Fraunhofer IIS

Combine clinical study contents with home monitoring safely and easily with DPM.research

Management System for Clinical Trials

www.iis.fraunhofer.de/clinical-trial-management

Participation in clinical studies has never been as easy or as safe as with »DPM.research« eCRF system: Data can be collected directly from the patient with the help of an app, GDPR-compliant and in medical quality, along with the connection of various wearables depending on the use case.

Features:

- Web-based application
- Adaptable to study protocol
- Customisable branding and themes
- Multi-client capability
- Roles and rights management
- Randomisation and pseudonymisation
- Adverse event reporting (special incidents) to the sponsor
- Audit trail
- Monitoring using queries (still in progress)
- Customised export interfaces (CSV, etc.)
- For decentralised studies:
  - Appointment planner
  - Informed consent interview via video tool
  - Digital signature for declaration of consent
  - Automated e-mail notifications

- Optimised for desktop and mobile devices
- Data storage in FHIR format
- Multilingual (multi-language support possible)
- On premise or in the cloud in ISO 27001-certified data centres in Germany.

Reference projects:

- NeuroMoves
- MSgoesHome
- DiGaitApp_PD
- MobilityApp
- ParkinsonGo
- Carna ProHeart

Reference hospitals:

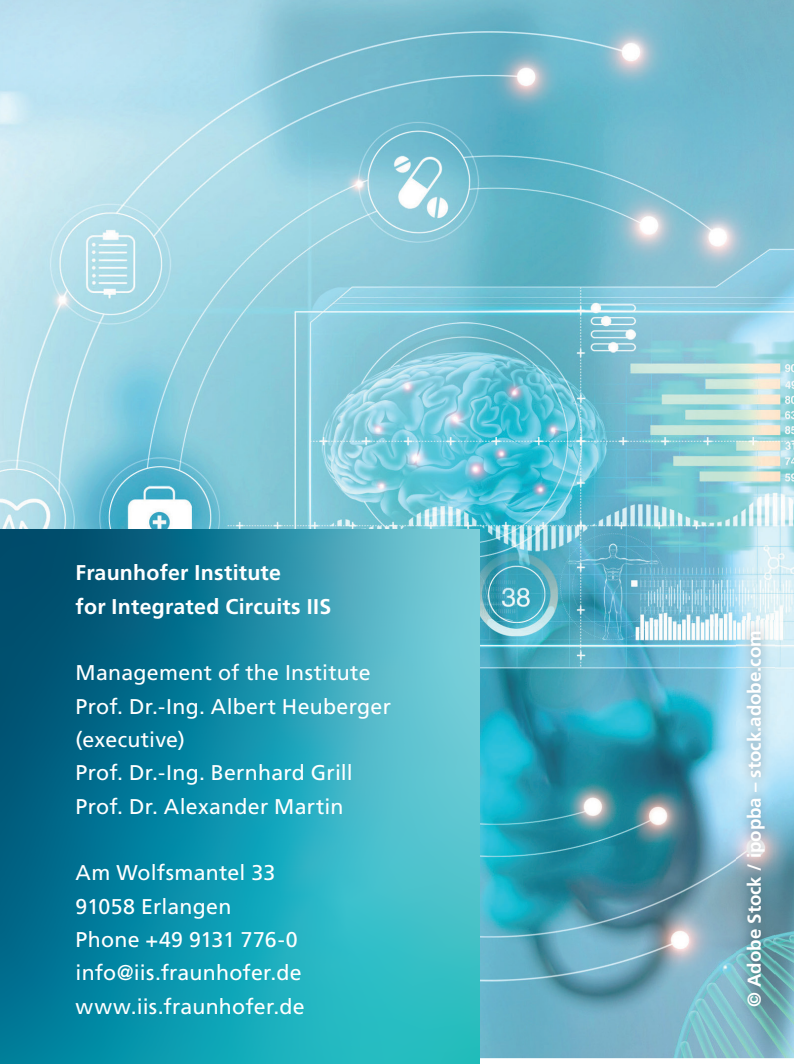
- Heidelberg University Hospital
- University Hospital Erlangen
- University Hospital Regensburg
- Nuremberg Hospital

Do you plan to conduct a study and need further information? Do not hesitate to contact us!

Regulations:

- GCP (good clinical practice)
- DSGVO General Data Protection Regulation (GDPR)
- EMA Guideline - EMA/INS/GCP/112288/2023

Type of study	Traditional, centre-based	Hybrid	Decentralised, digital
Description of the study	Mono or multi-center studies, traditionally conducted in clinical trial centres.	Traditional centre-based study that records so-called Patient Reported Outcomes (PROM) of the patient at home.	Purely digitally conducted studies without the involvement of a clinical centre. (The patients are digitally recruited and involved digitally. Study physicians are directly contracted).
Recording of the data	During clinic visits.	Partly using mobile devices and partly directly by means of wearables.	Data collected directly from the patient using mobile devices.
Doctor-patient communication	In the clinic on site and in person.	In the clinic on site and in person.	Doctors talk to patients via video tool.
Declaration of consent	Signed on paper on site.	Signed on paper on site.	The patient's consent is digitally signed.
Effort for patients	Patients must come to the clinic on site.	Patients must come to the clinic on site.	Patients can participate in the study from home.



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