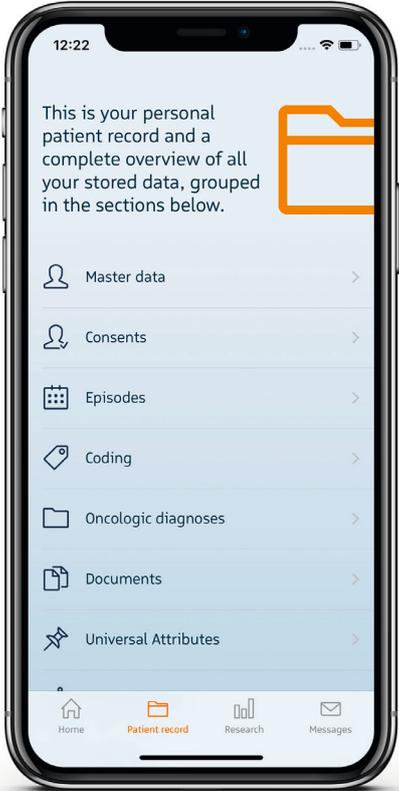
The patient app is divided into three main levels of application:



- > **Personalized Patient Record**
- > **Execution of Studies/  
Data Capturing**
- > **Messaging System**

# Personalized Patient Record

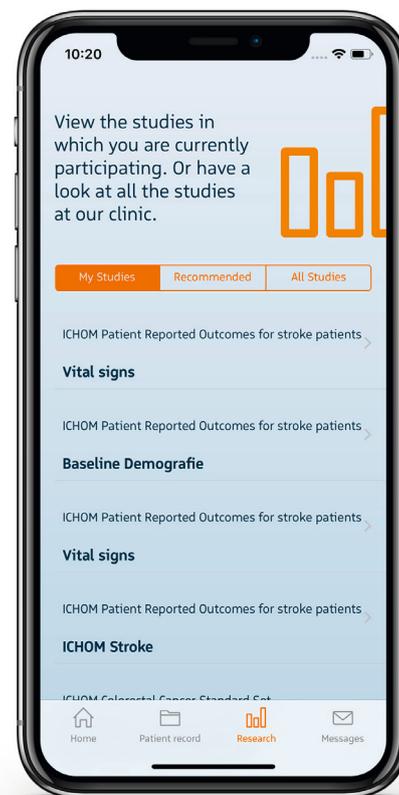
The patient has access to all data that is stored about him/her in a corresponding CentraXX instance. This data is retrieved in XML format via REST-API, processed in the app and divided into different areas, e.g., diagnoses, measurement results, etc. All content is displayed read-only and protected against any data changes by the user. At regular intervals and as required, the database can be recalled and thus synchronized. By implementing the FHIR protocol, further systems/sources can be seamlessly integrated and data exchange simplified. In addition, a connection to several CentraXX instances is currently being developed in order to combine data from several sources in the Patient App. An export of all data is available in PDF format for further use. A structured export of the data is also possible, allowing the patient to share important medical data with others.



# Execution of Studies/ Data Capturing

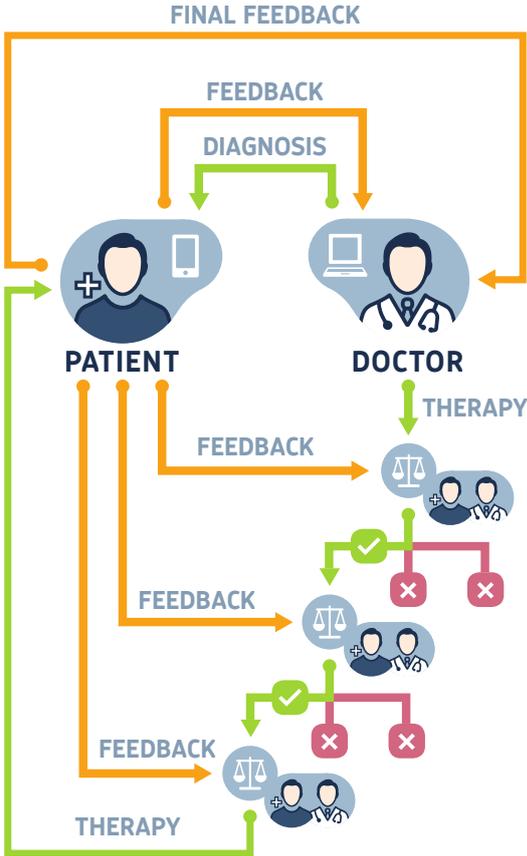
## Capturing of eCRFs and ICHOM

The patient is shown an overview of all studies or eCRFs visible to him/her for data capturing. In addition, suitable studies are recommended to the patient based on the inclusion and exclusion criteria mapped against his/her profile. Finally, the app offers an overview of all studies that are being carried out by the responsible sponsor and that have been published. Data capturing makes it possible to fill out eCRFs in studies that would otherwise be recorded in paper form. The eCRFs are generated from the CentraXX instance, which not only allows for regular use, but can also be used directly in the Patient App without lengthy adjustments needed. A native implementation of the eCRFs in the app is planned to further improve the user experience. The app also makes eCRFs available according to the ICHOM standard in order to capture information in structured form according to defined standard sets. The transmission of image data, from the mobile device directly to the associated CentraXX system will be included as a further feature.



## Apple Health

The patient can share data from his/her mobile device's Apple Health Repository with the CentraXX Patient App (Opt-In). All information that the patient collects with additional healthcare apps (e.g. dietary information, sleep monitoring, etc.) or using external devices (e.g. blood glucose meters, blood pressure monitors, scales, etc.) can also be transferred to the Patient-App and can thus be shared with the CentraXX infrastructure. Fitness information, such as number of steps taken, running distance covered, sports workouts or physiotherapeutic applications, can also actively support the course of therapy in the sense of shared decision support or permit further assessments.



## Messaging System

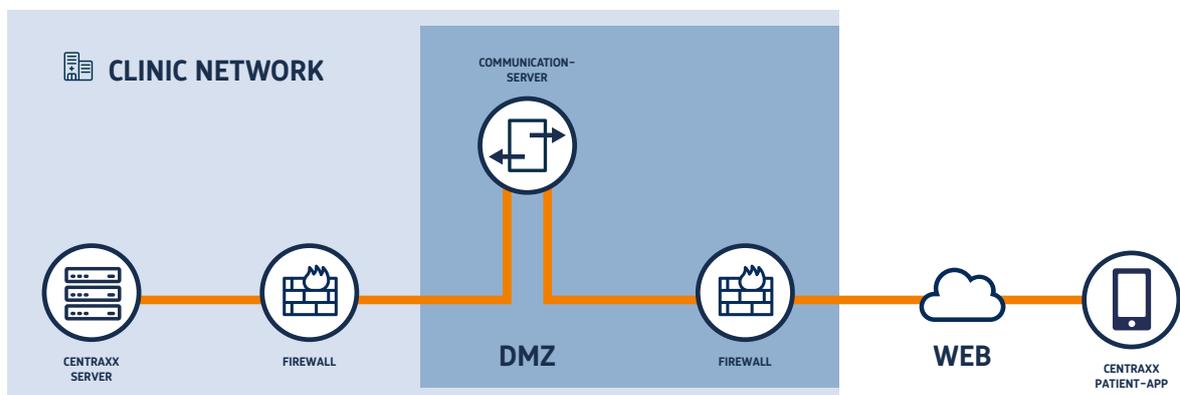
Direct and targeted communication takes place between the physician and the patient via the app's messaging system. This makes it possible for the treating institution to schedule appointments or to refer to new and available studies. The patient can send feedback or other information. Depending on consent management, samples or measurement data that had already been captured can be reconsented easily for use in new projects. The app will notify the

participating patient about new messages (after consent / opt-in) so that patients can be reached without having to log in to the app and actively retrieve the messages first. This also helps reach patients who no longer regularly use the app after completion of studies or therapies. This, coupled with the database already available in CentraXX, leads to the creation of a larger group of potential study members for the recruitment in new studies.

## Security

Due to the nature of the data treated, a strict security concept is required to prevent misuse of the data. The CentraXX Patient App is protected against access by third parties by a personally assigned password or biometric authentication (fingerprint, „FacelD“) each time it is accessed. Since the data can also be used offline, i.e. without a connection to the CentraXX server, the data is stored „hardware-encrypted“ on

the smartphone. The patient data is only decrypted when the app is started and unlocked. The data is encrypted again when the app is closed. Only encrypted data is included in device backups. The connection to the CentraXX server is established by two-factor authentication (user name/ password and a unique API key) to ensure that the data of the respective patient can only be retrieved by the associated device.



The connection to a CentraXX instance is possible via a security gateway or a communications server in a demilitarized zone (DMZ) to protect the instance against

access from outside of the institute. Only TLS-encrypted connections can be used, which can be secured with client certificates.

## Design

The target group being patients creates special requirements for usability/user experience. In order to increase acceptance and adherence to / usefulness in life, various design paradigms were followed. An adaptation to new operating system

versions, both from a design perspective and on a technical level (new frameworks, optimized security concepts), is undergoing continuous evaluation and successive implementation.

- > **Clear and comprehensible structure and information architecture**
- > **Simple, natural language**
- > **Onboarding as first step to familiarize user with functions and operating concepts**
- > **Following human interface guidelines by smartphone manufacturers to learn from existing best practice operating concepts and conventions**







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