



On clinical research, telemedicine and COVID-19

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Outline

- Introduction
- Telemedicine study of COVID-19 patients
- AIDMED system



Introduction

- “**Clinical research** is a branch of healthcare science that determines the safety and effectiveness (efficacy) of medications, devices, diagnostic products and treatment regimens intended for human use.” - wikipedia
- “**Clinical trials** are experiments or observations done in clinical research.” - wikipedia
 - Assessment of effectiveness in new application areas
- **Evidence based medicine** - Sackett DL, Rosenberg WM, Gray JA, Haynes RB, Richardson WS (1996). "Evidence based medicine: what it is and what it isn't". BMJ. 312 (7023): 71–72.



Introduction (clinical trials)

WHO Principles of GCP (https://www.who.int/medicines/areas/quality_safety/safety_efficacy/gcp1.pdf):

- Principle 1: Ethical Conduct
- Principle 2: Protocol
- Principle 3: Risk Identification
- Principle 4: Benefit-Risk Assessment
- Principle 5: Review by Independent Ethics Committee/Independent Review Board
- Principle 6: Protocol Compliance
- Principle 7: Informed Consent
- Principle 8: Continuing Review/Ongoing Benefit-Risk Assessment
- Principle 9: Investigator Qualifications
- Principle 10: Staff Qualifications
- Principle 11: Records
- Principle 12: Confidentiality/Privacy
- Principle 13: Good Manufacturing Practice
- Principle 14: Quality Systems



Introduction (clinical trials)

- Bioethics Committees
- Sponsor
- Principal Investigator
- Collaborators
- Description
- Design

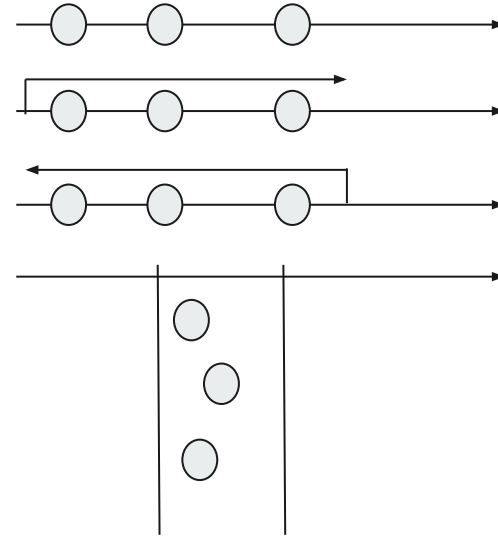


Introduction (clinical trials)

- Design
 - How many, how long
 - Interventional (clinical trial)/Observational
 - Allocation/Randomization
 - Intervention model: parallel, crossover
 - Masking/blinding
 - Arms, control
 - Outcome measures: primary, secondary
 - Eligibility Criteria: inclusion, exclusion

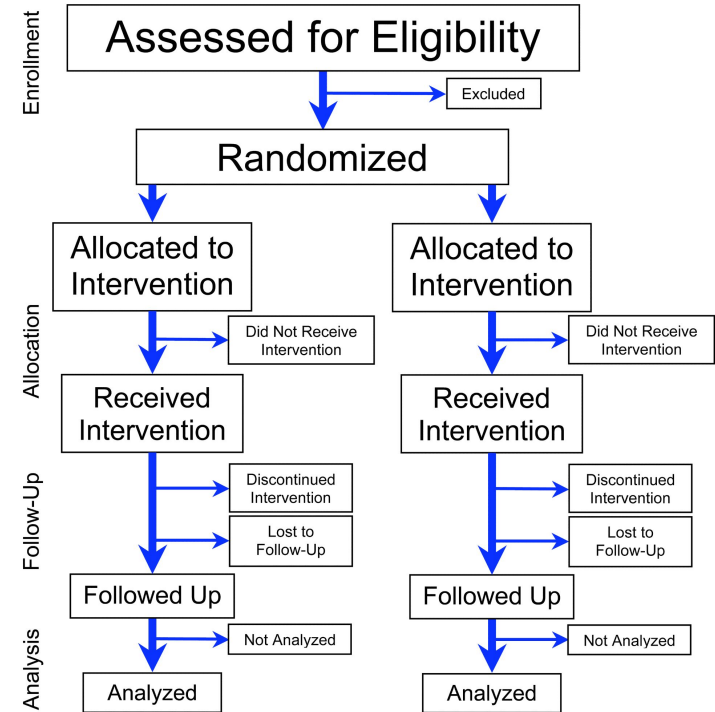
Introduction (clinical trials)

- Observational
 - Longitudinal study (prospective/retrospective)
 - cohort
 - Transversal study
 - Cross-sequential study
 - Case-control study



Introduction (clinical trials)

- Controlled





Introduction (clinical trials)

<https://clinicaltrials.gov/>

<https://www.clinicaltrialsregister.eu/ctr-search/search>

<https://www.centerwatch.com/clinical-trials/listings/location/international/Poland/>

Introduction (clinical trials)

Showing: 1-10 of 7,024 studies studies per page Show/Hide Columns

Row	Saved	Status	Study Title	Conditions	Interventions	Locations
1	<input type="checkbox"/>	Recruiting	Duvelisib to Combat COVID-19	• COVID-19	• Drug: Duvelisib • Procedure: Peripheral blood draw • Drug: Placebo	• Missouri Baptist Medical Center Saint Louis, Missouri, United States • Washington University School of Medicine Saint Louis, Missouri, United States
2	<input type="checkbox"/>	Recruiting	Relationship Between CT- Value With Prognosis in COVID-19 Patients	• COVID-19	• Diagnostic Test: Cycle threshold	• SBMU Tehran, Iran, Islamic Republic of • Nooshin Dalili Tehran, Iran, Islamic Republic of
3	<input type="checkbox"/>	Recruiting	Observational Cohort of COVID-19 Patients at Raymond-Poincare	• COVID-19		• Department of Infectiology, Raymond Poincaré Hospital, APHP Garches, France
4	<input type="checkbox"/>	Not yet recruiting	COVID-19 Surveillance Based on Smart Wearable Device	• COVID-19		• Peking University First Hospital Beijing, Beijing, China



Telemedicine study of COVID-19 patients

- A system supporting remote diagnostics of patients treated at home, enabling the detection of a sudden exacerbation of COVID-19 symptoms based on artificial intelligence methods.
- The project is carried out by consortium:
UWM w Olsztynie, AIDMED, KOR UCK w Gdańsku, Szpital MSWiA w Olsztynie, SSW w Ciechanowie
- The project is sponsored by ABM



Telemedicine study of COVID-19 patients - goals

- Build big dataset of biosignals from patients with mild COVID-19 (non - hospitalised):
 - 400 patients with mild COVID-19, 200 patients with chronic pulmonary or cardiac disease for control
 - 10-14 days of observations
 - Biosignals registration: 15 min x 3 per day, some registration during and after exercise (to see response for physical activity)
air flow, respiration (bioimpedance) + RR, ECG + HR, SpO2, activity, skin temperature, cough intensity (IMU + sound)
 - Questionnaires: symphonal questionnaire (every day), general physical conditions, The UCLA Loneliness Scale, anxiety scale, System Usability Scale, PI-eHEALS
 - Pulmonary rehabilitation
- Build ML detectors for cough and sudden exacerbation of COVID - 19 symptom
- Guidelines for the management of a patient with a diagnosis of COVID-19 treated at home
- Validation of the telemedical solution in COVID-19 home care



Telemedicine study of COVID-19 patients - design

- Building dataset
 - Mild Covid-19 (400); cohorts: acute-COVID, long-COVID, hospitalised-COVID
 - With recent recognition
 - Pulmonary and cardiac patients (200): non-COVID
- Dataset analysis, building ML models, development of guidelines
- Validation
 - Mild COVID-19 with treatment: standard + telemedical care; 100 patients
 - Mild COVID-19 with standard care; 100 patients
 - Outcomes: hospitalisation, comfort/sense of security



Telemedicine study ...

-

Rozpoznanie

Oświadczenie o pacjencie:

- Wiek <18
- Nie potrafi wyrazić lub nie wyraża świadomej zgody
- Niemożność wykonania minimalnego zestawu pomiarów klinicznych (np. ze zranioną skórą w miejscach, do których przyłożony jest wyrób oraz osoby z zapadniętą klatką piersiową, otyłość przekraczająca możliwość założenia opaski)
- Osoby ubezwłasnowolnione
- Żołnierz służby zasadniczej
- Osoba pozbawiona wolności
- Kobieta w ciąży
- Osoba z zaburzeniami funkcji poznawczych uniemożliwiającymi samodzielne funkcjonowanie (chyba, że pacjent pozostaje pod stałą opieką opiekuna)
- Rozrusznik serca

Potwierdzam, że nie występuje żadna okoliczność z powyższych

Zakończ

Potwierdzam

Numer karty pacjenta:

Data i czas badania:

📅 21-11-2021 20:49

Badanie

Pacjent skierowany z

Masa ciała

Wzrost

Ciepłota ciała (°C)

Ciepłota ciała (°C) po wysiłku

Temp (°C)

SpO2 (%)

Częstotliwość oddechów (/min)

HR (/min)

Skala mMRC (duszności)

Choroby współistniejące aktualnie

Przyjmowane leki

Przepisane leki w trakcie kwalifikacji

Czy pacjent ma wykonywać pomiary po obciążeniu wysiłkowym?

Pacjentowi wydany został rejestrator Aidmed One



Telemedicine study ...



Action plan

- 22-07-2021 18:00
Kwestionariusz
 - EQ_5D_5L[Show questionnaire >](#)
- 23-07-2021 10:00
Rejestracja sygnałów
- 23-07-2021 14:00
Rejestracja sygnałów
- 23-07-2021 18:00
Rejestracja sygnałów
- 23-07-2021 18:00
Kwestionariusz
 - Kwestionariusz symptomatyczny
 - Ankieta inicjująca
 - Poczucie samotności[Show questionnaire >](#)
- 24-07-2021 10:00
Rejestracja sygnałów
- 24-07-2021 14:00
Rejestracja sygnałów
- 24-07-2021 18:00
Rejestracja sygnałów
- 24-07-2021 18:00
Kwestionariusz
 - Kwestionariusz symptomatyczny



Telemedicine study ...

- Symptomatic questionnaire: headache, dry cough, wet cough, breathlessness
- The UCLA Loneliness Scale
- UX/System Usability
- PI-eHEALS
- Skala Makowska/CBOS lęku przed COVID-19
- ...



AIDMED system

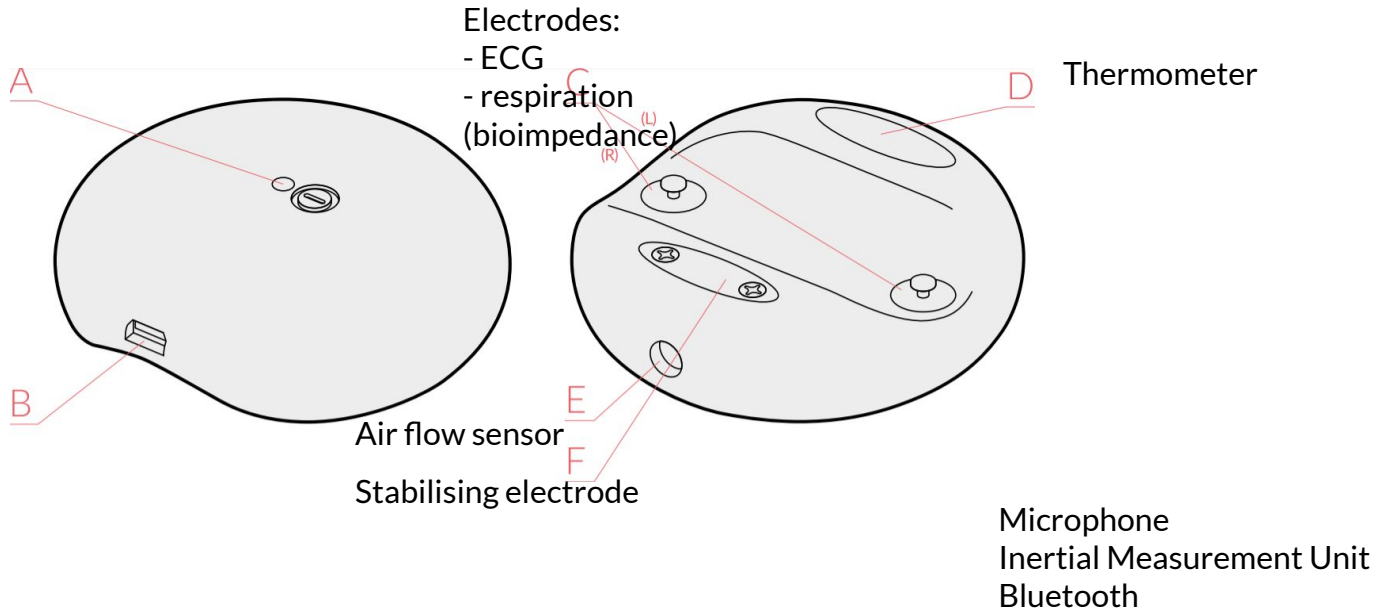
- AIDMED ONE - recorder
- AIDMED HEALTH - mobile application
- AIDMED CLOUD - web telemedical platform

AIDMED ONE - recorder

Multifunctional button:

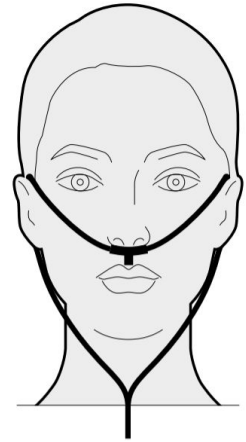
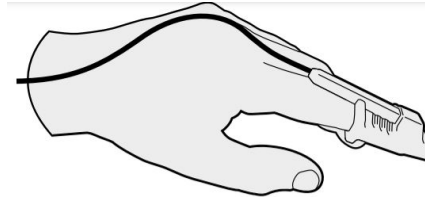
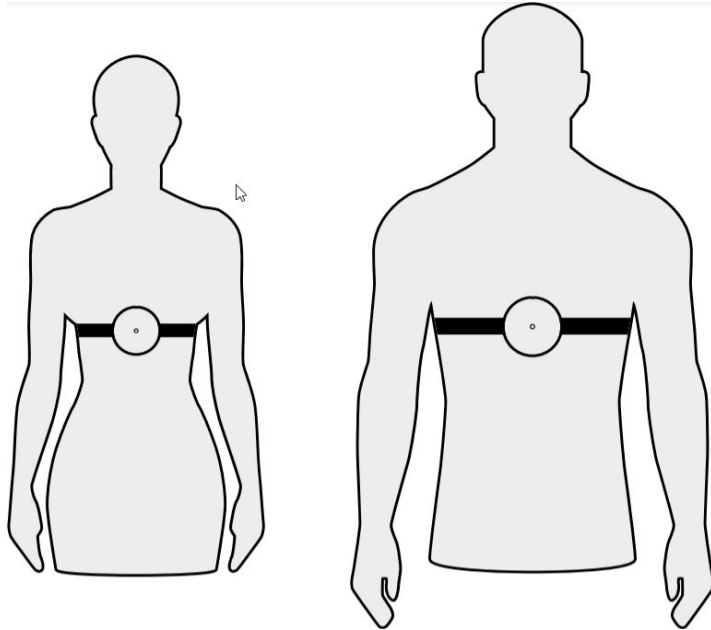
- start
- stop
- reset
- user event

USB charger port



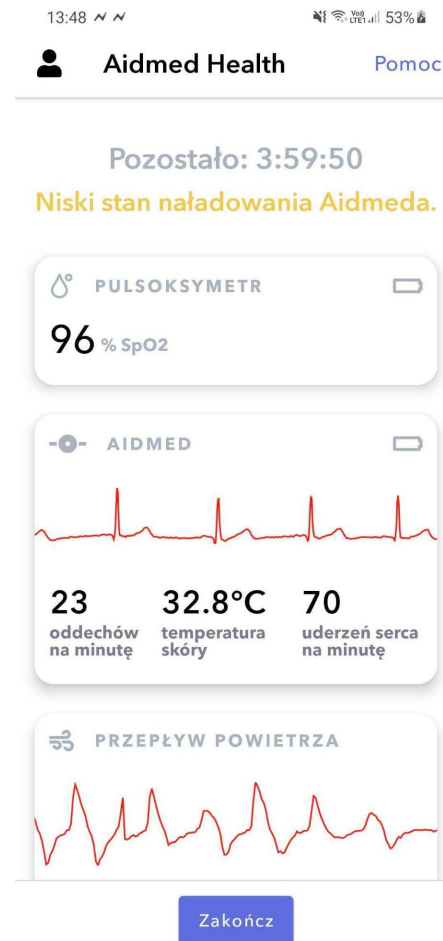


AIDMED ONE - recorder



AIDMED HEALTH - mobile application

- Preview signals
- List of tasks
- Questionnaire



AIDMED HEALTH - mobile application

- Preview signals
- List of tasks
- Questionnaire

13:14

63%



Oczekujące zadania

⚙️ Rejestracja sygnałów 13:00 - 15:00
30 kwietnia

⚙️ Kwestionariusz 13:00 - 15:00
30 kwietnia

Zaplanowane:

⚙️ Rejestracja sygnałów 14:00 - 16:00
30 kwietnia

⚙️ Rejestracja sygnałów z obciążeniem 14:00 - 16:00
30 kwietnia

⚙️ Pomiar całonocny 21:00 - 02:00
30 kwietnia

⚙️ Rejestracja sygnałów 13:00 - 15:00
1 maja

⚙️ Kwestionariusz 13:00 - 15:00
1 maja

⚙️ Rejestracja sygnałów 14:00 - 16:00
1 maja

⚙️ Rejestracja sygnałów z obciążeniem 14:00 - 16:00
1 maja



AIDMED HEALTH - mobile application

- Preview signals
- List of tasks
- Questionnaire

13:14

63%

← **Kwestionariusz**

Wyślij

Skala mierząca poziom samotności
(The UCLA Loneliness Scale).

Jak często brakowało Panu/i towarzystwa
innych osób?

czasami

Jak często czuł/a się Pan/i odrzucony/a?

rzadko kiedy

Jak często czuł/a się Pan/i odizolowany/a od
innych?

AIDMED CLOUD - web telemedical platform

Imię i nazwisko	Ostatnia Transmisja	24h Aktywność	SpO2	Respiracja	Puls	Kaszel	Temperatura	Długość badania
▼ LG K50S	17-05-2021	●	b/z	18	96/min	0.00/min	31.2°C	2 min.
▼ Xiaomi Redmi 9	28-04-2021	●	b/z	b/z	b/z	b/z	b/z	0 min.
▲ CUBOT	12-05-2021	●	b/z	0	117/min	0.00/min	b/z	1118 min.
🕒 29-04-2021 16:48			b/z	0	117	0	b/z	1118 min.
🕒 28-04-2021 18:26			b/z	0	117	0	b/z	907 min.
🕒 27-04-2021 19:29			b/z	0	117	0	b/z	997 min.
🕒 19-04-2021 08:19			b/z	b/z	b/z	b/z	b/z	3 min.
🕒 18-04-2021 18:09			b/z	0	117	b/z	b/z	784 min.
🕒 16-04-2021 18:30			b/z	0	117	0	b/z	1846 min.

AIDMED CLOUD - web telemedical platform






AIDMED CLOUD - web telemedical platform

examination	start	end	0:Tomasz Kowalski	1:lukasz.czekaj@aidlab.com
patient_5	Oct 29, 2021 9:08 PM	Oct 30, 2021 9:08 AM	FOR_DESCRIPTION : 4	FOR_DESCRIPTION : 3
patient_4	Oct 29, 2021 9:09 PM	Oct 30, 2021 9:09 AM	FOR_DESCRIPTION : 4	FOR_DESCRIPTION : 2

Showing 1-2 of 2

1 of 1



examination	start	end	annotator	status	events	examinationId
patient_5	Oct 29, 2021 9:08 PM	Oct 30, 2021 9:08 AM	Tomasz Kowalski	FOR_DESCRIPTION	4	link
patient_5	Oct 29, 2021 9:08 PM	Oct 30, 2021 9:08 AM	lukasz.czekaj@aidlab.com	FOR_DESCRIPTION	3	link
patient_4	Oct 29, 2021 9:09 PM	Oct 30, 2021 9:09 AM	Tomasz Kowalski	FOR_DESCRIPTION	4	link
patient_4	Oct 29, 2021 9:09 PM	Oct 30, 2021 9:09 AM	lukasz.czekaj@aidlab.com	FOR_DESCRIPTION	2	link



AIDMED CLOUD - AI

- Signal quality control
- Risk Index for qualification and during observation
- Automated detection of significant events:
 - Abnormal breathing/respiration
 - Cough detection and classification
 - Arrhythmia (COVID specific arrhythmia)
- Activity monitoring
- Exercise tests

Od

16-08-2021 00:00

Do

20-08-2021 23:59

16-08-2021 08:00-08:01

Wysokość



Dopasuj wartości

1m

Rytm serca



21-07-2021 04:09-04:24

Height

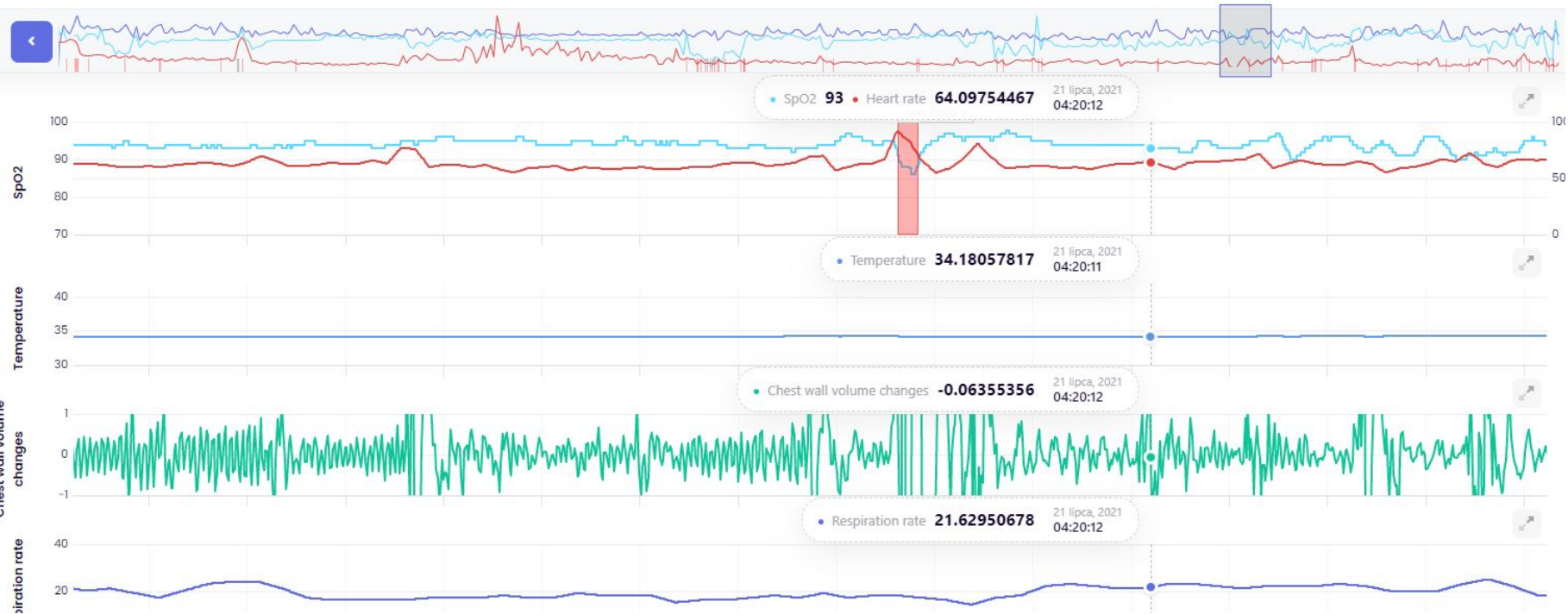


COVID

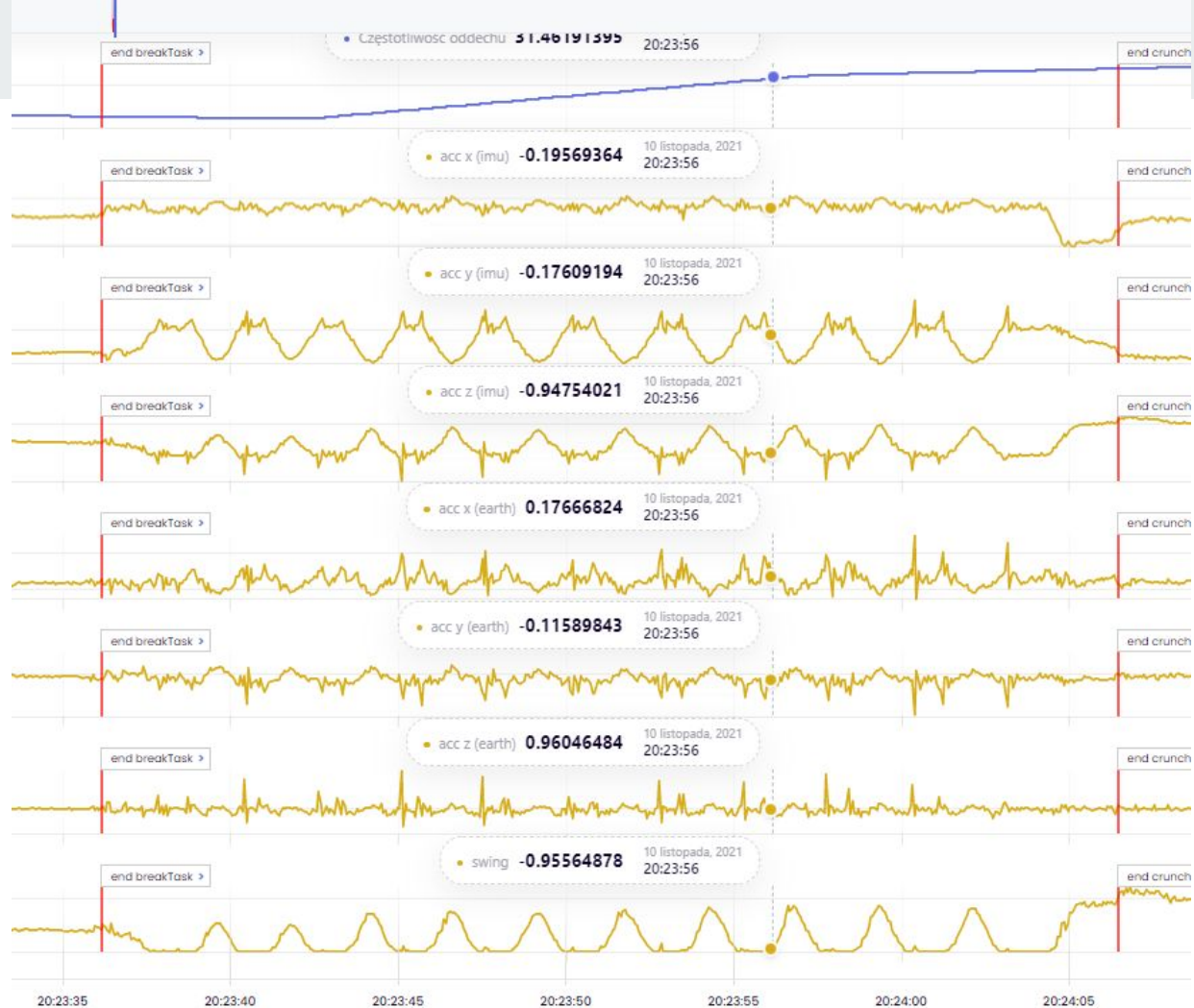
Fit All Scales

15r

Respiration rate SpO2 Heart rate



Activity



Apnea



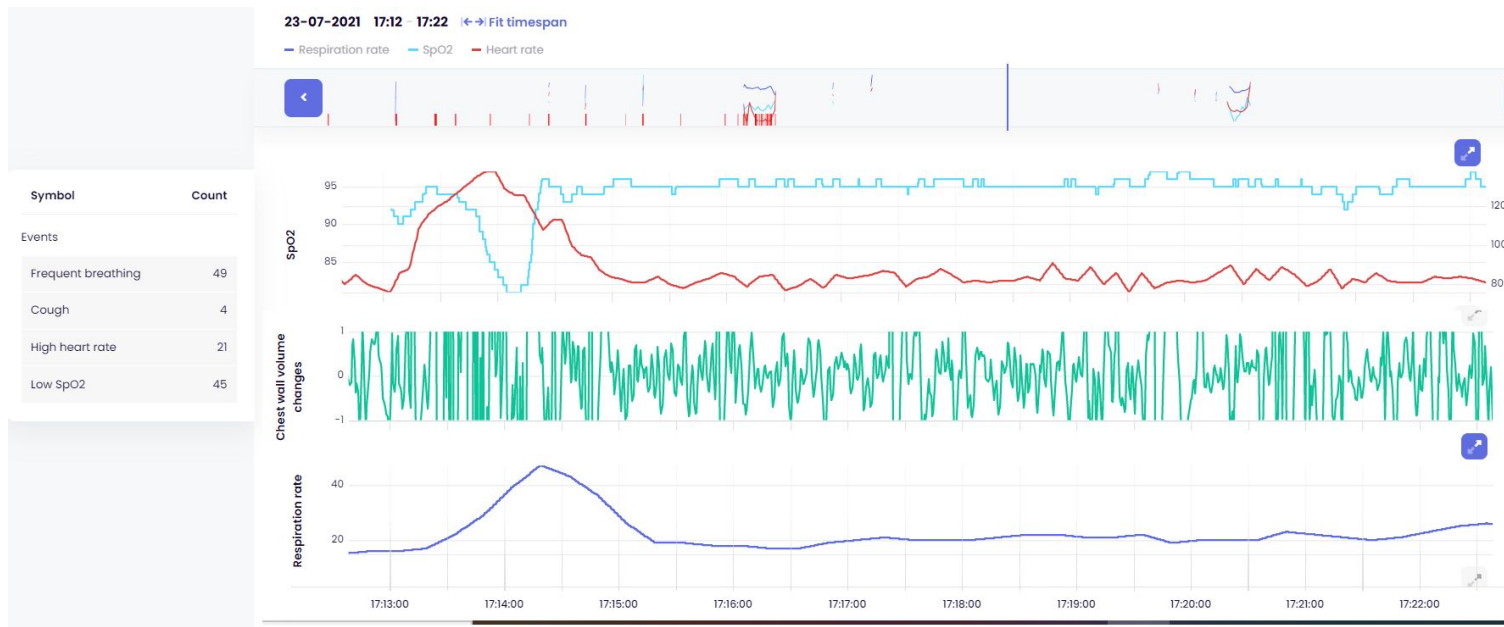
Case study 1. F 39, 9 days after J&J - atrial fibrillation

Adverse Event detection after vaccination?



Case study 3. M 39, strong autonomic reaction to exertion

Sit-to-Stand test





Applications

- Telemedicine / home observation
 - Fresh covid
 - Long covid
 - At risk (pumonatory/cardiological) patients
- Research
 - Adverse events and side effects observation