

# HOW TO MANAGE PATIENT WITH CHRONIC CONDITIONS REMOTELY?

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COCIR - Digitalisation of healthcare: The new normal  
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# e-Health in Heart Failure

1. **Telemedicine** und telecare
2. Clinical information systems
3. Integrated regional and national information networks and associated e-referrals and e-prescribing
4. Disease registries and other non-clinical systems used for education, public health, patient/disease related behavior and healthcare management
5. **Mobile health (including Apps)**
6. Personalised health
7. Big Data



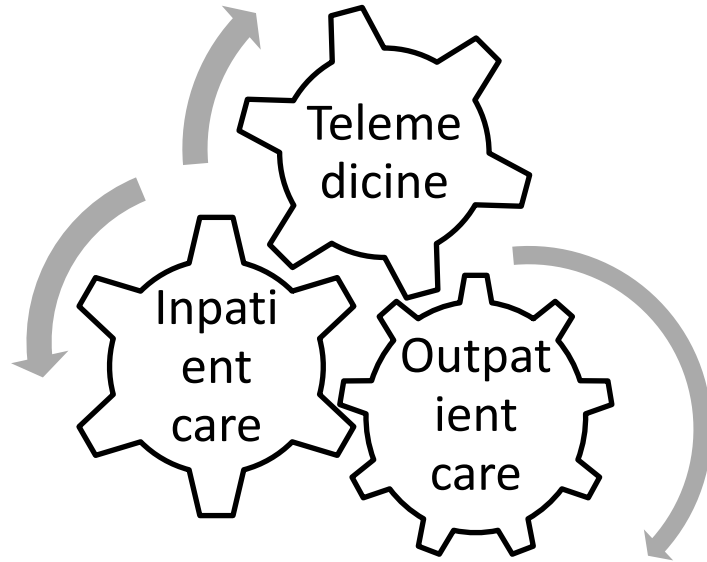
European Heart Journal  
doi:10.1093/eurheartj/ehv416

**EhJ POSITION STATEMENT**

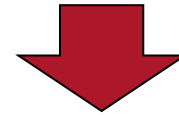
## **e-Health: a position statement of the European Society of Cardiology**

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# Telemedicine as Part of Healthcare System

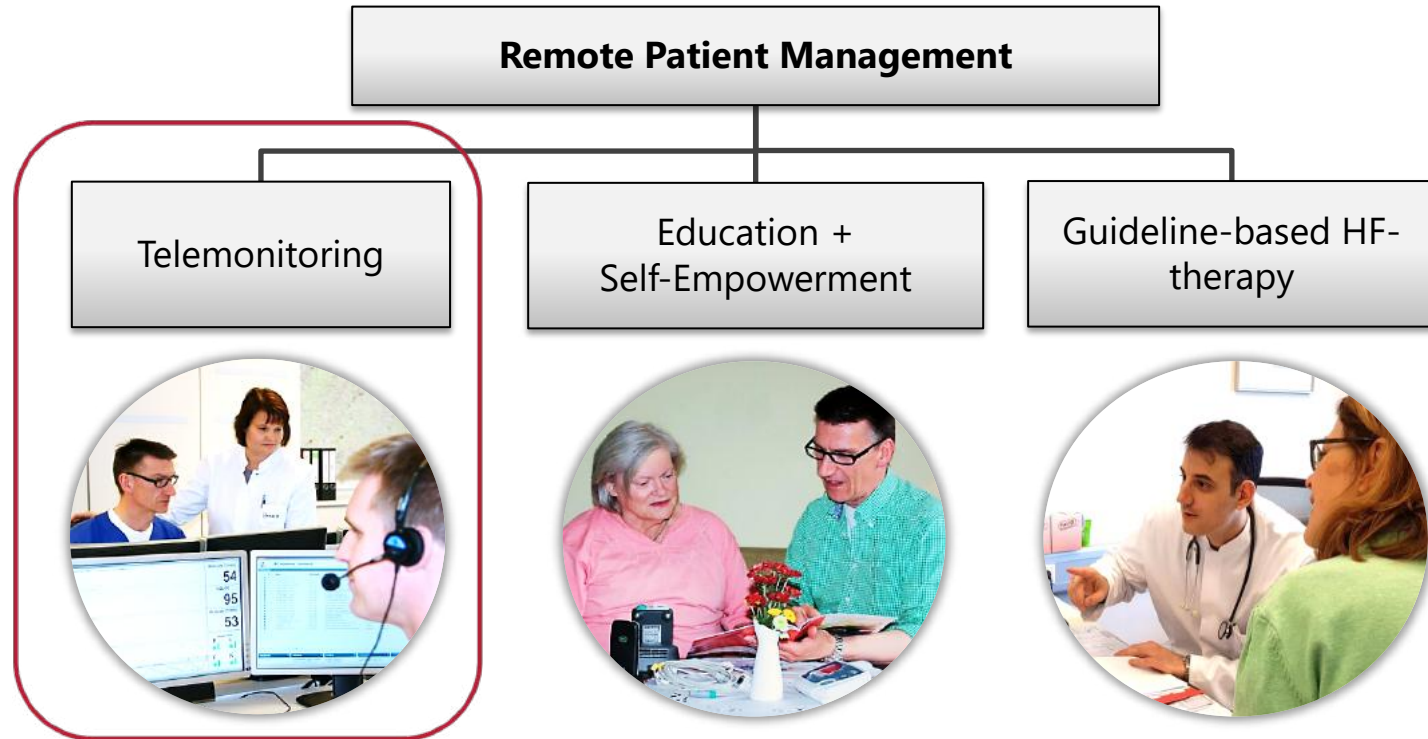


- Videoconsultations
- Remote Patient Management for chronic diseases
- Doc2doc consultations/ Telecouncil (e.g. virtual hospital)



**Interlocking of the healthcare sectors**

# Concept of Remote Patient Management (RPM)



# Telemonitoring as an Element of RPM

Non-invasive measurement  
of vital parameter



© Charité

Monitoring using  
diagnostic implantable  
device



© Abbott

Monitoring using  
active implantable  
devices



© Biotronik

Smartphones



© Withings

# RCTs for Telemedicine in HF

## RPM with noninvasive Telemedicine

<b>TIM-HF2</b>	<i>(Lancet 2018, Lancet Digital health 2020)</i>	<b>1,538 patients, Germany</b>
TIM-HF	<i>(Circulation 2011)</i>	710 patients, Germany
BEAT-HF	<i>(JAMA 2016)</i>	1,437 patients, USA
TELEREH-HF	<i>(JAMA Cardiology 2019)</i>	850 patients, Poland
OBSICAT	<i>(EJHF 2020)</i>	937 patients, France

## RPM with invasive Telemedicine (Implants)

REM-HF	<i>(Eur Heart J 2017)</i>	1,650 patients, United Kingdom
<b>IN-TIME</b>	<b><i>(Lancet 2014)</i></b>	<b>716 patients, Germany</b>
<b>CHAMPION-Trial</b>	<b><i>(Lancet 2011, 2016)</i></b>	<b>550 patients, USA</b>
OptiLINK-HF	<i>(Eur Heart J 2016)</i>	1,002 patients, Germany

# Summary of positive RCTs

In the recently hospitalized patients only (1/6 of the total HF-population), who were managed by a telemedical centre:

## 1. Reduction of all-cause mortality („IN-TIME“, „TIM-HF2“)

*Hindricks G et al., Lancet. 2014 Aug 16;384(9943):583-90.*

*Koehler F et al. Lancet. 2018 Sep 22;392(10152):1047-57.*

## 2. Reduction of HF-admission rate due to HF („Champion Trial“, „TIM-HF2“)

*Abraham WT et al. Lancet. 2011 Feb 19;377(9766):658-66.*

*Abraham WT et al. Lancet. 2016 Jan 30;387(10017):453-61*

*Koehler F et al. Lancet. 2018 Sep 22;392(10152):1047-57.*

## 3. Improvement of quality of life („Champion Trial“, „TIM-HF“)

*Abraham WT et al. Lancet. 2011 Feb 19;377(9766):658-66.*

*Koehler F et al. Circulation 2011 May 3;123(17):1873-80.*

# TIM-HF2: Study Design

## European Journal of Heart Failure

Telemedical Interventional Management in Heart Failure II (TIM-HF2), a randomised, controlled trial investigating the impact of telemedicine on unplanned cardiovascular hospitalisations and mortality in heart failure patients: study design and description of the intervention

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**Study design:** multicentre RCT in Germany, 1,538 heart failure (HF) patients, hospitalised for HF maximally 12 months previously, with no major depression (PHQ-9<10) and with a LVEF  $\leq 45\%$  or if  $>45\%$ , diuretics mandatory; Follow-up: 12-months follow-up under intervention + 12 months real-world (extended follow-up)

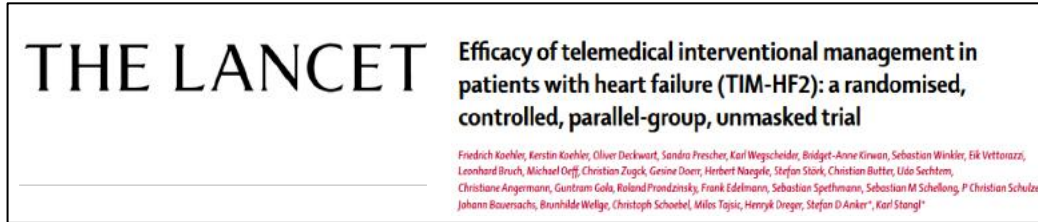
**Primary Endpoint:** % days lost due to unplanned CVhospital admissions and all-cause death

**Secondary Endpoints:** all-cause death, cardiovascular death, recurrent HF/CV-hospital admissions, health economics, biomarkers, quality of life

**Intervention:** Remote Patient Management (RPM) vs Usual Care (UC)



# TIM-HF2: Summary of Results



**Primary outcome** (% days lost due to unplanned CV hospital admissions & all-cause death)

- 20% reduction in favor of RPM (ratio 0.80, 95%, CI 0.65–1.00;  $p=0.046$ ).
- 17.8 days/year vs 24.2 days/year lost for RPM and UC, respectively

**All-cause death:**

- 30% reduction in favor of RPM (hazard ratio [HR] 0.70, 95%, CI 0.50–0.96;  $p=0.028$ ).

# Main Secondary Outcomes

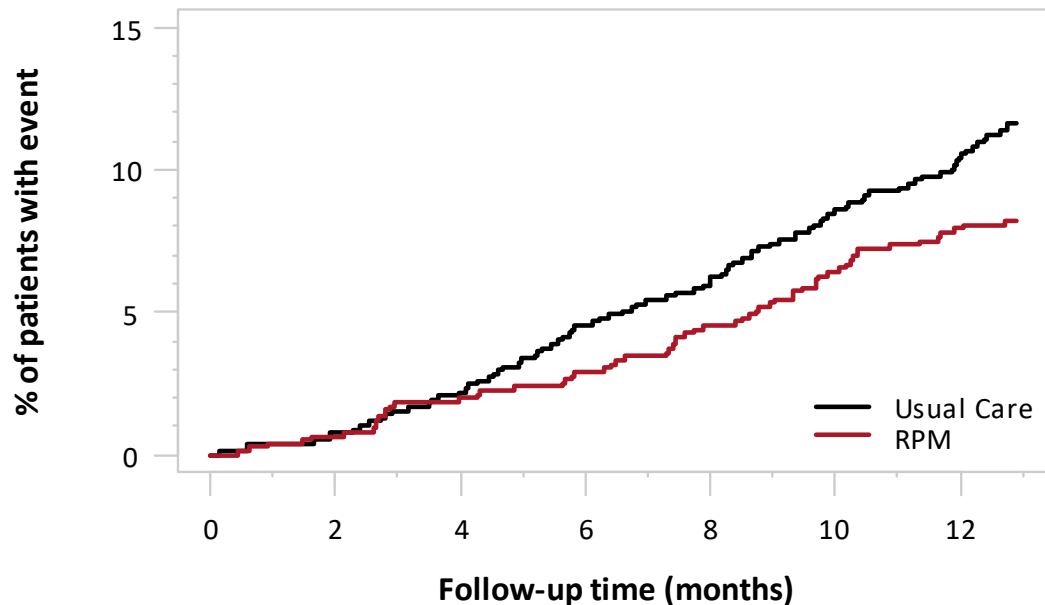
## All-cause mortality

RPM vs. UC

HR 0.70

95% CI 0.50, 0.96

P=0.028



### No. At Risk

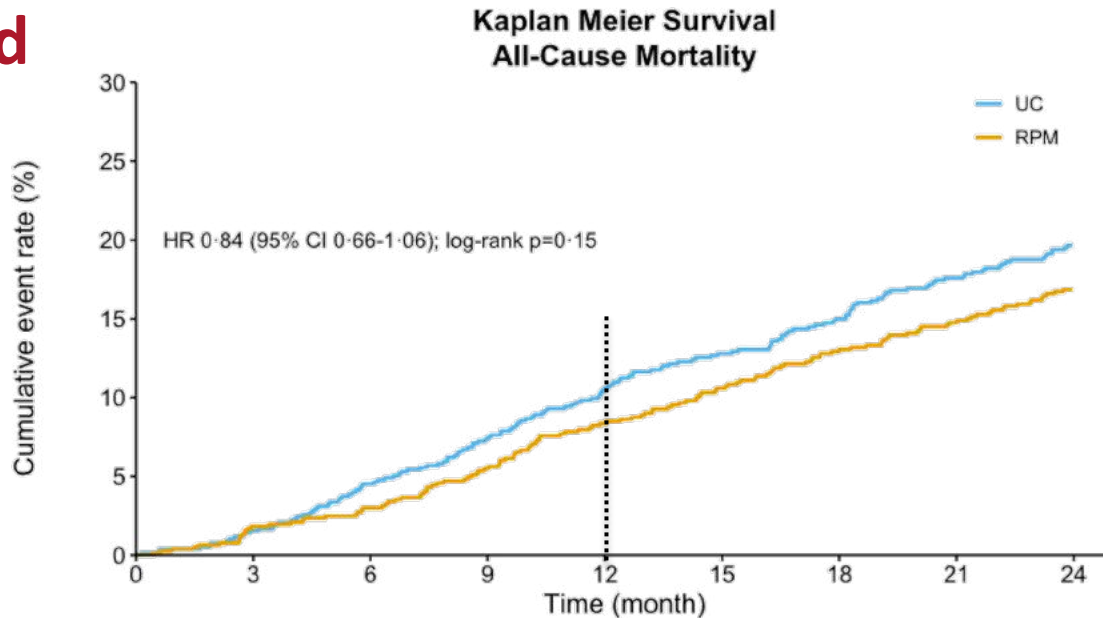
Usual Care	773	767	756	738	716	697	681
RPM	765	755	737	724	709	688	673

# Recurrent HF hospital admissions

	RPM (n=765, 739.6 patient years)			UC (n=773, 754.4 patient years)			Ratio RPM vs. UC (95% CI)	p
	No. of patients with HF hosp. (%)	No. of HF hosp.	Incidence (95% CI)	No. of patients with HF hosp. (%)	No. of HF hosp.	Incidence (95% CI)		
HF hospital admissions and all-cause death	164 (21)	280	0.441 (0.369–0.528)	223 (29)	405	0.653 (0.553–0.771)	<b>0.676</b> (0.529–0.862)	<b>0.0016</b>
HF hospital admissions and CV death	153 (20)	265	0.414 (0.345–0.498)	210 (27)	379	0.596 (0.502–0.707)	<b>0.696</b> (0.541–0.894)	<b>0.0047</b>

IRR=Incidence rate ratio; incidence = events/100 patient years of follow-up; CV=cardiovascular; HF=heart failure; hosp.=hospital admissions

# All-cause Death in TIM-HF2: Main Trial & extended Follow-up combined



Number at risk

UC	773	761	738	716	692	674	657	637	621
RPM	765	751	742	723	701	684	666	652	636

# ESC-Guidelines and Telemonitoring

## Remote Patient Monitoring (implanted devices) class II-B recommendation for

- Consideration of monitoring of pulmonary artery pressures with implantable haemodynamic monitoring system (CardioMems) in patients with previous hospitalization
- Consideration of multiparameter ICD-monitoring (IN-TIME approach) in HF-patients with LVEF  $\leq 35\%$

**Clinical practice update 2019:** “Home telemonitoring using an approach that is similar to the one used in TIM-HF2 may be considered for patients with HF in order to reduce the risk recurrent cardiovascular and HF hospitalizations and cardiovascular death”<sup>1</sup>

**New guidelines planned for 2021**

# Digital Strategy and open questions in HF 2020

- 1) Research on new sensor technology
- 2) Upscaling of telemedical settings for usage in the real world (inclusion of artificial intelligence technologies)
- 3) Duration of RPM: Evidence for intervention of RPM for 12 Months - no evidence for lifelong RPM
- 4) (Profiling of profiting patients)
- 5) (No Evidence for RPM in different health care systems)

# New Sensor Technologies to detect Pulmonary Congestion

## Implants:

- Pulmonary artery pressure sensor – Endotronix, Inc.
- Atrial pressure sensor – V-LAP™

## m-Health:

- Voice recognition systems

# Digital health care solution for proactive heart failure management with the Cordella Heart Failure System: results of the SIRONA first-in-human study

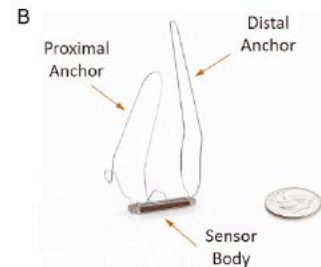
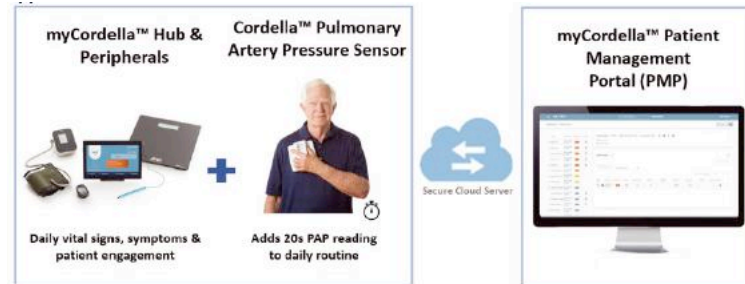
**Study type/patient characteristics:** multicentre, open-label, feasibility study, n=15 HF patients in class NYHA III, follow-up: 90 days, NCT03375710

**Primary efficacy Endpoint:** Mean pulmonary artery pressure

**Intervention:** Implantation of Cordella Pulmonary Artery Pressure (PAP) Sensor

## Results:

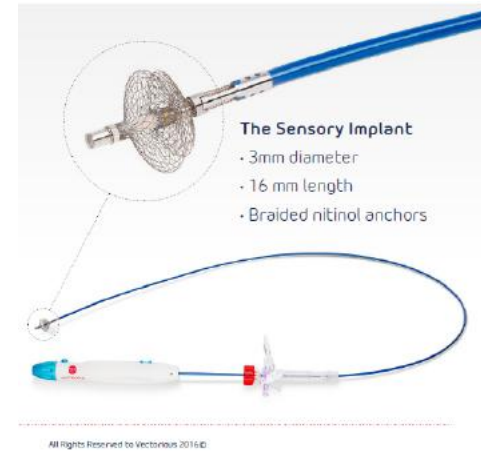
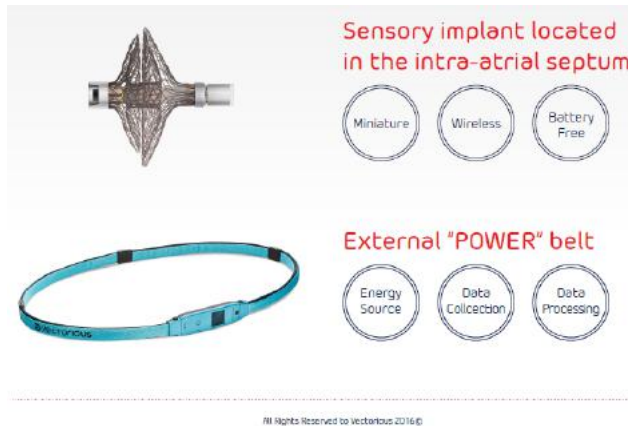
- No device-related complications (invasive treatment, device explant or death)
- Patient adherence to daily measurement, transmission of vital signs and PAP sensor readings: 99%
- Difference of PAP of 2.7mmHg (Cordella:  $22.5 \pm 11.8$  mmHg, Swan-Ganz catheter:  $25.2 \pm 8.5$  mmHg)





# LA-Pressure Sensor – V-LAP™

- Left ventricular end diastolic pressure is the best pressure to use when considering left ventricular function<sup>1</sup>.
- Left pressure measurement is second best to estimate left sided filling pressures and provides atrial rhythm analysis indirectly



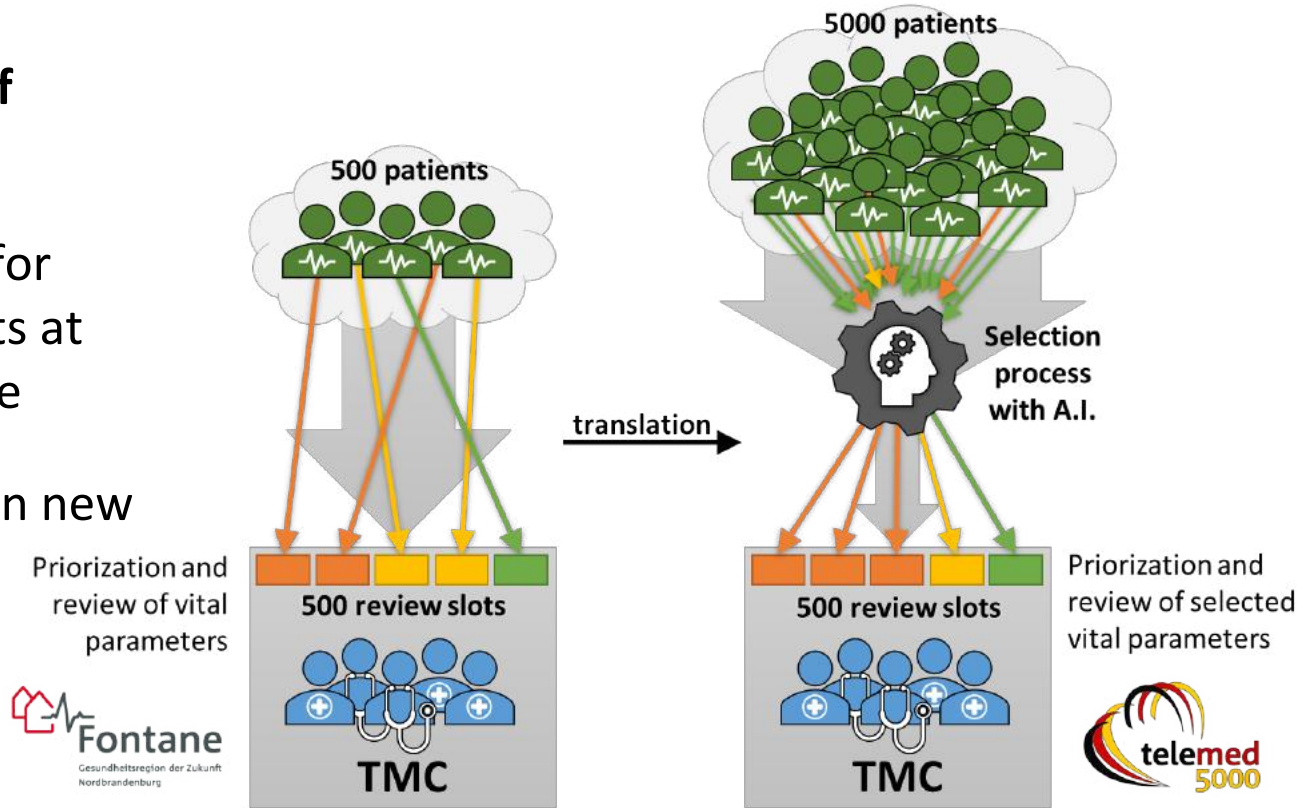


# Artificial Intelligence and Telemedical Centre

Scaling up the number of patients per TMC:

a) Artificial Intelligence for prioritization of patients at the telemedical centre

b) Artificial Intelligence in new devices



# Remote Patient Management for COVID-19

- Proof of benefits for Heart Failure Patients regarding mortality and morbidity
- Also possible for COVID-19 patients at home, e.g. daily or daily measurement of oxygen saturation to detect deterioration and long-term follow-up
- RPM for Patients with Aortic Stenosis

# Telemed5000- COVID-19



Telemedical longterm follow-up of recently hospitalised COVID-19 patients

**Study design:** single arm, prospective, multicentric, open, observational

**Planned study start:** Q4/2020

**Follow-Up:** 12 month for 100 patients

- Daily measurement of weight, blood pressure, SpO2, self-assessment and ECG
- Weekly: voice recording
- Monthly: 6-Minutes-Walk-Test



Supported by:



on the basis of a decision  
by the German Bundestag

# Conclusion

1. Remote Patient Management (RPM) is a holistic HF care intervention „add-on“ to guideline-based therapy of GPs, HF-nurses and specialists
2. Telemedicine in HF-patients could show the most robust evidence for a clinical benefit within the whole field of e-health in cardiology
3. Current proof of benefits is only for HF-patients in functional class NYHA II/III after hospitalization due to hydroptic decompensation
4. Development of telemedicine technologies for HF-Patients includes the sensor technologies and telemedical centers (artificial intelligence).
5. Remote patient management with non-invasive devices has high potential for longterm follow up of COVID-19 patient, but is not reimbursed yet