COVID-19 Trials@Charité

Charité COVID-19 Trial Platform

Pa-COVID-19

CoronaBoXX

Charité COVID Master
Charité COVID-19 Trial Platform

• **Pa-COVID-19** – Charité sampling trial (surveillance, minimal invasive diagnostics, deep phenotyping)

• **CoronaBoXX** – Charité COVID-19 patient data box and reporting app (PROM)

• **Charité COVID Master** – Charité COVID-19 WHO intervention prototype
Overview Charité COVID-19 Trials

Symptoms → COVID positive → Hospital Admission
Charité COVID ward / ICU

Pa-COVID-19

D1 Inclusion of patients after confirmation of SARS-CoV-2

History/Risk factors
Clinical data
Deep phenotyping

Home care/ Quarantine

Inclusion of patients after confirmation of SARS-CoV-2

Data collection
Covid – 19 Study - Team:
eCRF Biobank

Day 0: Medical staff (Charité)
n=1,000

SARS-CoV-2-Infection ?

Day 180

SARS-CoV-2-Infection ?

Day 360
Pa-COVID-19

- Recruitment of all consenting COVID-19 patients at the Charité (EA2/066/20)
- Longitudinal analysis of clinical parameters (eCRF SecuTrial)
- Longitudinal bio-sampling for deep molecular phenotyping (BIH-CRU & BIH-Biobank)
  - Identification of risk factors, prognostic biomarkers and molecular targets for interventions
  - Central clinical platform for additional observation and interventional trials (AMG / MPG)

COVID-19 Patients Charité

Mon/Wed/Fri

eCRF (SecuTrial) databank

Biosamples BIH-biobank

Multiple Trials / Baskets
(incl. AMG / MPG)

Recruitment / data collection / biosampling
COVID-19 Study team
pa-covid-19-studie@charite.de

Coordination of additional studies & subprojects
COVID-19 Study team &
Corona Forschung Task Force
CoronaBoXX

- Recruitment of COVID-19 outpatients (home quarantine)
- Self-reporting App and Data-Box (CoronaBoXX)
- Baseline assessment of medical parameters
- Clinical Characterization of mild forms of COVID-19 and prodromal states of severe disease
CoronaBoXX

**CORONABOXX®**
IHRE PERSÖNLICHE PATIENTEN-APP.

- **HALLO FRANZY HOHNSTÄDTER. WAS MÖCHTEN SIE TUN?**
  - Symptomtagebuch führen

**Unterbringung**

- Wo befinden Sie sich gerade?
  - [ ] Zu Hause
  - [ ] Im Krankenhaus

- Wenn Sie sich im Krankenhaus befinden, auf welcher Station liegen Sie?
  - [ ] Notaufnahme
  - [ ] Normalstation
  - [ ] Intensivstation
  - [ ] Anderer Ort im Krankenhaus

- Bitte geben Sie an, seit wann Sie sich auf Station befinden.
  - 27. März 2020 um 12:45

**Symptome**
Master Trial Concept

Creation of an adaptive Master Trial with multi-arm design as a way to develop different therapy strategies for several subpopulations.
COVID-19 Master Trial Protocol

Charité coronavirus disease 2019 (COVID-19) trial

Protocol according to the master protocol “A Multi-center, Adaptive, Randomized Blinded Controlled Trial of the Safety and Efficacy of Investigational Therapeutics for the Treatment of COVID-19 in Hospitalized Patients”

Short title / Acronym
TBA

EudraCT-Number:
TBA

Protocol code:
TBA

Protocol