



# Projection® EPRO

## Up-to-date solution

Since smartphones are used by millions of users in the world (24.1 users of smartphones and 44.4% of the population in France and 18.4% of families equipped of tablets in France), Projection® EPRO is the perfect tool to collect data easily in any kind of survey.

Projection® EPRO is a flexible, scalable and reliable solution for patients' questionnaire. It can be used online or offline and runs on smartphones or tablets.

## Main concept

- Projection® EPRO allows patients to register daily information regarding various types of quality of life questionnaires
- As it can be used by patients of various ages and different digital levels, the application is especially easy to use, intuitive and provides context-sensitive help
- A self-training is available under the supervision of the investigator
- Projection ePro can be adapted to any study format, requirements and quality standards
- Offline data entry is available and transparent for the patient
- Data is automatically synchronized in real-time between the tablet and a central database or an Arone eCRF database using secured connections
  - In case of an offline data entry, the synchronization will be done automatically as soon as a connection will be available



## References

Development of the software ItchApp® in partnership with Pr Sonja Stander for UKM in Münster (Germany). Many studies in production with short daily questionnaires.

Daily questionnaire for patients of a local US study for an american pharmaceutical company based in Washington DC (references can be provided if needed).

Questionnaire for a survey on sexual troubles on high level athletes.

Questionnaire used for registering medical practices used during a symposium.

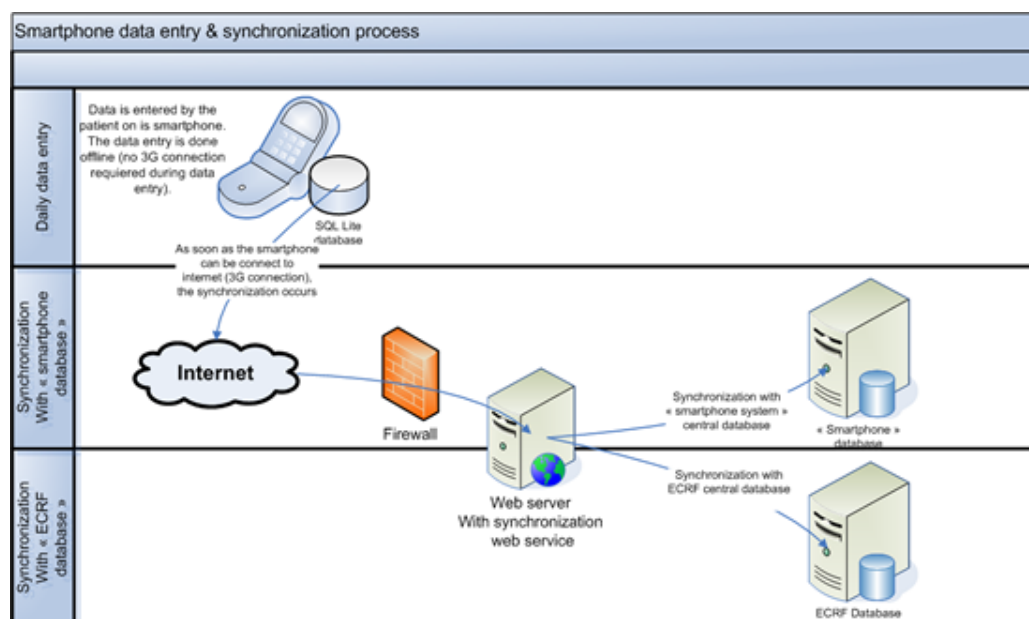
## Regulatory compliance

Projection® EPRO is fully compliant with 21CFR Part 11. All data transmissions are encrypted through an SSL connection and all actions are tracked in the audit trail. Projection® EPRO includes electronic signature.

All the modules in the Projection® System have been fully validated.

## Technical requirements

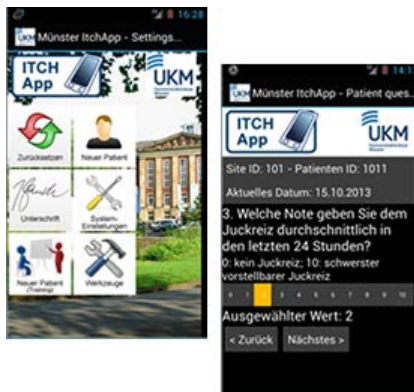
Projection® EPRO is supported by Android devices.



## Software distribution

Two solutions can be considered depending of the study type and budget:

- Tablet or Smartphone can be dedicated to the application and provided by the sponsor of the study
  - In this case at the inclusion visit, the tablet or smartphone is given to the patient and a demonstration or a training session is done with the investigator or with the technical assistant,
  - The tablet or smartphone cannot be used for anything else than the study purpose.
- The application can be downloaded by the patient on his own tablet or smartphone.
  - In this case at the inclusion visit, a card is given to the patient with the instructions to download the application,
  - A self-training can or must be done by the patient before the real data entry.



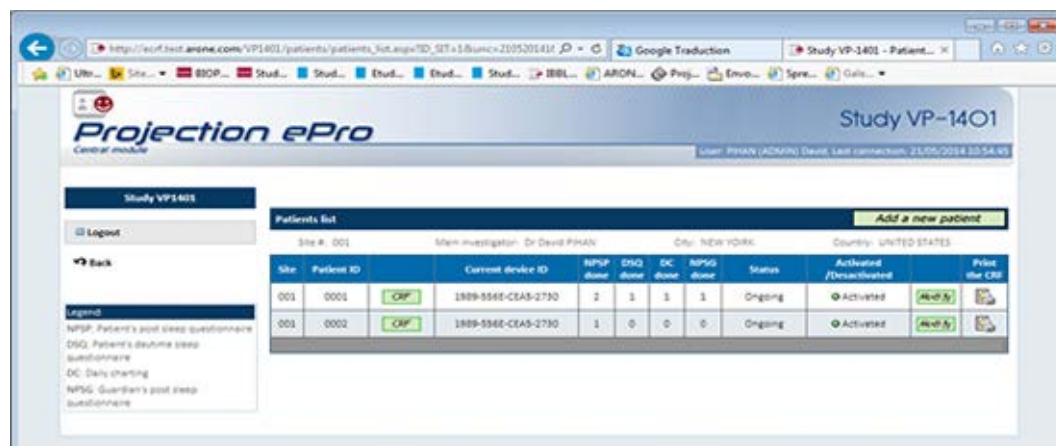
## Projection® EPRO architecture

The Projection® EPRO system includes:

- An Android application running on devices which permits to the patients to register daily information about quality of life or any other information.
- A central database where patient's data is stored.
- A secured web service permitting data to be synchronized between the devices and the central database.
- A web application:
  - where data collected can be reviewed in real-time and administered.
  - where data collected can be exported in CSV/CDISC format.
  - where administrators can:
    - follow the study activity with dashboard and reporting
    - detect abnormalities for patients (regarding a score evolution or alarmistic

answer, ...)

- manage devices (used/not used, last synchronization date, last entry date, version of the application installed on the device...)
- launch messages to the patient through the device,
- ...



## Management

In addition to data entry, the Projection® EPRO solution offers a wide range of functions designed to simplify the monitoring of patients by investigators and technical administrators, according to the study requirements, i.e.:

- Transmit information, alerts and reminders to the patient
- Display the visit planning if relevant
- Score calculations
- Display evolution curves and charts
- Dashboard including reports and usage statistics
- Software update
- Stock management
- Material issues
- Connections issues
- Data export
- Link with an eCRF database ...

## Security

Projection® EPRO is fully secured. Data can be signed at the end of data entry regarding studies requirements. Many kinds of signature can be used from passphrase to real manual signature.

Devices can be locked for the study purpose and so devices are dedicated to the study. Data changes are tracked in an audit trail.

## Interface

Projection® EPRO can be linked to external system and more especially to ARONE Projection® EDC.

## Multi-lingual interface

Projection® EPRO is fully multi lingual. The language is automatically detected by the system regarding the language set on the device.

### Contact :

**ARONE**

4 rue Leroux  
94100 Saint-Maur des  
Fossés

Phone : +33 1 49 77 23 30

Fax : +33 9 70 32 62 47

Email : [info-arone@arone.com](mailto:info-arone@arone.com)

ARONE

S.A.S. au capital de 40000 €  
RCS Créteil B 417 714 805 00039  
NAF 6202A