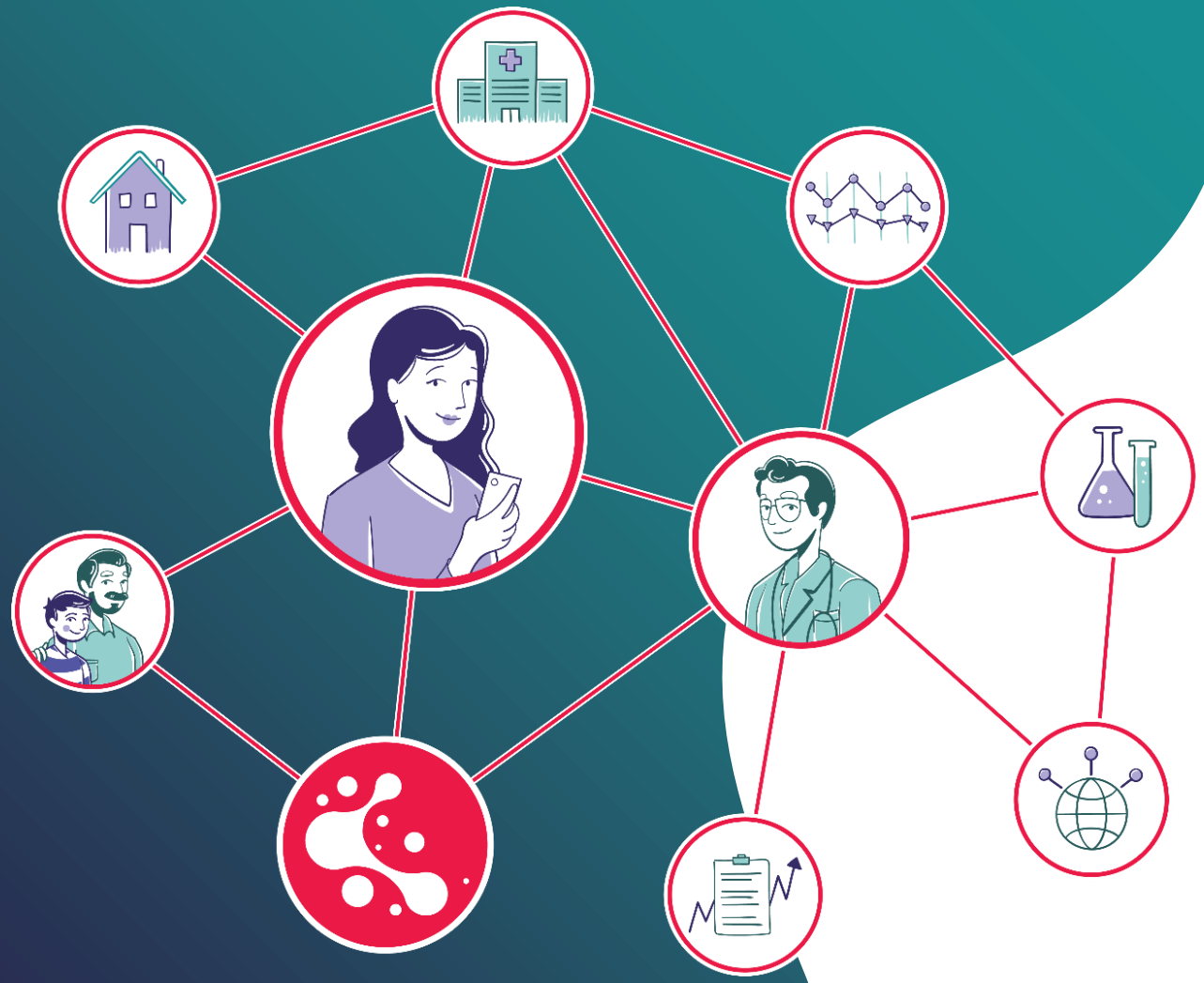

https://medidux.com/en/

FMH SAQM ASQM

CAS
Qualität im Gesundheitswesen für die patienten-nahe Arbeitspraxis
interprofessionell und sektorenübergreifend

Berner Fachhochschule Gesundheit

Einsatz der medidux-App in der Früherkennung von Symptomen und Therapienebenwirkungen bei ambulanten Krebspatienten – Stand heute

Prof. Dr. med. Andreas Trojan
CMO mobile Health AG

24.5.2024, Uni Bern, Schanzeneckstr. 1, Hörsaal S 003, EG

Digital Solutions

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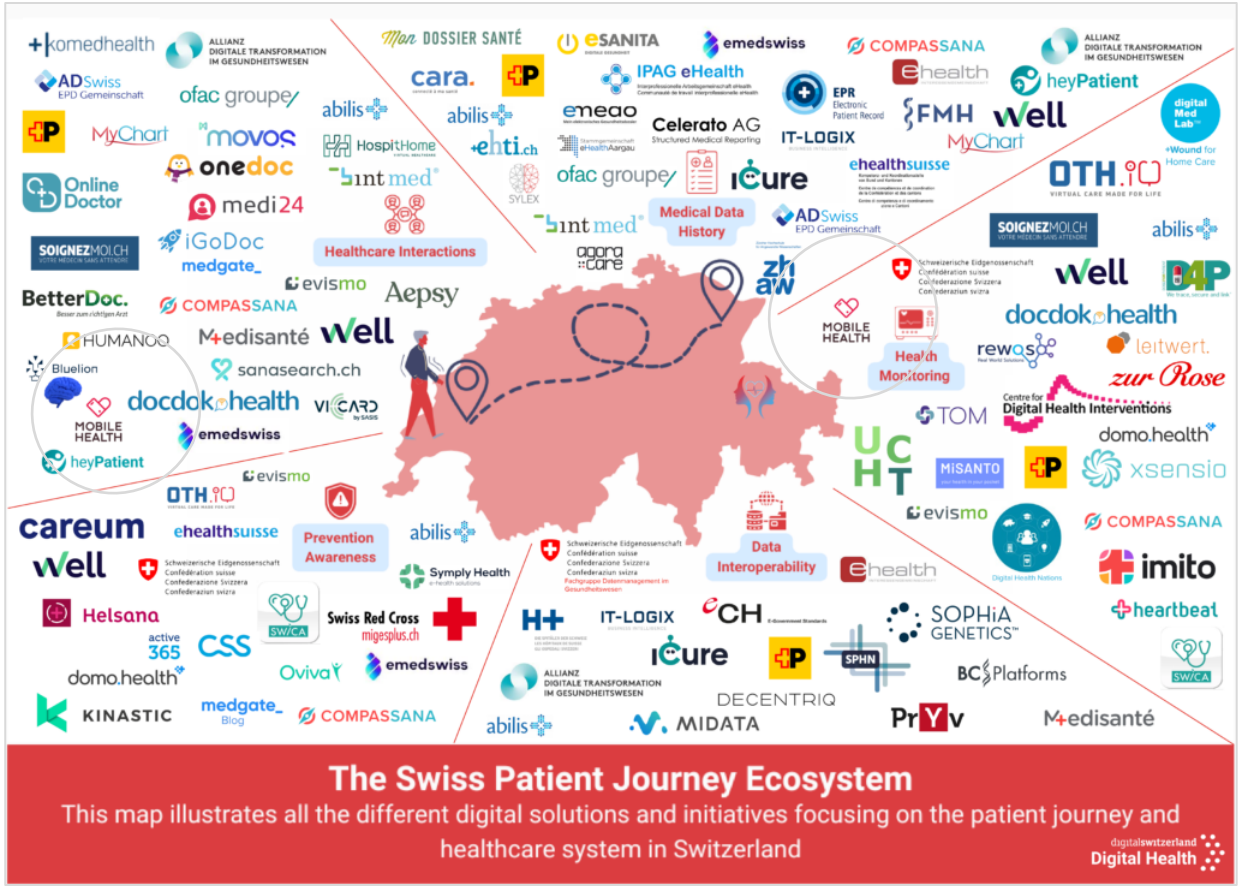
INNOVATION QUALITÉ

- Aktivität und Wohlbefinden von Brustkrebspatientinnen stabilisieren
- Kommunikation zwischen Patient und Arzt und die Identifikation von relevanten Symptomen anregen



J Med Internet Res. 2016 Sep 6;18(9):e238

https://www.fmh.ch/fr/themes/qualite-asqm/innovation-qualite.cfm#i150904

Patient Journey Companion

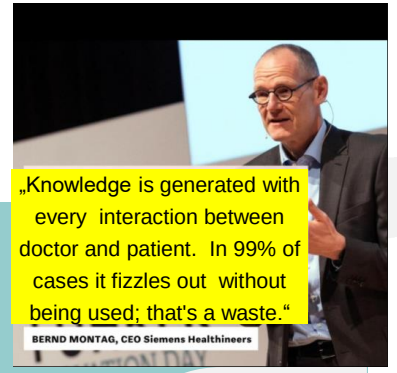
Qualität im Gesundheitswesen für die patienten-nahe Arbeitspraxis

Problem: Patients forget which and when exactly symptoms arose, and doctors spend substantial time to understand patients' condition with inefficient communication → 90% undocumented knowledge

Doctor provides **Patient APP** for collaborative reporting

between Visits
- Patient dynamically tracks symptoms,wellbeing, cognition, medication & vitals

App intelligence
- provides real-time recommendations
- tips and alerts



Diagnosis

Start of Treatment

Doctor Visit

Follow-Up Visit

Remission or Change of Therapy

Progression or Palliation

Symptom Review

1st doctor visit
information on
- diagnosis
- treatment
- side effects

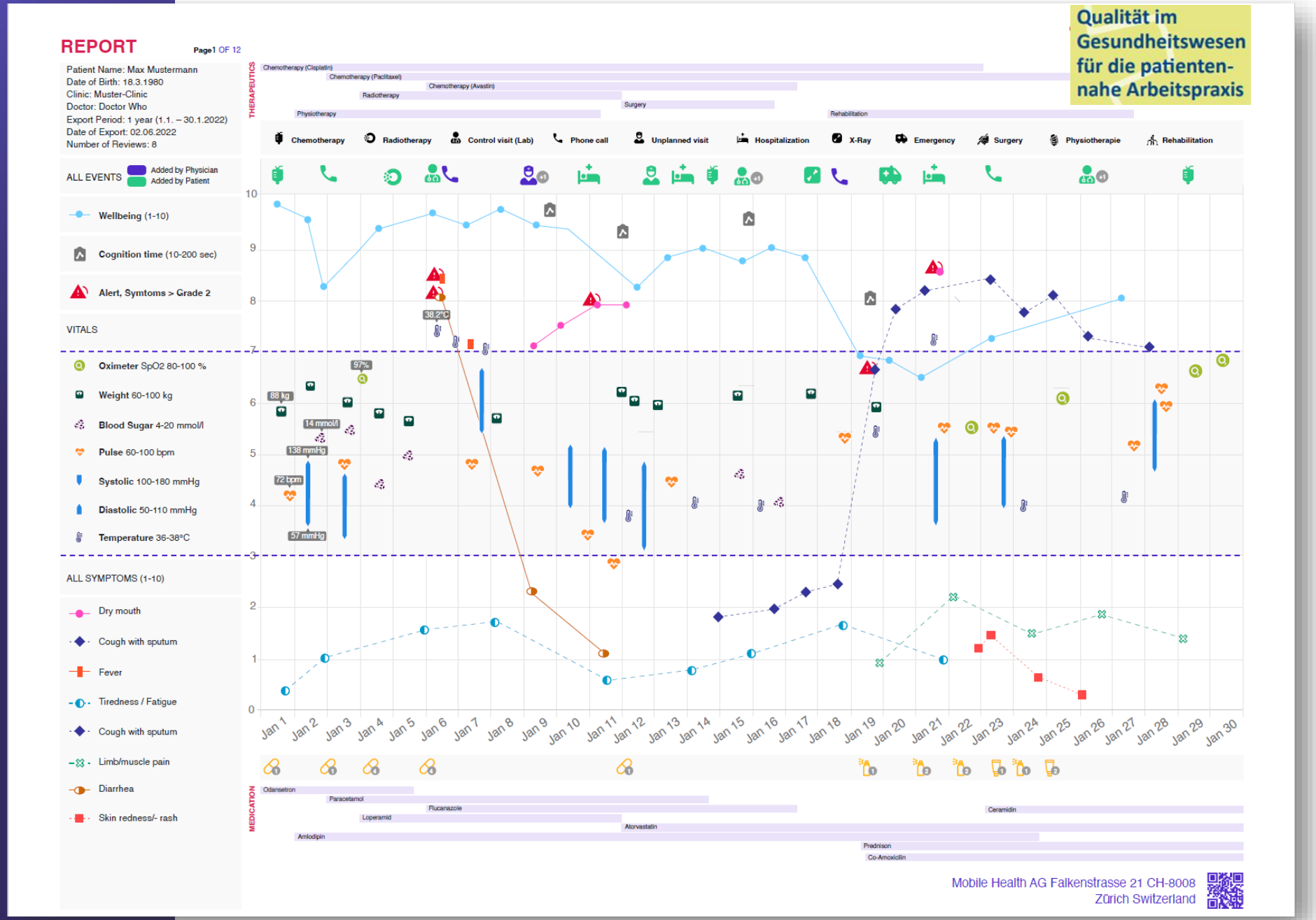
Personalized care
- dosage adjustment
- unplanned visits
- targeted drugs

Self Empowerment.
- Patient reflects on trends and recommendations

Outpatient Data Report

⬇

90% Clinical Information



Benefit for Patients

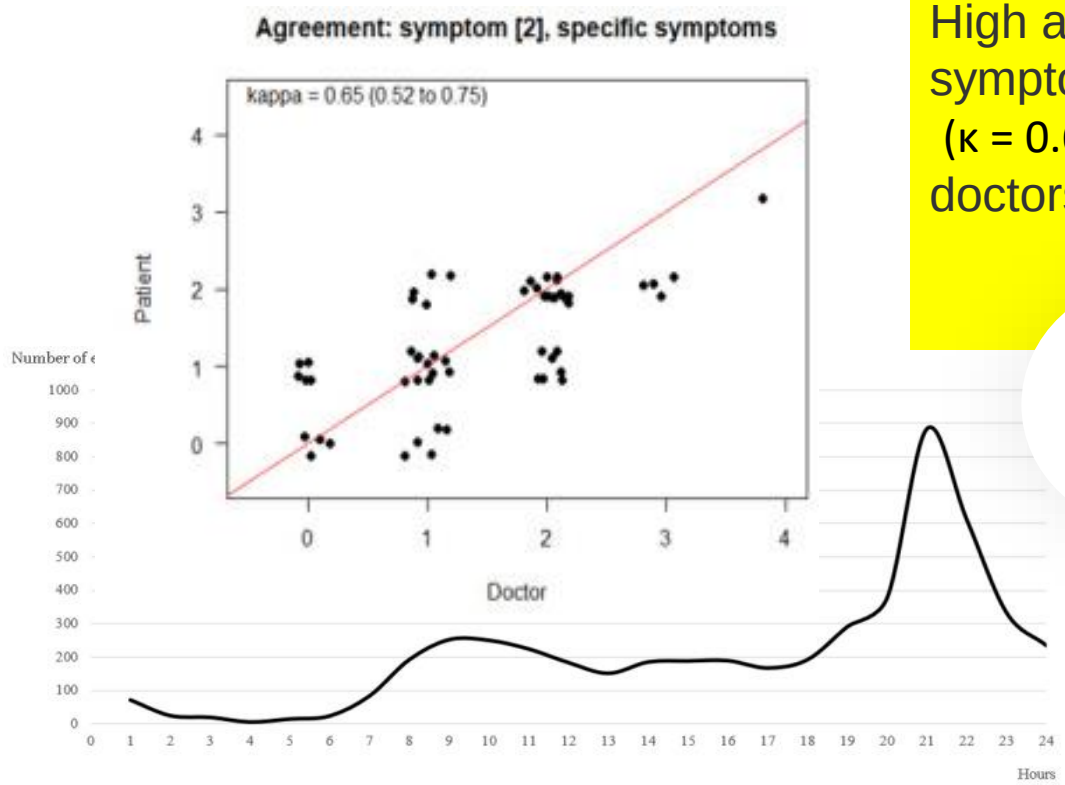
MOBILE HEALTH

Medidux App Utility

	Question	Mean
Q1	I find the app helpful.	73
Q2	The app is easy to use.	90
Q3	The App helps me deal with the symptoms of my illness.	67
Q4	The app has a positive effect on outpatient visits	69
Q5	My records were taken into account by the physician during consultations.	78
Q6	My symptoms were taken seriously by the physician	91
Q7	I believe that my personal data are treated confidentially and used securely.	94
Q8	I would recommend the app to other patients.	82
Q9	The tips from the "Swiss Cancer League" were helpful.	68

Trojan A, et al.; JMIRCancer 2021

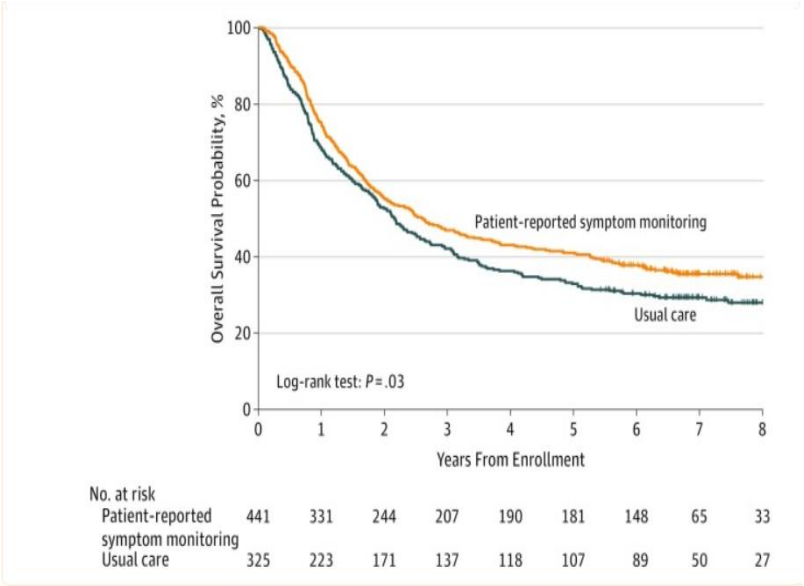
Medidux App: Reliablity of Symptom Reporting from Patients



High agreement on symptom severity (κ = 0.65) between doctors & patients

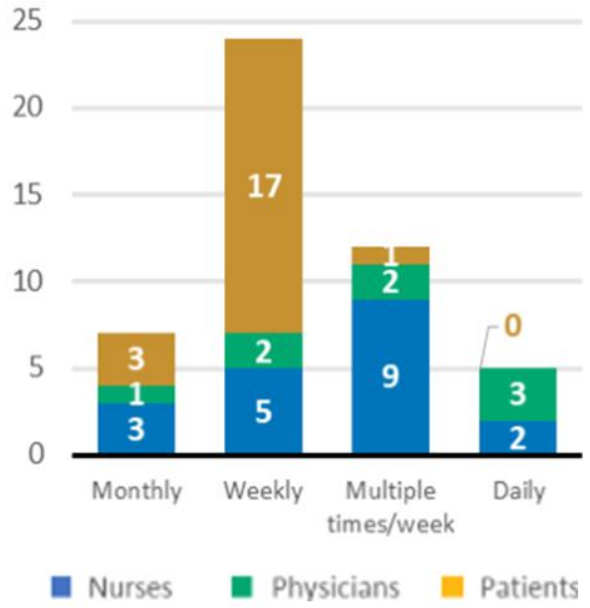
Trojan A, et al.; JMIR 2021;

Benefit for Doctors



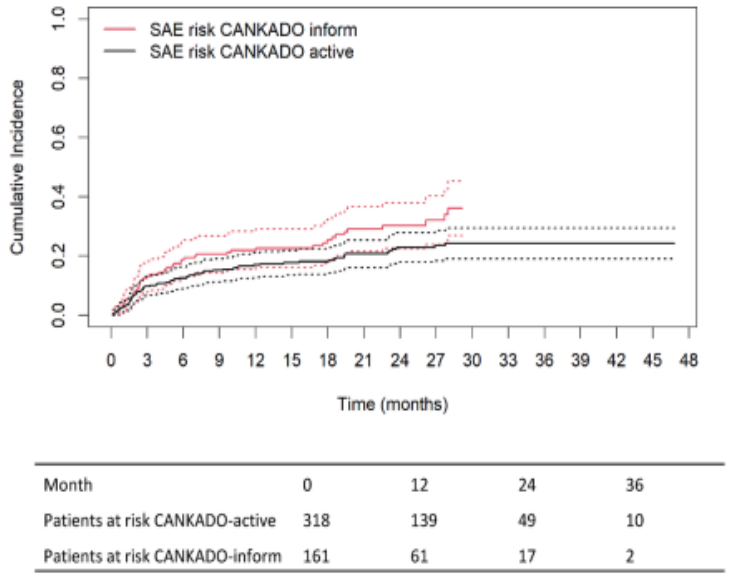
OS among Patients with metastatic Cancer assigned to ePRO Symptom Monitoring during Routine Chemotherapy vs Usual Care

Basch E, et al.; JAMA; 2017



More efficient, focused discussions between pts and HCPs, time saving 5-10 min/ cons, less hospitalization

Schmalz O, Popescu RA; JMIR 2020



Month	0	12	24	36
Patients at risk CANKADO-active	318	139	49	10
Patients at risk CANKADO-inform	161	61	17	2

Favorable impact of therapy management by an interactive eHealth system, delayed SAEs

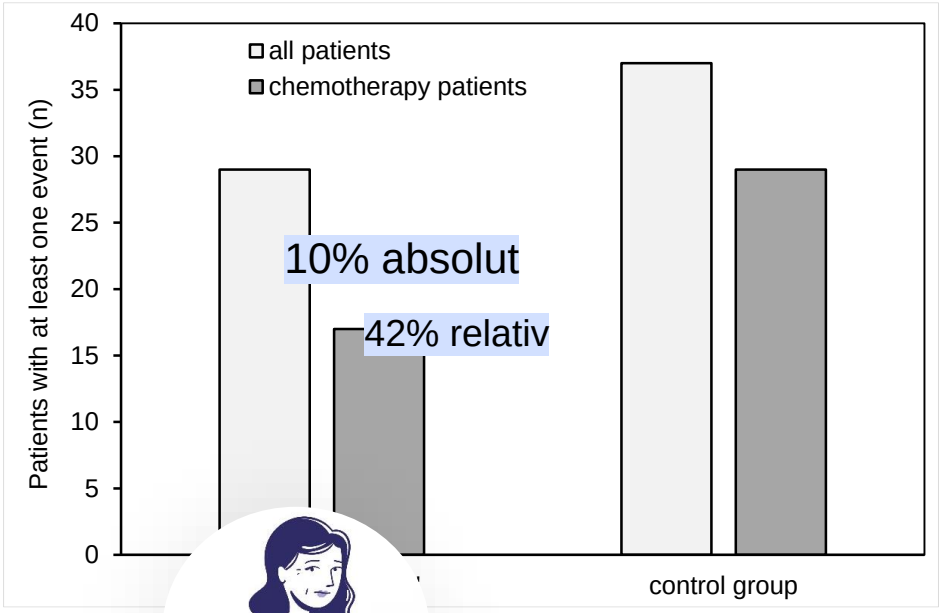
Habeck N, et al.; AnnOncol 2023

Medidux reduces Hospitalisations

Table 2 Occurrence of at least one event in patients

Events	«medidux-cohort	Historical cohort
Number of patients (n)	178	178
Patients with ≥ 1 event, n (%)	29 (16,29)	37 (20,78)
Total number of events (n)	36	38
Unplanned (emergency) consultations	23	29
Hospitalizations ≤ 2 days (n)	5	4
Hospitalizations > 2 days (n)	8	5
Subgroups tumor stages		
AJCC-stage I (n event/ n total)	1/22	0/25
AJCC- stage II (n event/ n total)	9/68	9/51
AJCC- stage III (n event/ n total)	4/37	9/16
AJCC- stage IV (n event/ n total)	15/51	19/41
Subgroups therapies		
Chemotherapy (n event/ n total)	17/139	29/139
Non-Chemotherapy (n event/ n total)	12/39	8/39
Subgroups cancer entities		
Breast cancer (n)	22	23
Lung cancer (n)	2	4
Prostate cancer (n)	1	2
Colorectal cancer (n)	1	6
Haematological malignancies (n)	3	2

Medidux App: Improves Safety



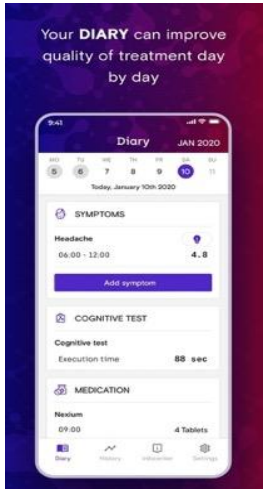
Impact of "electronic Patient Reported Outcomes" (ePRO) on unplanned consultations and hospitalizations in cancer patients undergoing systemic therapy: results of the PRO study compared with matched retrospective data

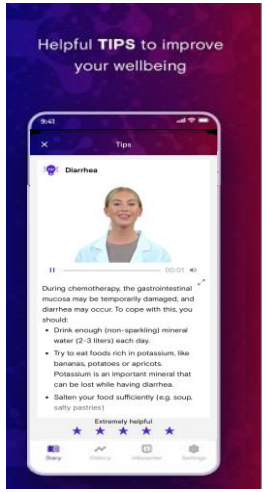
Trojan A, et al. JMIR Formative Research 2024

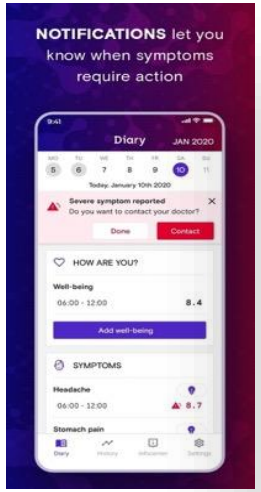
Medical Device App – ePROs comparsion

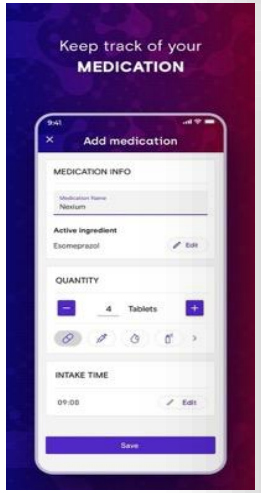
ePROs	medidux	Kaiku HEALTH	noona	oleena	heartbeat	CANKADO	miika	RESILIENCE
Data accuracy (κ)	0.68	0.48	n.a.	n.a.	n.a.	n.a	n.a.	0.48
Data amount	**+++**	++	++	+	+	+	+	+
Medical device	Class I	Class I	Class II/FDA	FDA	n.a.	Class I	Class I	Class I
Modularity	**++**	+	+	-	++	+	-	+
Symptoms	114 **CTCAE**	28+ *PROM*	24+ *PROM*	7	5 -30 QLQ	84 *PROM*	20 Psycho	28+ *PROM*
Review (κ)	**++**	n.a.	+	n.a.	n.a.	n.a.	n.a.	n.a.
Symptom chart	dynamic	1-3 weeks	1- 3 weeks	weeks	weeks	1- 3 weeks	weeks	1-3 weeks
Studies	++	++	++	+	n.a.	**+++**	+	+
Adherence	++	++	+	+	+	++	+	+
Interoperabilty	**++**	-	-	+	+	+	-	-

mediduxTM - a trusted therapy companion for patients









FMH SAQM ASQM

INNOVATION QUALITÉ

Medical Device
CE - Class I

Available in:
- ✓ English
- ✓ German
- ✓ French
- ✓ Italian

JETZT BEI Google Play

Laden im App Store

Studies and Publications

- **Proprietary medidux™ platform & app, CE- Class I (MDD Class I)** symptom progression charts notifies patient & oncologist as defined according to CTCAE (2020)
- **Clinical Trial Patient-App improves Daily Activity** (JMIR 2016) randomized trial in symptom recording in 140 breast cancer patients undergoing Chemotherapy
- **Symptom recording in cancer patients undergoing Immunotherapy** (SAKK- Alpine TIR) temporary Collaboration
- **Clinical Trial Patient-App improves Symptom Recording** (JMIR cancer 2021) digital symptom recording improves patient- doctor experience in 192 cancer patients
- **Report on medication Effectiveness in personalized medicine** (Case Rep Oncol 2021) durable response documentation and tolerability in breast cancer
- **Review of ePROs improves Congruence of Patient- and Clinician- reported Toxicity** (JMIR 2021) collaborative & shared monitoring of treatment related symptoms in 224 cancer patients
- **DiGA- Evaluation of the positive care effect of the digital health app medidux™ in Oncology:** multicentre randomised controlled trial 560 patients, 36 centres in D + CH *(NCT05425550) (open 11/2022)*

Clinical Trials and Registries

SOHC
SWISS ONCOLOGY & HEMATOLOGY CONGRESS

- **HER2-Biosimilar in Breast Cancer**: Real world ePRO observational trial for description of Quality of life and Outcome - 80 patients, 8 centers in CH, „*Flat Iron„- like* approach
  Industry Funding: 05/2021 -05/2023 -> (Link to study)

- **Ovarian Cancer relapse:** ePROs and Quality of Life depending on Follow-up Care
  Observational Trial, 450 patients, 10 centers, International Study „womens health“
  Various Foundations: submission 07/2021 -> Link to study

- **THC-CBD for nausea, emesis, sleeplessness, pain, anxiety, appetite loss in cancer assessed via ePRO.** prospective randomized control study: 150 patients, 6 centers
  Industry Funding: submission 08/2021 -> Registry website

- **ePROs and biomonitoring for early detection/ management of side effects in cancer Immunotherapy**: Feasibility Study, 20 pts, “implant medical device”
  Industry Funding & mHealth AG: submission 02/2024 -> Link to study

- **medidux + IoTs / wearables for tracking chronic Care Patiemnts**
  Observational Trial study on effects in home Care Settinmgs
  Various Funding: submission 08/2024

- **Efficiency of “ medidux” for tracking symptoms in patients medicated in Acute Admission Units (AAU)**
  Randomized Control Trial (RCT) study on cost reducing effects in emergencies
  Various Funding: submission 05/2024

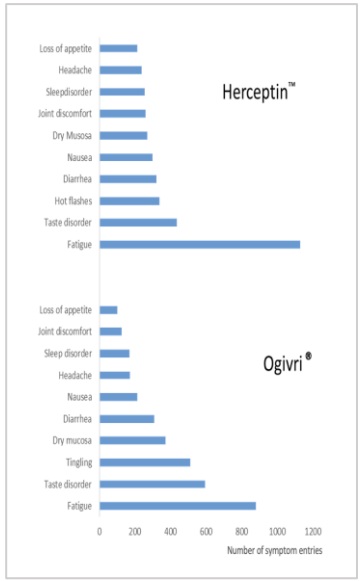
Predictive Analytics

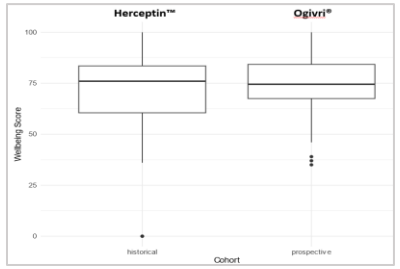
JMIR Publications
The Leading eHealth Publisher

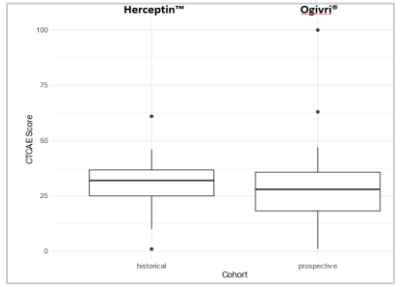
HER2-directed biosimilar Ogivri® in the treatment of breast cancer: real-world reporting of symptoms and well-being using electronic patient-reported outcome (ePRO): results of the OGIPRO study

Andreas Trojan, Sven Roth, Ziad Atassi, Michael K. Kiessling, Reinhard Zenhäusern, Yannick Kadvany, Johannes Schuhmacher, Gerd A. Kullak-Ublick, Matti Aapro, Alexandru Eniu

Submitted to: Journal of Medical Internet Research
on: November 01, 2023





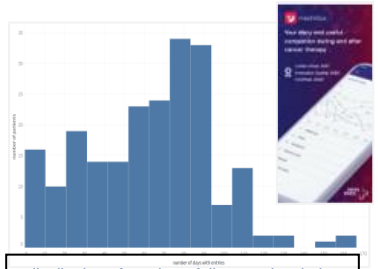


Towards an Early Warning System for Monitoring of Cancer Patients Using Hybrid Interactive Machine Learning

Andreas Trojan*[1,2], Emanuele Laurenzi[3], Stephan Jüngling[3], Michael Kiessling[1], Ziad Atassi[1], Yannick Kadvany[4], Meinrad Mannhart[5], Christian Jackisch[6], Hans-Friedrich Witschel[3]

[1] Breast Center Zürich-See, Zürich, Switzerland
[2] Clinic for Clinical Pharmacology and Toxicology, University Hospital, Zürich,
[3] FHNW, University of Applied Sciences and Arts Northwestern Switzerland
[4] mobile Health AG, Zürich, Switzerland
[5] Onko-Hämatologisches Zentrum Zug, Switzerland
[6] Sana Klinikum Offenbach GmbH, Offenbach, Germany

Digital Health, 2024



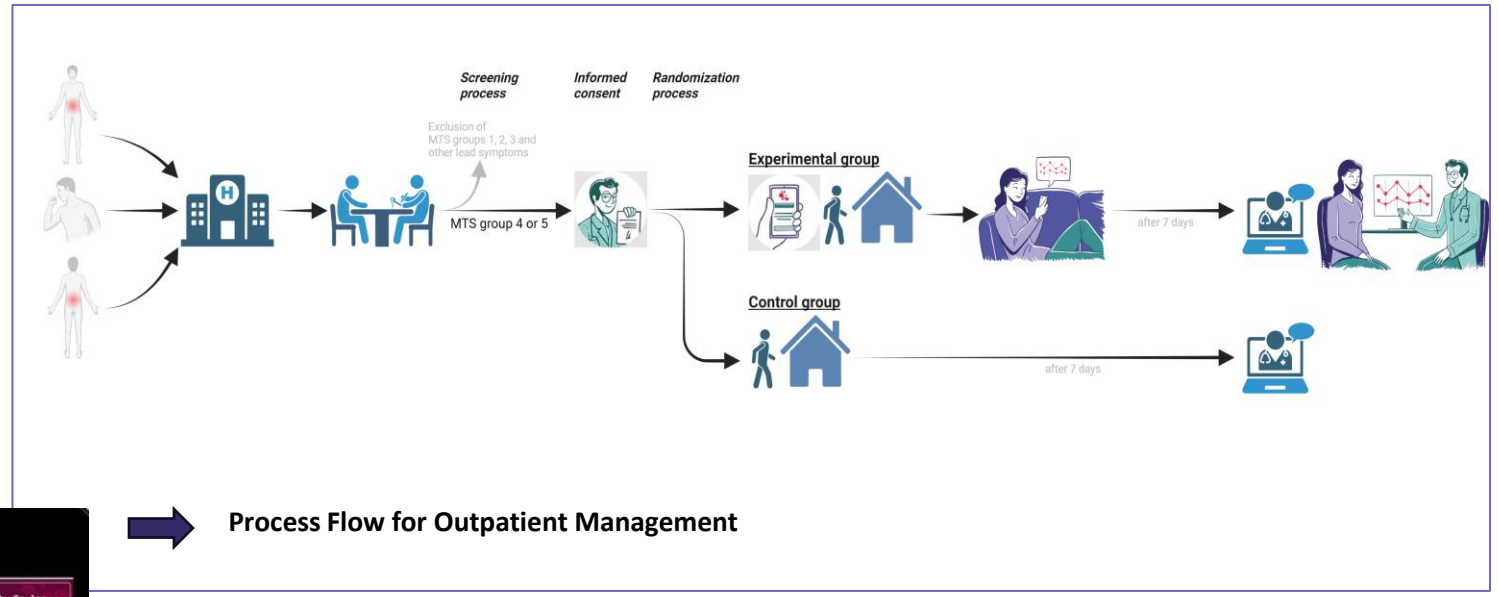
distribution of number of diary entries during a maximum observational period of 170 days

Attribute(s)	Number	Description	Type / values
Birth year	1		Numeric
Sex	1		{male, female}
Primary tumor	1		{breast, gut, blood/lymph, lung, Prostate}
Well-being	1	Subjective well-being	[0,...,100]
Therapy form	1	Frequency of treatment	{daily, weekly, bi-weekly, 3-weekly, 4-weekly}
Drugs	88	Cancer drugs, other drugs	[1,nan]
Symptom grading	52	Strength of relevant symptoms, based on CTCAE	[0,...,1,nan]
Diagnosis terms	246	Terms occurring in diagnosis details of patient	Numeric (TF/IDF)
Note terms	311	Terms occurring in patient notes	Numeric (TF/IDF)
Unplanned visit	1	Class attribute	{yes, no}

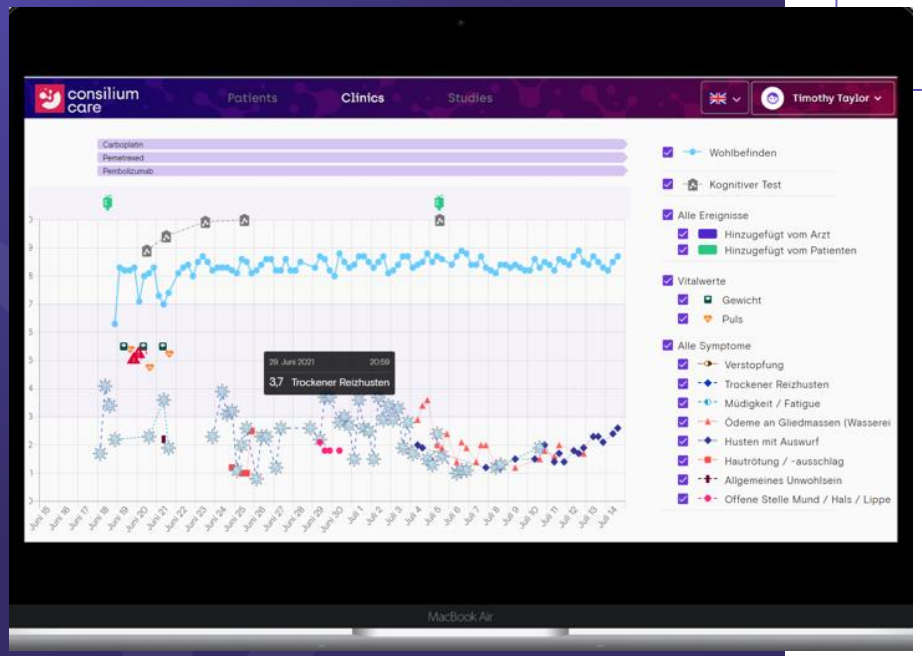
Table 1: Data available for patients' diary entries (ePROs)

60`000 data entries overall, the ML-learned rule set achieved a recall of ~30% (166 = 47/119) on the entire dataset and a precision of 15%

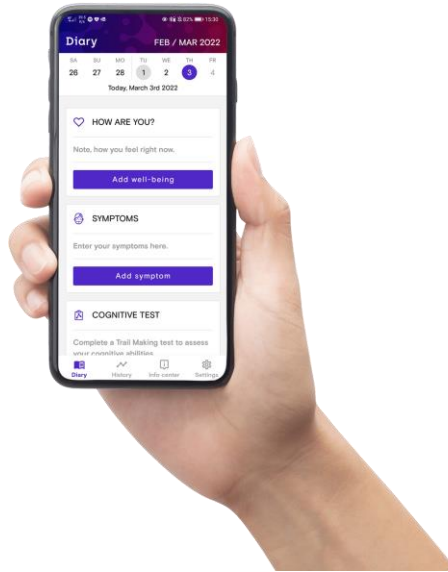
Discharge management @home



Process Flow for Outpatient Management



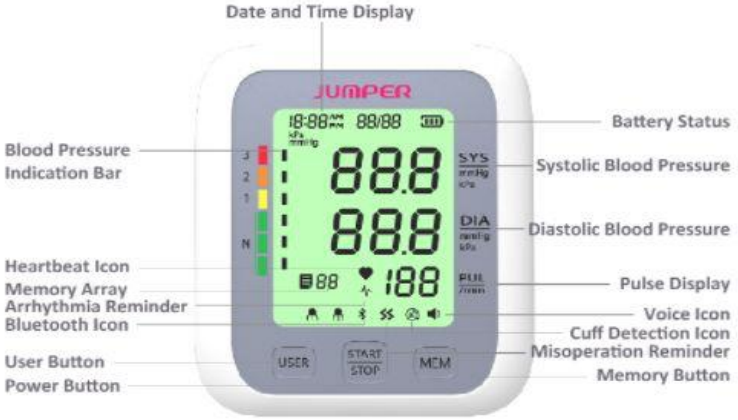
- Predictive Analytics for Early Warnings (standardized, structured, reviewed CTCAE, IoT, ECG, CRP test)



Wearable Devices for management @home

Thermometer

Blood Pressure



Integrated CRP @home test

Weight Scale

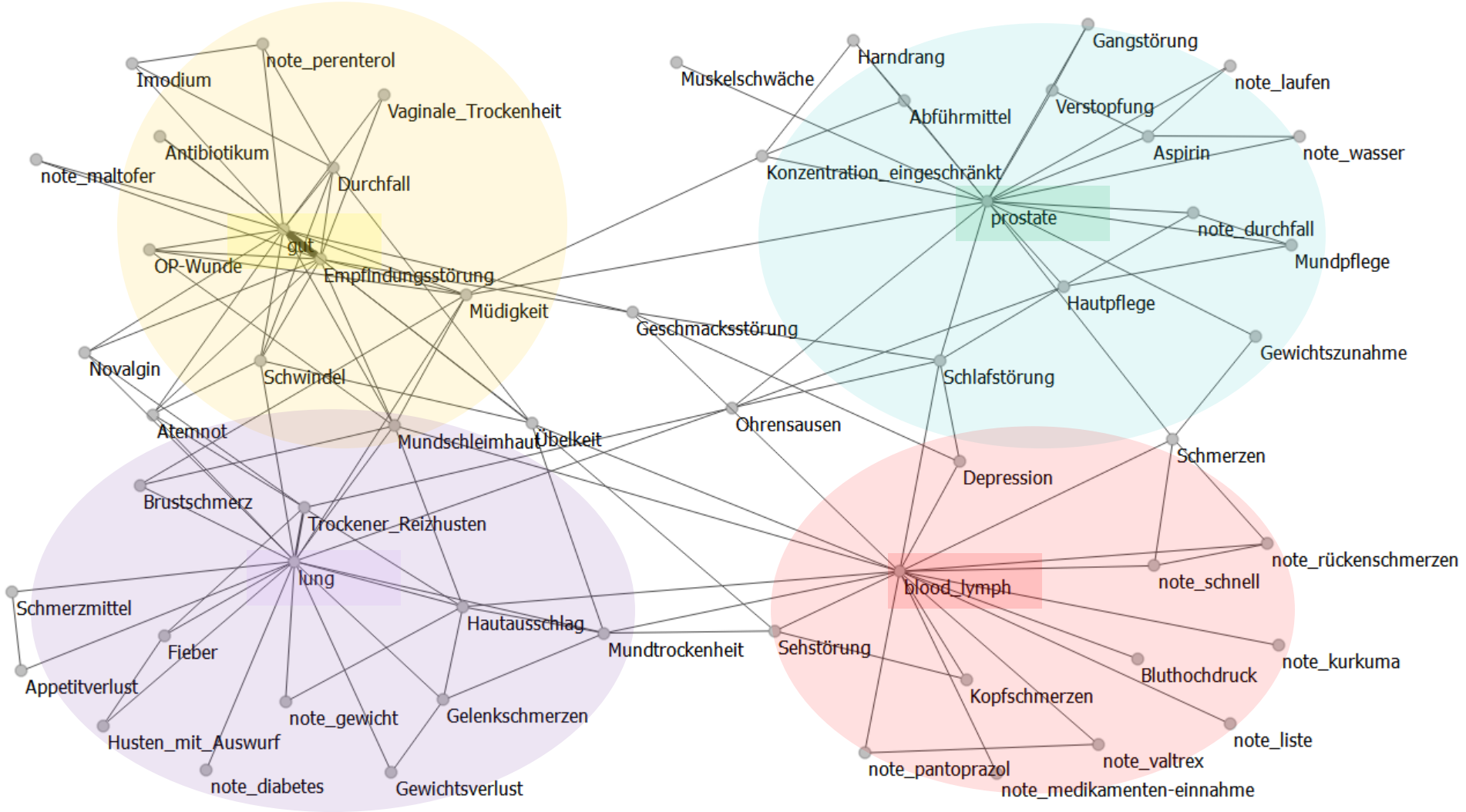
Dedicated High-end Design

Oximeter

Mobile ECG

Eurostars Funding *(2024) submitted*

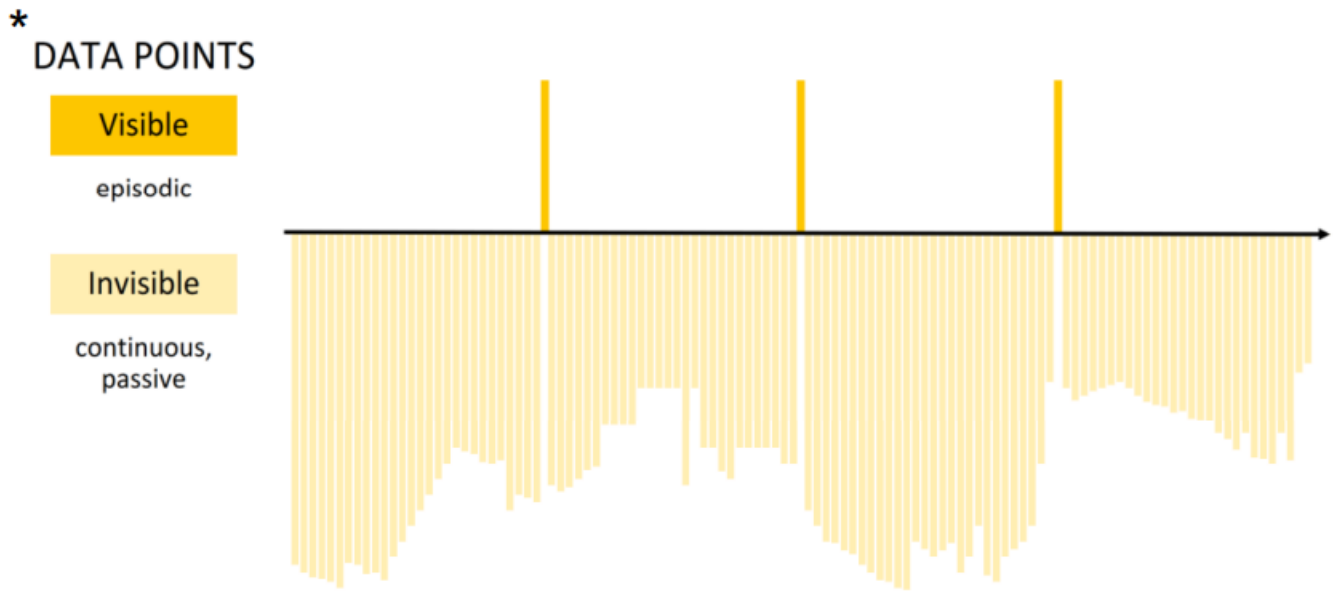
Reverse Cluster of differentiation with mediduX®



Accuracy of symptom reporting from patients can identifiy type of cancer or adherence to medication

Trojan A, et al.; submitted; & ESMO 2024

Historically, patient outcomes have been characterized using limited, visible-to the-system data sets with key data sources from clinical trials



Visible Data

- Episodic data collection based on patient visits with limited data (e.g. check-ups, treatment visits, etc.)
- Data collected within clinical trials

Invisible Data

- No or limited direct patient reporting with non-continuous observation methods
- e.g. questionnaires, telephone calls

➢ *These visible data sets often do not capture the full spectrum of patient experiences and may not reflect the variability encountered in everyday clinical practice*

Publications

“Stand heute”

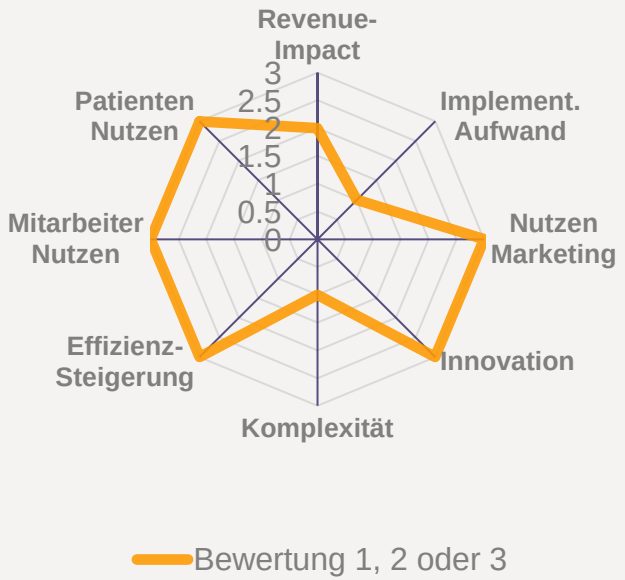
- Egbring M, Trojan A et al.: A mobile app to stabilize daily functional activity of breast cancer patients in collaboration with the physician: a randomized controlled clinical trial. J Med Internet Res 2016;18(9):e238
- Trojan A, Leuthold N, Thomssen C, Rody A, Winder T, Jakob A, Egger C, Held U, Jackisch C. J Med Internet Res. 2021 Aug 5;23(8):e29271.
- Pircher M, Winder T, Trojan A. Response to Vemurafenib in Metastatic Triple-Negative Breast Cancer Harbouring a BRAF V600E Mutation: A Case Report and Electronically Captured Patient-Reported Outcome. Case Rep Oncol. 2021 Mar 29;14(1):616-621
- Trojan A, Bättig B, Mannhart M, et al. Effect of Collaborative Review of Electronic Patient-Reported Outcomes for Shared Reporting in Breast Cancer Patients: Descriptive Comparative Study. JMIR Cancer. 2021 Mar 17;7(1):e26950.
- Asper N, Roth KS, Hany TF, Salzberg SP, Tinguely M, Kadvany Y, Trojan A. Metastatic Salivary Duct Carcinoma with ERBB2 Amplification and Sequential Response to Ado-Trastuzumab Emtansine and Neratinib: A Case Report. Case Rep Oncol. 2023 Nov 29;16(1):1500-07
- Himmelreich F, Jetter A, Kiessling MK, Kadvany Y, Trojan A. Interference of Herbal Medicine with Axitinib in Metastatic Renal Cell Cancer Treatment. Case Rep Oncol. 2023 Nov 9;16(1):1362-69.
- Trojan A, Brauchbar M, et al. Smartphone App for Real-World electronically captured Patient-Reported Outcome Monitoring in Cancer Patients Undergoing anti-PD-L1-Directed Treatment. Case Rep Oncol. 2020 May 12;13(2):491-496.
- Trojan A, et al. Towards an Early Warning System for Monitoring of Cancer Patients Using Hybrid Interactive Machine Learning (JMIR AI, submitted 09.12.2023)
- Trojan A, et al. Comparing HER2-directed biosimilar Ogivri® with Herceptin™ in the treatment of breast cancer by real-world reporting of symptoms and well-being using electronic patient-reported outcome (ePRO): results of the OGIPRO study. (JMIR cancer; Feb2024)
- Trojan A, et al. Impact of "electronic Patient Reported Outcomes" (ePRO) on unplanned consultations and hospitalizations in cancer patients undergoing systemic therapy: results of the PRO study compared with matched retrospective data (JMIR Formative Research, 2024)
- Trojan A, et al. Reverse Cluster of differentiation with medidux through accuracy of symptom reporting from patients can identifiy type of cancer or adherence to medication (submitted)

ePROs by mediduxTM

MOBILE HEALTH

Bewertung

1 = tief, komplex, benötigt Zeit
3 = hoch, einfach, schnell



Beschreibung

Mobile Health bietet eine patientenzentrierte Softwareanwendung an, mit der Patient*innen ihr Wohlbefinden und Symptome sowie Vitalparameter und die Einnahme von Medikamenten strukturiert und standardisiert elektronisch (sogenannte electronic patient-reported outcomes; ePROs) erfassen können. Zudem können Patienten ihre Vitalwerte mit verschiedenen Medical Devices automatisch erfassen. Der Arzt erhält ein strukturiertes Bild des Befindens des Patienten und des aktuellen und historischen Therapieverlaufs. Die Entscheidungsfindung des Arztes wird durch AI Module unterstützt.

Benefit für Mediziner

- Effizientere Nutzung der ärztlichen Ressourcen mit möglichen Kosteneinsparungen (weniger Admin Aufwand)
- Optimierter Therapieverlauf durch personalisierte und evidenzbasierte Schaffung von Entscheidungsgrundlagen
- Bessere Betreuung und Behandlung von Patienten durch real world data (RWD).
- Zertifiziertes und erprobtes Medizinprodukt mit grosser wissenschaftlicher Evidenz

Benefit für Patienten

- Optimierter Therapieverlauf durch höhere Adherence
- Einfachere Dokumentation von Symptomen und Medikation.
- Einfacher Austausch der Daten mit zusätzlichen HCPs via PDFs.
- Geringere Inanspruchnahme medizinischer Ressourcen
- Besseres Wohlbefinden während Therapie
- Tipps für eigenständige Behandlung von Symptomen

Next Steps

Nationale Register- Studien; Digital Health Academy: AI, Health monitoring@home
Internationale Studien Kooperationen
Dezentralisierte Klinische Studien

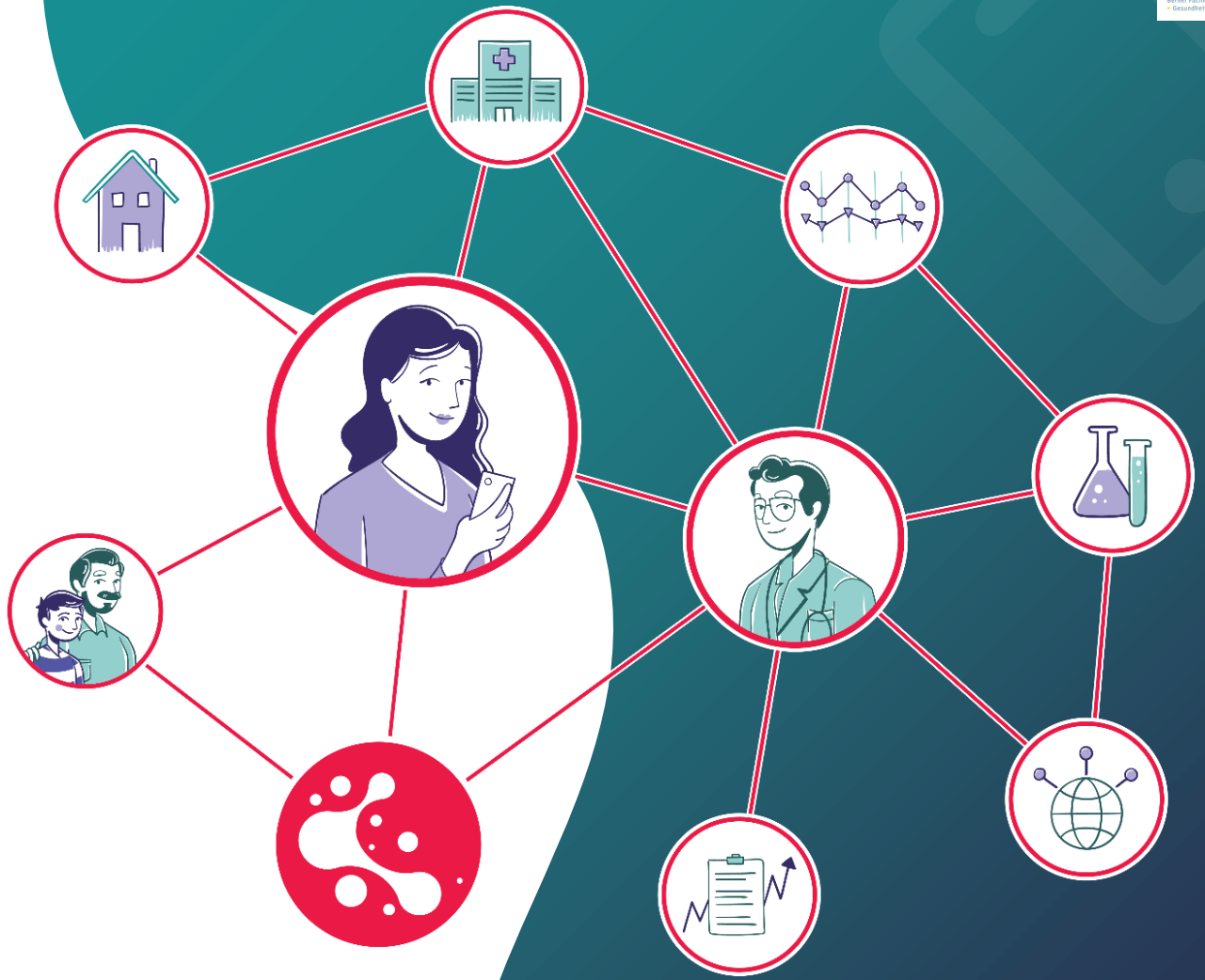
Empfehlung / Priorität

Patienten Organisationen / Patient-Advocats
Universitäre Anbindung
Erstattungsfähigkeit Versicherungen

Thank You !

Let’s transform the way we communicate and think …

… in clinical care and decentralized clinical trials



FMH SAQM ASQM

CAS
Qualität im Gesundheitswesen für die patienten-nahe Arbeitspraxis
interprofessionell und sektorenübergreifend

Berner Fachhochschule Gesundheit