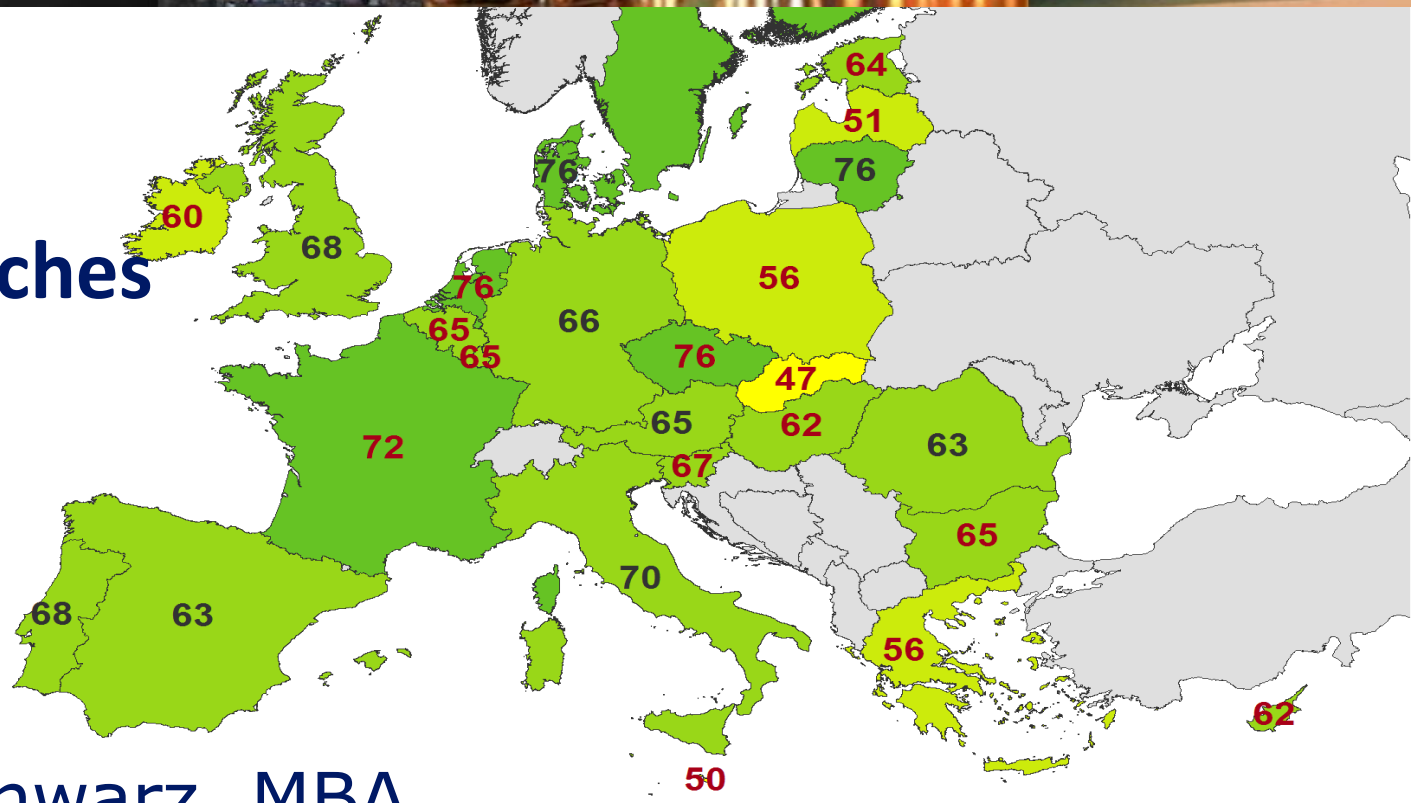
Digital Diabetes Therapeutics
new challenges – new approaches



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President elect of the International Diabetes Federation

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Conflict of Interest / Disclosures,
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Prof. Dr. med. habil. Peter E. H. Schwarz, MBA

- International Expert for the Prevention of Diabetes
- First Professor for Prevention and Care of Diabetes in Europe
- MBA for International Business
- Coordinator of large Europepan and Global Prevention initatives (IMAGE - 107 partners, MANAGE CARE - 87 part., APPways - 55 part., Global Diabetes Survey)
- Coordinator of larger clinical Studies (CONGO, Metabolyx, DIAGEN, PLIS, epredice)
- President of the 6th World Congress on the Prevention of Diabetes and National meetings
- Executive Board member in national and international org. (Global Diabetes Plan, DASG, IDF, active in diabetesprevention, Global Diabetes Survey)
- Special Focus: Knowledge transfer into practice and know how management
- Med. Training in Germany, USA, Tanzania, South Africa, Finland ; MBA in Germany, Spain, India, China, Brazil)
- 335 peer reviewed publications, total impact factor of 2354, Hirsch index 52, 43 book chapters, more than 350 presentations to peer-reviewed, internationally conferences
- CHAIR of the Strategic Forum on Self-care, Technology & Digitalisation at the European Diabetes Forum (EASD/IDF)
- **President elect of the International Diabetes Federation**
- **Member of the Board of the NCD Alliance**

YES

Smart health

…… is a disruptive innovation in the diabetes sector

European Diabetes Forum

The promise of digital tools in diabetes

A roadmap for apps

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Department of Medicine III,
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University of Dresden

European
Diabetes Forum

BENEFITS OF APPS

Follow targets

- Glucose levels
- Physical activity
- Medications
- Social activities
- Daily behaviour
- Literacy
- Individual need

Data

- Access to data can support decision making
- Clinical break points
- Behavior change
- Comorbidities
- Targeted motivational messaging

Social Support

- access to the patient community
- Social networks
- Behaviour support between medical visits
- Empowerment
- self-management decision making

Access to Care

- Communication with HCP`s
- Telemedicine
- E-prescriptions
- Motivational intervention
- Direct access to the patient
- Diabetes Bots
- Virtual Clinic

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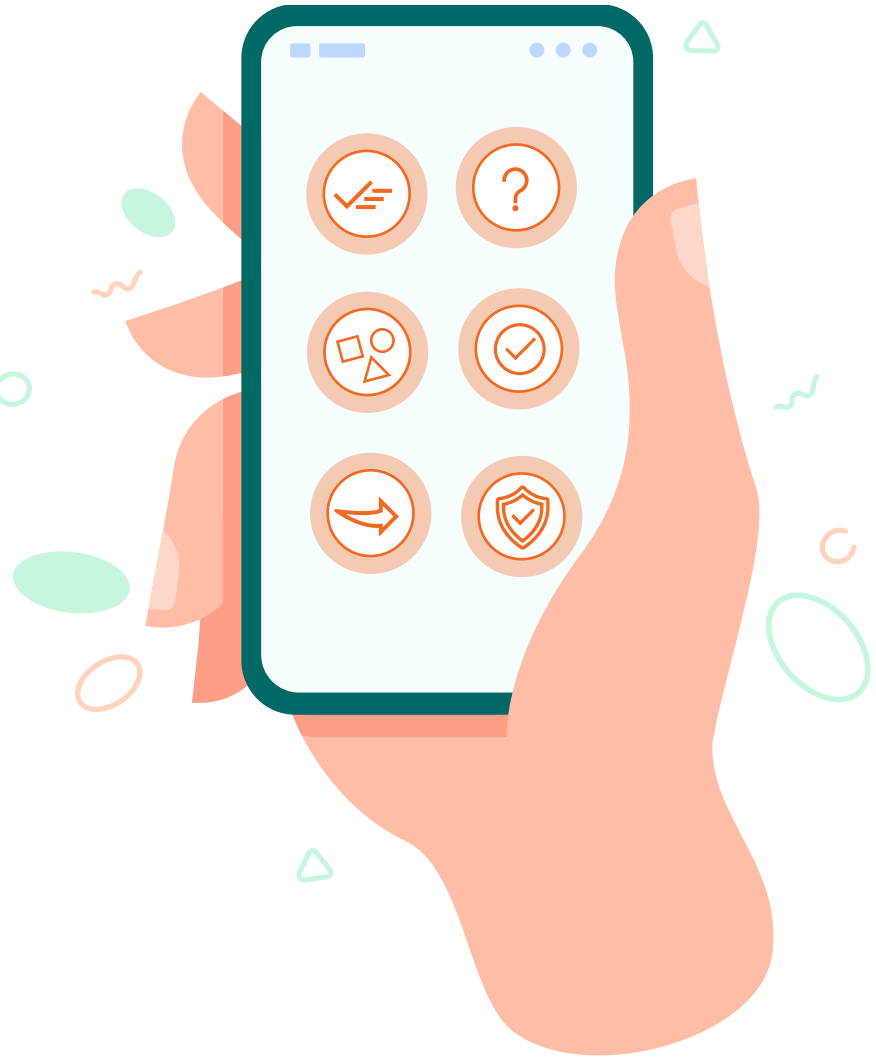
CHALLENGES



Quantity and Quality:

The sheer number of health apps in the marketplace makes it difficult for people with diabetes and healthcare professionals to sort through the vast and overwhelming jungle of digital solutions.

Similarly, while there are many good apps on the marketplace, there are many poor ones as well. People with diabetes typically have to peruse through blogs, forums, or literature to learn more about apps. Finding a way to identify and then guide people living with diabetes and HCPs towards trustworthy and useful apps is a prerequisite to playing a more prominent role in diabetes care.

Digital Hesitancy:

The awareness of digital solutions both among people with diabetes and their healthcare providers remains rather low. Moreover, knowledge about how to use and take advantage of apps can be lacking. There is a risk that a widening digital divide could lead to schisms in diabetes care and outcomes. Though in Type I diabetes, which often affects people at a younger age, the issue of digital literacy is not as strong.

In addition, for a variety of reasons, physicians and payers sometimes feel indifferent towards digitalisation. Overcoming this hesitancy will be critical to achieve a more widespread use of apps.

Attrition:

The uptake of many digital apps can be small, and many people with diabetes abandon apps after only a short period of use. A framework or perceived added value of an app is needed – with backing from HCPs – to increase usage over the long-term.

Evidence:

Evidence supporting the effectiveness of apps can be difficult to obtain. There is no agreement on even how to measure the effectiveness of an app. There are multiple factors influencing the effectiveness of an app and it is highly dependent on how it is used. Must clinical evidence and real-world performance link apps to improvements in quality of care and the management of health conditions? Or is to some extent the satisfaction of those with diabetes – in terms of ease of use or quality of life – itself a validation of efficacy?

Furthermore, to accumulate evidence takes time and requires resources. This often discourages the development of new apps because of the uncertainty of financial viability. There is typically a trade-off between evidence and availability. In regulatory systems that impose comprehensive efficacy requirements, there may be fewer apps that make it to the marketplace. While clear guidance and transparency on evidence are certainly needed, the regulatory environment should be sufficiently flexible to account for different evidence levels, depending on the function and the relative medical risk levels of the app.

Integration:

For meaningful uptake by people with diabetes and HCPs, apps need to be more integrated into healthcare processes and pathways. This requires more reimbursement/funding, investing in the appropriate technical infrastructure, and putting incentives in place to encourage healthcare providers to prescribe apps. The key requirement for the integration of apps is the need to demonstrate benefits for all actors in the diabetes landscape – people with diabetes, HCPs, payers, and app developers. Otherwise, success is not guaranteed.

Data security & interoperability:

Health data is by its nature sensitive which creates challenges in navigating the balance between privacy and security, and the ability to access, integrate, and share data.

RECOMMENDATIONS

1. Develop a User-Centred App
2. Develop a best practice access pathway for apps
3. Support the integration and uptake of high-quality apps into the health ecosystem

1 Develop a User-Centred App

Design and technical specifications:

- People with diabetes and healthcare professionals should be included in all stages in the development and validation of apps
- The app should be user-friendly and easy to navigate
- High standards of data security are essential, and consideration must be given to ownership of data
- Data must be interoperable

Objectives/features of the app:

- Apps should focus on empowering people with diabetes by offering support for self-management
- Apps should support a personalised, data-driven approach to diabetes care, one that improves decision-making in a meaningful way
- Data collected should be relevant and actionable

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2

Develop a best practice access pathway for apps

Identify requirements for access:

- Each member state should create a process to enable/accelerate access to digital health apps and agree on requirements/criteria… The process should be harmonised at the EU level
- People with the diabetes should be consulted throughout the process
- Patient-reported outcomes (PROMS criteria) should be part of the evaluation of apps

Reimbursement:

- Apps that can prove real value – by supporting patient self-management and reducing the efforts of HCPs – should be reimbursed/funded.
- Real life evaluations of apps should be published to provide data to payers to assess apps

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3 Support the integration and uptake of high-quality apps into the health ecosystem

Develop training opportunities to become more familiar with apps

- Develop "digital diabetes training programs" for healthcare professionals and people with diabetes that includes education on the use of selected apps. HCPs should be able to advise people living with diabetes about which app to use. And people with diabetes should have a better sense of what is currently on the market.
- Digital health training should be incorporated into all healthcare professional and specialist training
- Highlight the benefits of apps to payers to ensure they are allocated proper funding

Encourage uptake and integration of apps into healthcare pathways:

- Apps should be prescribed, as a drug or a medical device, to increase credibility and encourage full patient involvement.
- Data should be automated as much as possible to encourage the long-term use of these apps.
- Incentives should be in place for HCPs to recommend apps
- Payment models should focus more on outcomes versus visits. Likewise, the clinical model should be person-centred instead of service-based.
- Engage with medical societies to elicit the support HCPs for apps and digital solutions

Integrate apps in diabetes treatments and care:

- Apps can play an important role in telemedicine and personalised care, although they should complement, not restrict, access to in-person care
- Apps should share information with HCPs , and data should be integrated into monitoring and treatment schemes.
- Apps that are validated, licensed, and have proven efficacy should be considered for inclusion in chronic disease including diabetes management programs and guidelines

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Different views on digital tools in patient care

user view

HCP view

patient view

Peer group view

behaviour

preferences and need

treatment

?

Toward equal access to the right quality treatment at the right time and place

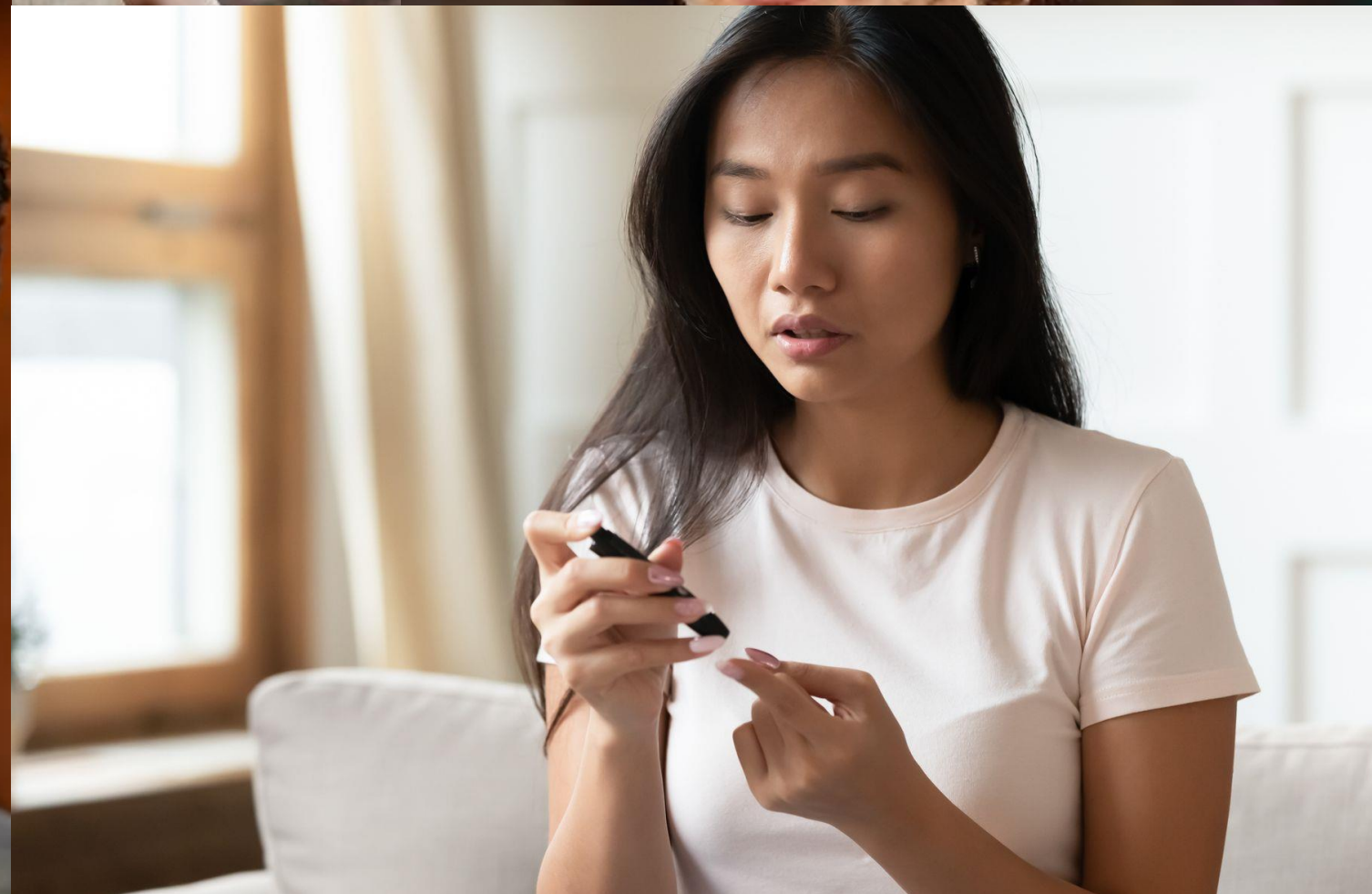
“Digitalisation is not about providing new opportunities for physicians or about providing new ways to store data.

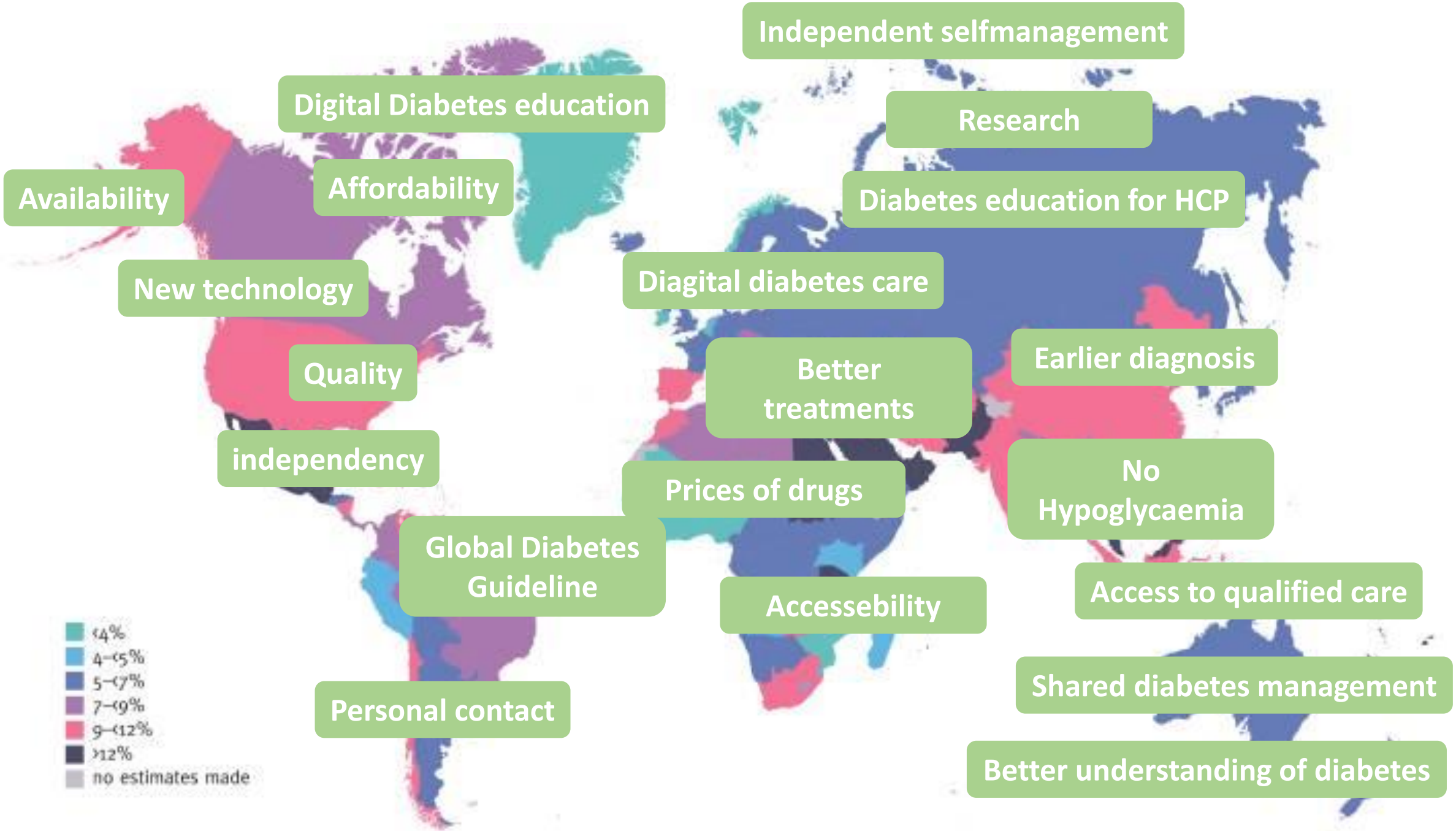
It is a big chance to address the need of people living with diabetes”

Understanding Patient Needs


adidas
adidas

Need





Estimated age-adjusted comparative prevalence of diabetes in adults (20–79 years) in 2021

Why are digital Therapeutics effective?

Systematic review of reviews of intervention components associated with increased effectiveness in dietary and physical activity interventions

Goals

- Summary of evidence from
- Increasing the effectiveness of the intervention
- Identify priorities for future research

Daily routine

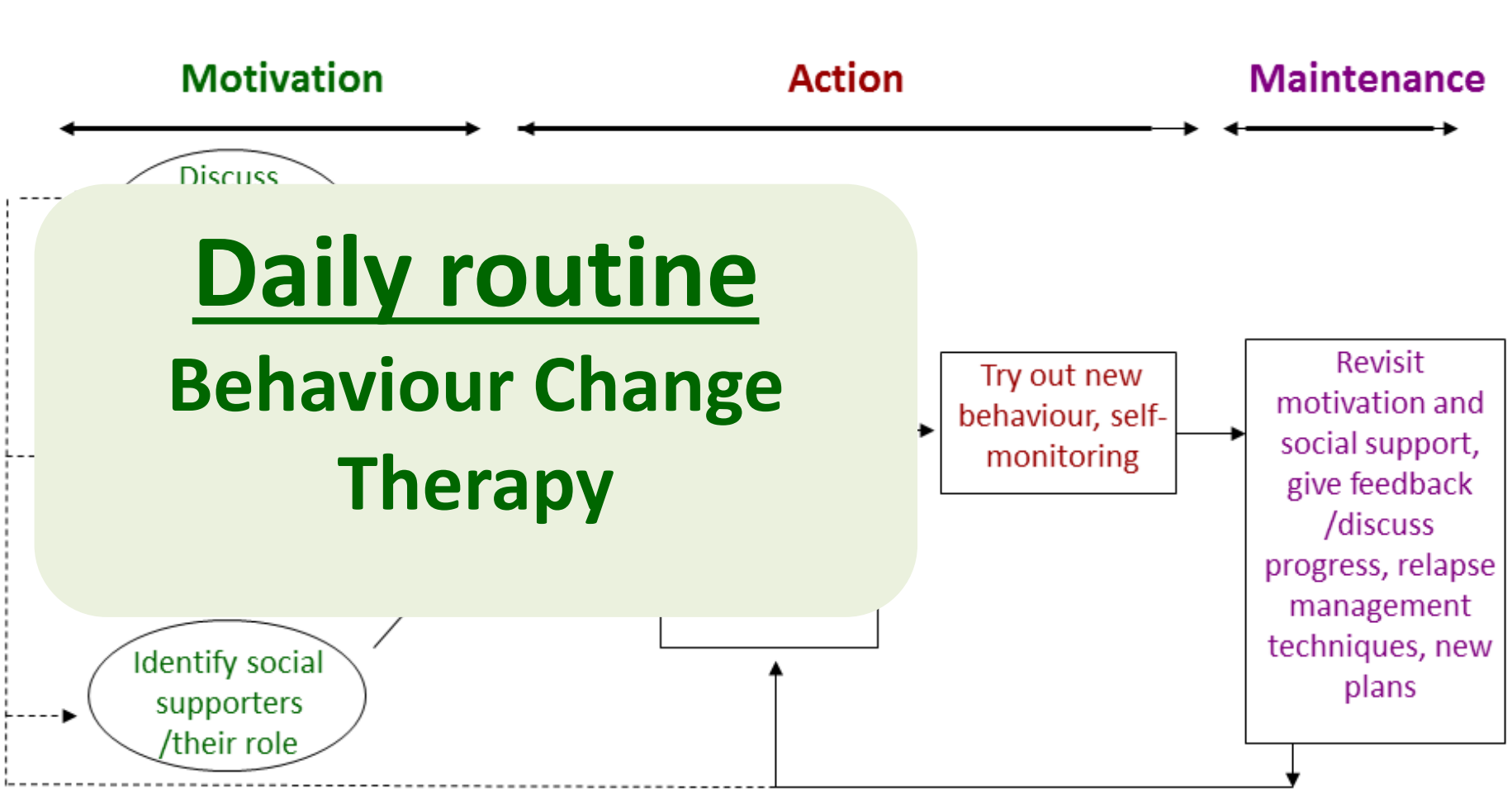
Frequency of contacts

Social support

- It is possible to achieve clinically meaningful behavioral changes in both eating habits and increased physical activity.
- This requires interventions that support the person at risk in their individual behavior change process.
- ntion plan should define the change processes and specific and methods for implementing these processes
- and well-defined behavioral therapy techniques should be
- l should be encouraged alongside other self-regulatory in the context of control theory
- **ould be a strong focus on maintenance**
- **The frequency or number of contacts should be as high as possible**
- **The inclusion of social support should be worked out together with the participants**

Quelle: aus dem IMAGE-Toolkit „Take action to prevent diabetes“

Behaviour Change Model and Techniques

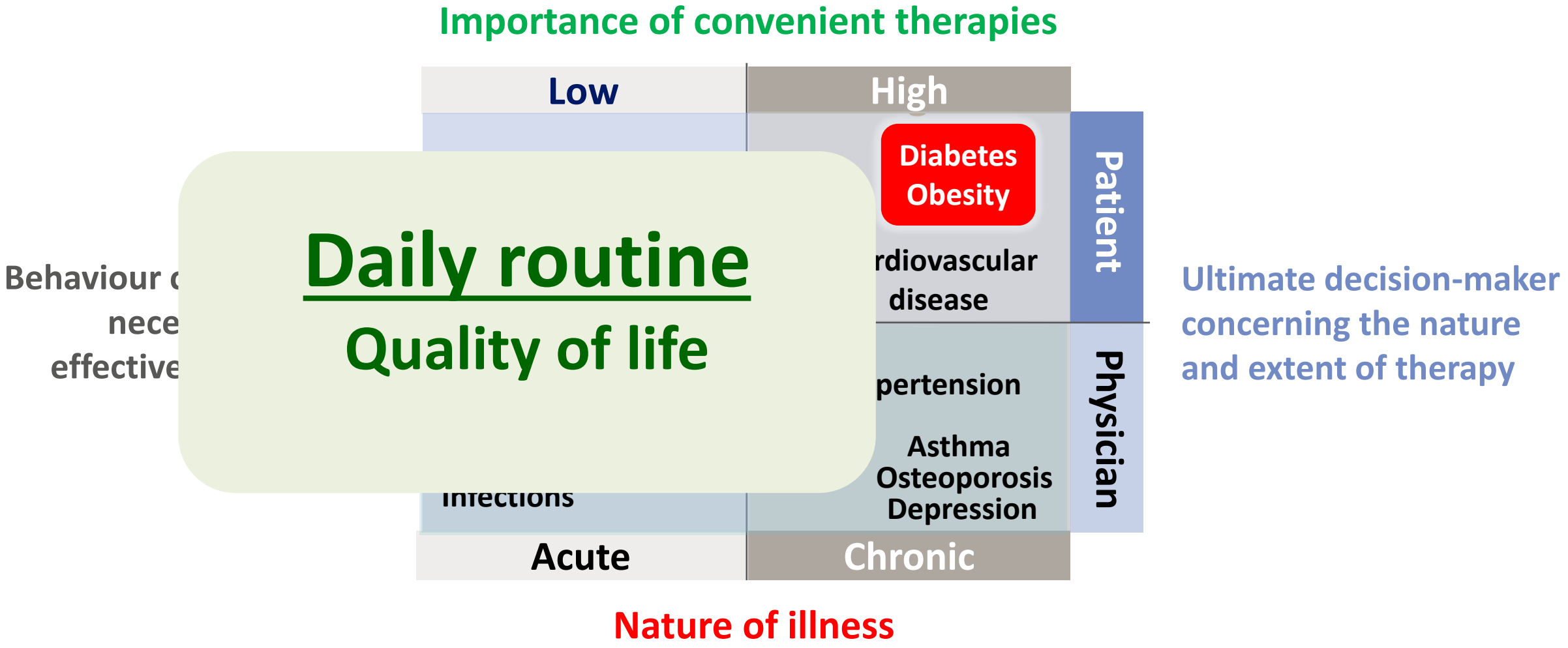


Astrid Krag, MoH Denmark
Self-management is the only way. Educational programs must support Self-management and informed decision making

Desislava Dimitrova, DMoH, Bulgaris
Chronic Care Management ist the most effective way to improve Self-Management

Greaves CJ et al. BMC Public Health. 2011 Feb 18;11(1):119.

Quality of life drives adherence



Personal responsibility for daily therapy decisions

Therapy requirements for the patient per year:

- Approx. 2100 blood sugar measurements/CGM/FGM sev times a day

- Approx. 1700 insulin injectio >120 x catheter changes

- 365 days: Multiple independ therapy decisions

- 365 days of reflection on everyday activities (nutrition, exercise, stress...) -approx. 6000 hours

Daily routine

Behaviour

Self management

Physician contact because of diabetes / discussion of blood sugar levels

round 1 hour
ope of a training course:
x 90 minutes = 18 hours

e behavior of the patient
decisive for the outcome of
e therapy and the
prognosis of the diabetes

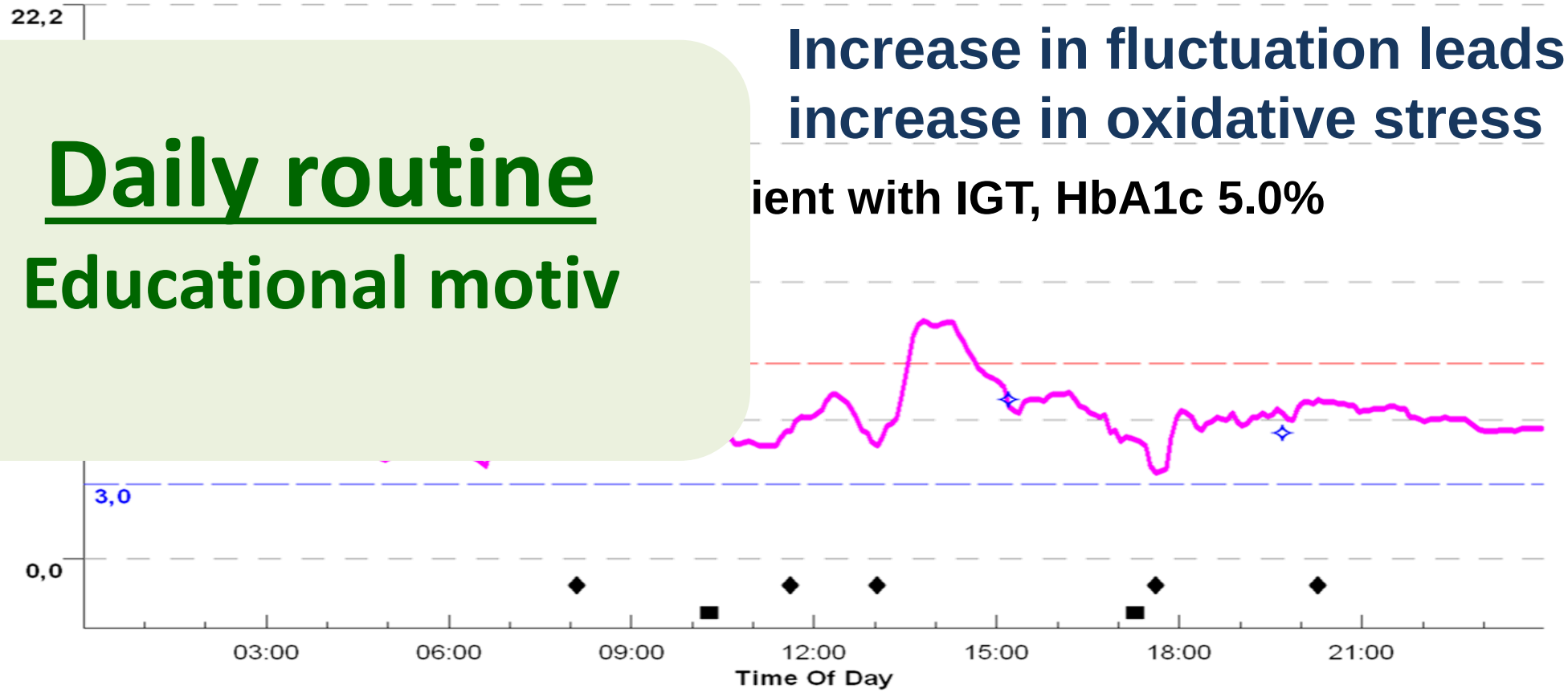
Prediabetes starts with postprandial glucose peaks

Daily routine

Educational motiv

Increase in fluctuation leads to increase in oxidative stress

ient with IGT, HbA1c 5.0%



Slides with permission from Prof. Hanefeld

Zusammenfassung der Ergebnisse zur Wirksamkeit von digital unterstütztem Selbstmanagement auf den HbA1c bei Typ 2 Diabetes Patienten

Category of application	characteristics	n of trials	n of patients	Outcome	MD (95% CI) of %-change in HbA1c	*P*
Digital self-management	≤ 3 months	10		↓	-0.51 (CI -0.71, -0.31)	< .001
	> 3 ≤ 6months	10		↘	-0.48 (CI -0.68, -0.28)	< .001
	> 6 months	15		↘	-0.35 (CI -0.53, -0.18)	< .001
	6 -8 months	14	2389	↓	-0.59 (CI -0.78, -0.39)	< .001
Digital self-management (SMS)	< 6 months	6		↓	-0.60 (CI -0.80, -0.40)	< .001
	≥ 6months	4		↘	-0.40 (CI -0.56, -0.24)	< .001
					-0.54 (CI -0.80, -0.28)	< .001
					41 (CI -0.63, -0.19)	< .001
					(CI -0.59, -0.14)	< .002
					(CI -1.51, -0.75)	< .05
					(CI -0.81, -0.26)	< .001
					(CI -0.74, -0.15)	= .039
					(CI -0.65, –0.34)	< .001
					(CI –0.69, –0.32)	< .001
					(CI -0.47, -0.24)	n.s.
					(CI -1.04, 0.00)	< .05
					(CI -0.55, -0.27)	< .05
					(CI -0.82, -0.42)	< .001
					(CI -0.59, -0.07)	= .01
					(CI -1.32, -0-91)	< .001
					(CI -0.74, -0.12)	< .001
					(CI -1.40, 0.19)	= .001
					0 (CI -0.9, -0.4)	= .27
					.0 (CI -0.6, 0.2)	= .27
					40 (CI -0.5, -0.2)	= .27
					0.85 (CI -1.79, 0.10)	= .07
(SMS)	Age 41 to 50 years	8	n.s.	↓	-1.83 (CI -3.17, -0.48)	< .001
	Age > 50 years	17	n.s.	↓	-1.05 (CI -1.50, -0.60)	< .001
	Diagnosis < 7 years ago	4		↓	-0.61 (CI -0.79, -0.42)	< .001
	Diagnosis ≥ 7 years ago	3		↘	-0.37 (CI -0.62, -0.13)	= .031
	Baseline HbA1c < 8.0 %	6	n.s.	↘	-0.26 (CI -0.43, -0.10)	= .027
	Baseline HbA1c ≥ 8.0 %	8	n.s.	↓	-0.64 (CI -0.93, -0.35)	= .027
	Baseline HbA1c < 9.0 %	n.s.	n.s.	↘	-0.35	n.s.
	Baseline HbA1c ≥ 9.0 %	n.s.	n.s.	↓	-1.22	n.s.

Daily routine

Frequency of contacts

Individualisation

Wirksamkeit mit HbA1c Senkung bei:

- **3-12 Monaten**
- **< 55 Jahre bei Anwendung der DiGA**
- **< 7 Jahre Diabetesdauer**
- **HbA1c <8%**
- **Individualisierte Betreuung (persönlich und automatisiert)**
- **Höhere Frequenz an Interventionen**

Timpel, P., et al., ***Mapping the Evidence on the Effectiveness of Telemedicine Interventions in Diabetes,*** **Journal of Medical Internet Research, 2020. 22(3).**

How digitalization is transforming all aspects of diabetes care

……and how does it support

- **access to the right treatment → at the right time and → at the right place?**

- Improved self-management through for example access to their own data, and well as access to educational resources, potentially peer support as well. Also improved self-management simply as a result of tools which help support decision-making for the PwD (CGMs/AID)
- Quality of the interaction between HCPs and PwD & shared-decision making
- Reduction of therapeutic inertia
- More personalised and person-centred care, including more targeted through increased support to HCPs in the form of decision-support systems
- Improved prevention of T2D and diabetes-related complications through predictive risk stratification models
- Telehealth, remote monitoring, and other similar applications including those driven by increased use of AI (e.g. for reading of eye scans) allow PwD to gain access to the care/services they need in a more flexible/at a frequency which is adapted to their needs

Kontakthäufigkeit

Selbstmanagement

Verhaltensänderung

Individualisierung

Verhaltenstherapie

Kontakthäufigkeit

Soziale Unterstützung

Schulungsanlässe

Lebensqualität

Alltag

Diabetes Digital App Technology –
EASD ADA Empfehlungen

6. HCPs should:
   a. be knowledgeable of digital health apps and their strengths and weaknesses
   b. support and inform people with diabetes on the use of digital health apps to augment diabetes management and lifestyle modification
   c. use health data to improve quality of care and health outcomes

HCPs should:

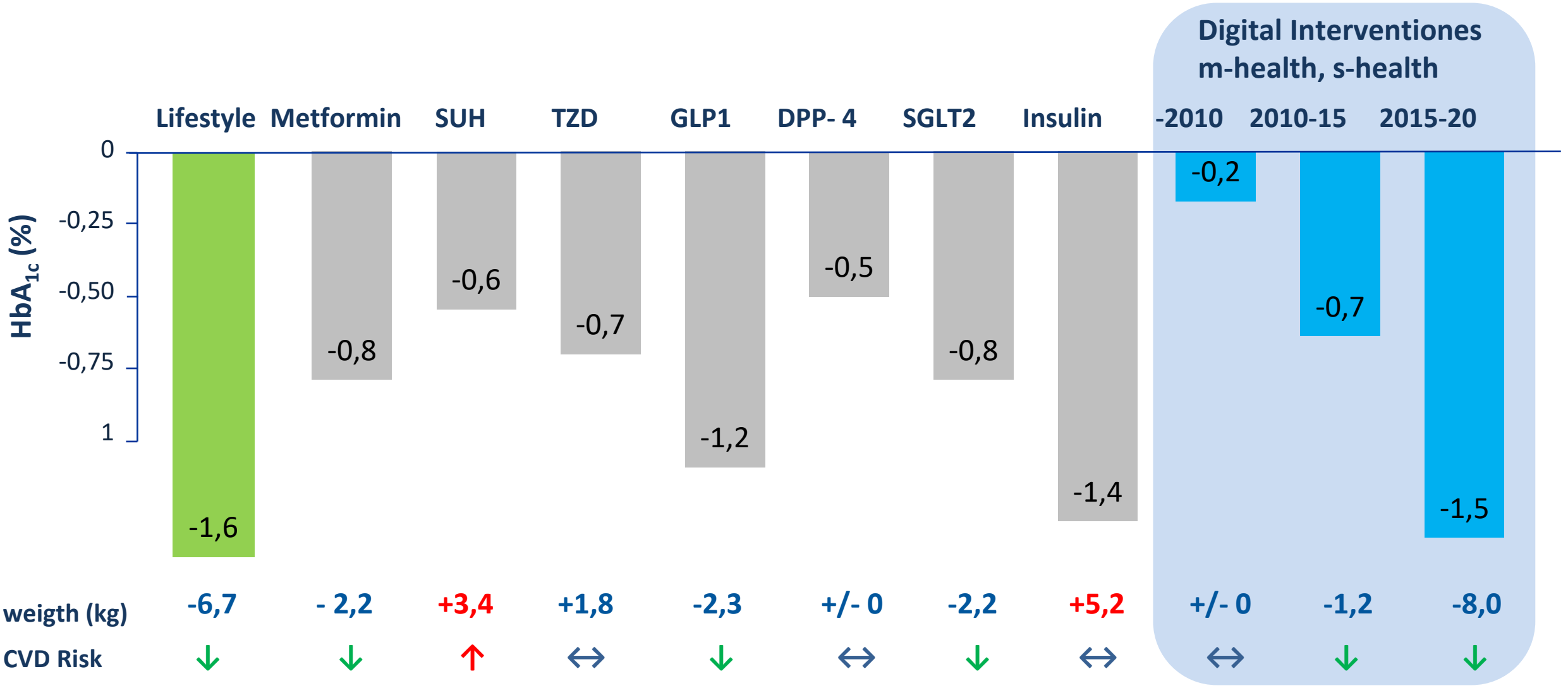
a. be knowledgeable of digital health apps and their strengths and weaknesses

b. support and inform people with diabetes on the use of digital health apps to augment diabetes management and lifestyle
modification

c. use health data to improve quality of care and health outcomes

Flemming et al., Diabetes Care Dec 2019, dci190062;

Telehealth – Chance with Perspective



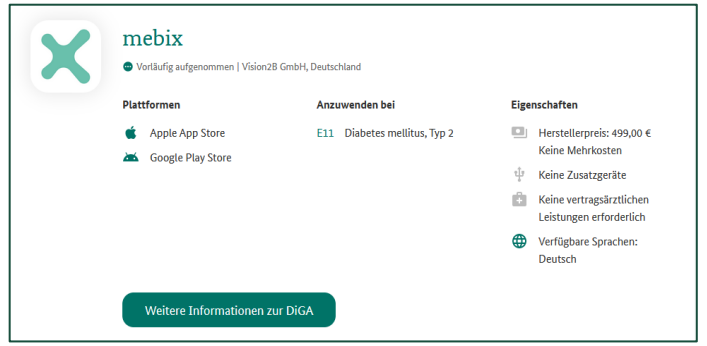
Schwarz, P.E.H., et al.,. J Am Coll Cardiol

Diabetes DiGA`s

Übersicht über die zugelassenen und im Verfahren befindlichen DiGA`s, die relevant für Diabetespatienten sind – Aktueller Stand zum 16.01.2024

	HelloBetter	Zanadio	Oviva Direkt für Adipositas	Vitadio	Mebix	Glucura	Una Health	DiaNow	Gro Health	Diaxilo	ONETWO DiGA	Diamontech	Diabook	VIDEAimpuls	VIDEAmellitus	ESYSTA App & Portal	My Dose Coach	MySugr	Liva Diabetes
Hersteller	Get.On Institut für Online-Gesundheitstrainings GmbH	aidhere GmbH	Oviva AG	Vitadio Health Technologies GmbH	Vision2Be	Perfood GmbH	Una Health GmbH	EvivaMed Distribution GmbH	Technology House, University of Warwick UK	aidhere GmbH		DiaMonTech AG		TUDresden und VIDEA medical	TUDresden und TUMAINI Institut	EMPERRA GmbH	Sanofi-Aventis Deutschland GmbH	mySugr GmbH (Roche Holding AG)	Liva Healthcare
DiGA-Verfahren	Zulassung vollständig	Zulassung vollständig	Zulassung vollständig	Vorläufige Zulassung Q4/2022	vorläufige Zulassung Q7/2023	Vorläufige Zulassung Q1/2024	vorläufige Zulassung Q4/2023 erwartet	In Entwicklung	In Entwicklung	In Entwicklung	In Entwicklung	In Entwicklung	In Entwicklung	In Entwicklung	In Entwicklung	zurückgezogen, Zulassung Q3/2023 erwartet	verschoben	Bisher abgelehnt	zurückgezogen
Indikation	E10, T1DM E11, T2DM	E66, Adipositas	E66, Adipositas	E11, T2DM	E11, T2DM	E11, T2DM	E11, T2DM	E11, T2DM	E11, T2DM	E11, T2DM	E10, T1DM E11, T2DM	E10, T1DM E11, T2DM	E11, T2DM	E10, T1DM E11, T2DM	E11, T2DM	E10, T1DM E11, T2DM	E11, T2DM	E10, T1DM E11, T2DM O24.4, GDM	E11, T2DM
Kontraindikation	Kein Vorliegen einer Depression	~~F03~~, F23 , F24 , F66.02	F03, E10, ~~F23~~, F24	keine	keine	keine	Behandlung mit Insulin oder Sulfonylharnstoffe	keine		keine	keine	keine	keine	keine	keine	keine	Behandlung ~~mit~~ humanen Insulin, Mischinsulin oder mehrfach Basalinsulins		keine
PZN	**17167827**	**16898701**	**17850257**	**18107046**	**18851431**	Nach Abschluss DiGA Verfahren	Nach Abschluss DiGA Verfahren	Nach Abschluss DiGA Verfahren	Nach Abschluss DiGA Verfahren	Nach Abschluss DiGA Verfahren	Nach Abschluss DiGA Verfahren	Nach Abschluss DiGA Verfahren	Nach Abschluss DiGA Verfahren	Nach Abschluss DiGA Verfahren	Nach Abschluss DiGA Verfahren		Nach Abschluss DiGA Verfahren	Nach Abschluss DiGA Verfahren	Nach Abschluss DiGA Verfahren
Belastung des Heilmittelbudgets	Nein	Nein	Nein	Nein	Nein	Nein	Nein	Nein		Nein	Nein	Nein	Nein	Nein	Nein	Nein	Nein	Nein	Nein
Kosten für den Patienten	keine	keine	keine	keine	keine	keine	keine	keine		keine	keine	keine	keine	keine	keine	keine	keine	keine	keine
Empfohlene Dauer der Anwendung	6-12 Monate	6-12 Monate	3-12 Monate	6-12 Monate	6-12 Monate	3 Monate	3 Monate	6 – 12 Monate		6-12 Monate	6-12 Monate	6-12 Monate	6-12 Monate	6-12 Monate	6-12 Monate	min. 12 Monate			6-12 Monate
Ziel		langfristige Gewichtsreduktion sowie eine Verbesserung der Lebensqualität und des Wohlbefindens durch Unterstützung von Lebensstiländerungen im Bereich Ernährung, Bewegung und Verhalten.	Gewichtsreduktion, Verbesserung Gesundheitsverhalten sowie Etablierung neuer gesundheitsförderlicher Ernährungs- und Bewegungsgewohnheiten	multimodaler Therapieansatz nach S3-Leitlinien, um zu einer verbesserten Diabeteskontrolle durch Unterstützung des Selbstmanagements von Typ-2-Diabetikern, zu motivieren	Mebix bietet einen multimodalen Therapieansatz nach S3-Leitlinien, um zu einer verbesserten Diabeteskontrolle durch Unterstützung des Selbstmanagements von Typ-2-Diabetikern, zu motivieren, eine Therapiemanager unterstützt die Arzt-Patienten-Interaktion	Glucura bietet Patientinnen mit Diabetes Typ 2 personalisierte Einblicke in den Einfluss ihres Lebensstils auf ihren Stoffwechsel. Und eine personalisierte Ernährungsberatung	Una Health bietet Patientinnen mit Diabetes Typ 2 personalisierte Einblicke in den Einfluss ihres Lebensstils auf ihren Stoffwechsel. Diese Einblicke werden mit strukturierten Bildungsinhalten kombiniert, um ein verbessertes Selbstmanagement und eine nachhaltige Verhaltensänderung zu fördern	DiaNow bietet einen multimodalen Therapieansatz nach S3-Leitlinien für ein verbessertes Diabetes-Selbstmanagement von Patienten mit Typ-2-Diabetes. Außerdem soll eine Motivation zur Lebensstil-Veränderung (Gewichtsoptimierung, gesunde Ernährung und Steigerung der körperlichen Aktivität) unterstützt werden.	Die evidenzbasierte, digitale Gesundheitsarchitektur von Gro Health wurde entwickelt, um Menschen auf eine speziell auf sie zugeschnittene Weise zu helfen ihre selbst gewählten Ziele zu erreichen	Edukativer Therapieansatz nach S3-Leitlinien, um eine verbesserte Diabeteskontrolle von Typ-2-Diabetikern zu unterstützen	Digitaler multimodaler Therapieansatz nach S3-Leitlinien, um zu einer geglätteten Glukosekurve zu kommen durch AI basierte Unterstützung des Selbstmanagements von Typ-2-Diabetikern, zu motivieren	Diamontech nutzt, nicht-invasive photothermische Detektion, um Blutzuckermessung möglich zu machen, um die Stoffwechsel-situation von Diabetikerinnen und Diabetikern verbessern.	BE Berechnung	Digitaler multimodaler Therapieansatz nach S3-Leitlinien, um zu einer verbesserten Diabeteskontrolle durch Unterstützung des Selbstmanagements von Typ-2-Diabetikern, zu motivieren	Digitales Bewegungsprogramm für Diabetiker, um den Patienten zu mehr Bewegung, muskulärer Kräftigung und Alltagsaktivität zu motivieren und zur verbesserten Diabeteskontrolle beizutragen	Stoffwechsel-situation von insulinpflichtigen Diabetikerinnen und Diabetikern verbessern	Patienten bei der Durchführung einer basalunterstützten oralen Therapie (BOT) durch automatisierte Dosisempfehlungen und Erinnerungsfunktion zu unterstützen und das Selbstmanagement der Therapie zu verbessern.	mySugr nutzt eine spielerische Herangehensweise, um Patienten zu motivieren ihr Selbstmanagement zu verbessern	nutzt eine spielerische Herangehensweise, um Patienten zu motivieren ihr Selbstmanagement zu verbessern
Registrierte Studien	DRKS00004748 Leuphana Universität Lüneburg	DRKS00024415 DRKS00026606 mit Uni Leipzig	Studie in Durchführung mit TU München	NCT04573296 DRKS00027392 DRKS00027405 mit TU Dresden	DRKS00032547 DRKS00032395 RCT Studie im Antragsprozess mit TU Dresden	Studien in Vorbereitung mit verschiedenen Partnern	DRKS00027392, Studien in Vorbereitung	Studien in Vorbereitung mit verschiedenen Partnern	Studien in Vorbereitung mit verschiedenen Partnern			Studien in Vorbereitung mit verschiedenen Partnern		DRKS00017392 Weitere Studie in Vorbereitung mit TU Dresden	DRKS00017392 Weitere Studie in Vorbereitung mit TU Dresden	DRKS00025996 Studie in Vorbereitung mit TU Dresden	DRKS00024861 mit Bad Mergentheim	DRKS00022923 mit Bad Mergentheim	Studien in Vorbereitung mit verschiedenen Partnern
Risikoklasse	RK I MDD	RK I MDD	RK I MDD	RK I MDD	RK I MDR (erwartet)	RK IIa MDR	RK I MDR (erwartet)	RK IIa MDR		RK I MDD				RK I MDR	RK I MDR	RK I MDD	RK IIa MDR		RK IIa MDR
Referenzen	[1]	[2, 3] [4]	[5-8]	[13][14]	in Vorbereitung		in Vorbereitung							[9, 15-20]	[9, 15-20]	[26-28]	[9, 29]	[30-34]	[21-25]
Patientenklientel	HelloBetter Diabetes und Depression kann als nachweislich wirksam in der Reduktion depressiver Symptome bei Patienten mit Diabetes mellitus Typ I oder Typ II eingestuft werden	Übergewichtige Typ 2 Diabetiker mit digitaler Affinität	Übergewichtige Typ-2 Diabetiker, mit digitaler Affinität, die sich erstmals vertieft mit ihrer Ernährung und ihren Gewohnheiten auseinandersetzen möchten.	Typ 2 Diabetiker mit Interesse an Lebensstiländerung und die sich digitale Unterstützung wünschen	Patienten mit Diabetes Typ 2 mit Interesse an einem besseren Verständnis ihres Stoffwechsels und einer gezielten Lebensstilanpassung	Patienten mit Diabetes Typ 2 mit Interesse an einem besseren Verständnis ihres Stoffwechsels und einer gezielten Lebensstilanpassung	Patienten mit Diabetes Typ 2 mit Interesse an einem besseren Verständnis ihres Stoffwechsels und einer gezielten Lebensstilanpassung	Patienten mit Typ-2-Diabetes (alle Therapieformen) mit Interesse an digitalem Diabetes-Selbstmanagement und Lebensstiländerung	Typ 2 Diabetiker mit Interesse an Lebensstiländerung und die sich digitale Unterstützung wünschen	Typ 2 Diabetiker mit Interesse an Lebensstiländerung und die sich digitale Unterstützung wünschen	Typ 1 Diabetiker mit Interesse verbessertem Selbstmanagement mithilfe digitaler Unterstützung	Patienten mit Diabetes Typ 2 mit Interesse an einem besseren Verständnis ihres Stoffwechsels und einer gezielten Lebensstilanpassung	Typ 2 Diabetiker mit Interesse an einer Ernährungsumstellung mithilfe digitaler Unterstützung	*Typ 2 Diabetiker mit Interesse verbessertem Selbstmanagement mithilfe digitaler Unterstützung*	Typ 2 Diabetiker mit Interesse an Lebensstiländerung und dem Interesse sich mit digitaler Unterstützung mehr zu bewegen	Diabetiker, die mit Insulin behandelt werden	Menschen mit Typ-2-Diabetes, die die Umsetzung ihrer BOT im Alltag verbessern möchten.		Menschen mit Typ-2-Diabetes, die die Umsetzung ihrer BOT im Alltag verbessern möchten.

Klassifikation für DiGAs/Software - Hintergrund



Übersicht zu Funktionalitäten der zugelassenen und im DIGA-Verfahren befindlichen DiGAs mit Relevanz für Diabetespatienten – Stand 16.01.2024

	Hello Better	Zanadio	Oviva Direkt	Vitadio	Mebix	Glucura	Una Health	DiaNow	Gro Health	Diaxilo	ONE TWO DiGA	Diamon tech	Diabook	VIDEA impuls	VIDEA mellitus	ESYSTA App & Portal	My Dose Coach	Mysugr	Liva Diabetes
Einbindung von Geräten							X	X	X		X	X				X	X	X	
Dokumentation von BZ/Insulin								X			X	X				X	X	X	
Feedback Ampelfunktion				X	X	X	X	X			X	X				X		X	
Tracken von Bewegung		X	X	X	X	X	X		X		X			X	X			X	
Tracken von Ernährung	X	X	X	X	X	X	X	X	X	X	X		X	X	X			X	
Tracken von QoL	X	X			X	X	X		X	X	X			X	X				
CGM-Sensor eingebunden						X	X	X			X								
Intervention (Bewegung)	X							X	X		X			X	X				
Intervention (Ernährung)	X							X		X	X		X	X					
Intervention (Motivation)	X							X	X		X			X	X				
Motivational messaging		X		X				X	X					X	X			X	
Intervention (Verhalten/Selbstmanagement)	X	X		X				X			X			X	X				X
KVT	X	X		X										X	X				
Gezielte Ernährungsberatung	X	X	X	X		X	X							X					
Gezielte Diabetesberatung				X		X	X				X			X				X	
Gezielte Bolusempfehlung																	X	X	
Persönliche Beratung	X	X		X										X	X		X		X
AI basierte Intervention				X		X			X		X								
Strukturierte Diabetesschulung										X				X					
Einbindung in Diseasemanagement				X	X			X						X		X			
Nachhaltige Verhaltensänderung	X	X		X	X			X						X					

India

Schweden

Digital transformation of diabetes care in order to help healthcare providers to better and faster interpret the large amount of CGM data

Data upload from CGM to OneTwo Analytics

Based on CGM data uploaded to the cloud, OneTwo Analytics generates automatic clinical knowledge.

Basis for better decisions about care & prioritizations

- Automatic meal analysis without manual logging of meals
- Individual glucose profiling with root causes and explanations
- Periodic summaries including glucose control and risk score

OneTwo Diabetes - Patient self monitoring App with clinical coaching

Time in range

Shows the part of the day as you have a glucose value between 3,9 and 10,1 mmol/l

Meals

Automatic identification of meal events and calculation of pre, post, peak and other metrics

Low values

Analyzing episodes with low values or severe low values, including duration

High values

Analyzing episodes with high values or severe high values, including duration

Fluctuations

Shows how much your glucose varies in per cent

Insulin effect

shows how much the glucose level increases or decreases per hour in absence of meals

- Coaching to the individual with T1 or T2 who is using a CGM continuously.
- Providing coaching on the same level as a diabetes nurse or a diabetes educator.
- Six main analysis as well as comprehensive summaries in easy-to-understand language.
- Scoring system for gamification.

Download on the App Store

GET IT ON Google Play

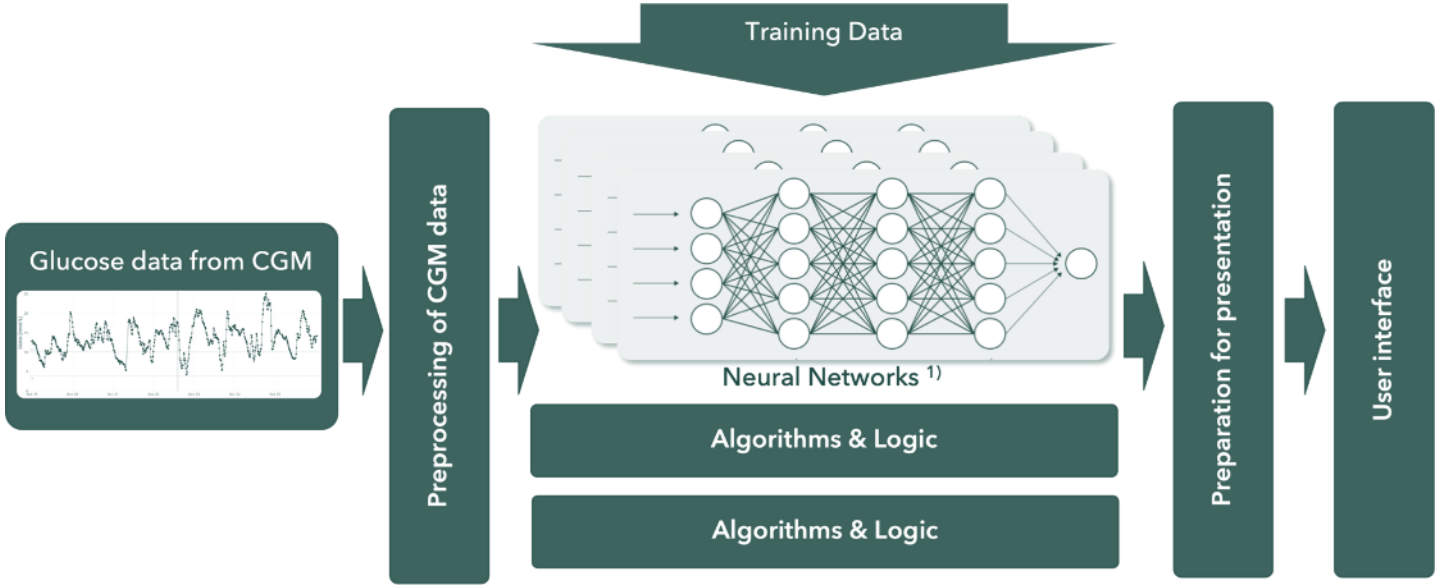
OneTwo Diabetes

www.onetwo-diabetes.com

OneTwo Analytics

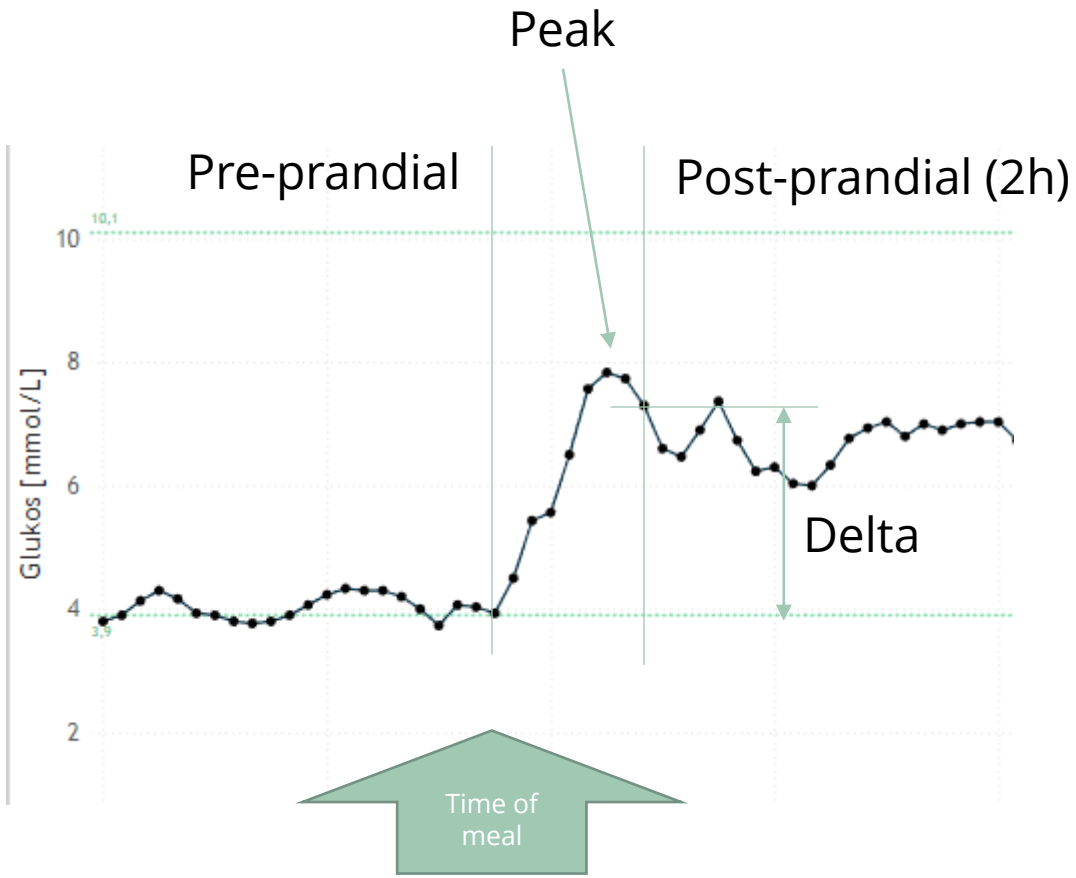
The flow of data though the AI / ML based analysis engine

- The AI/ML improves the analytic abilities to analyze patient CGM data and detect events such as meals and abnormalities for faster interpretation.
- The AI/ML engine is trained by research data from Uppsala University on over 1000 patients including 50,000 hypoglycemic events.
- Algorithms are currently Rev 3.



OneTwo Analytics

Automatic meal analysis

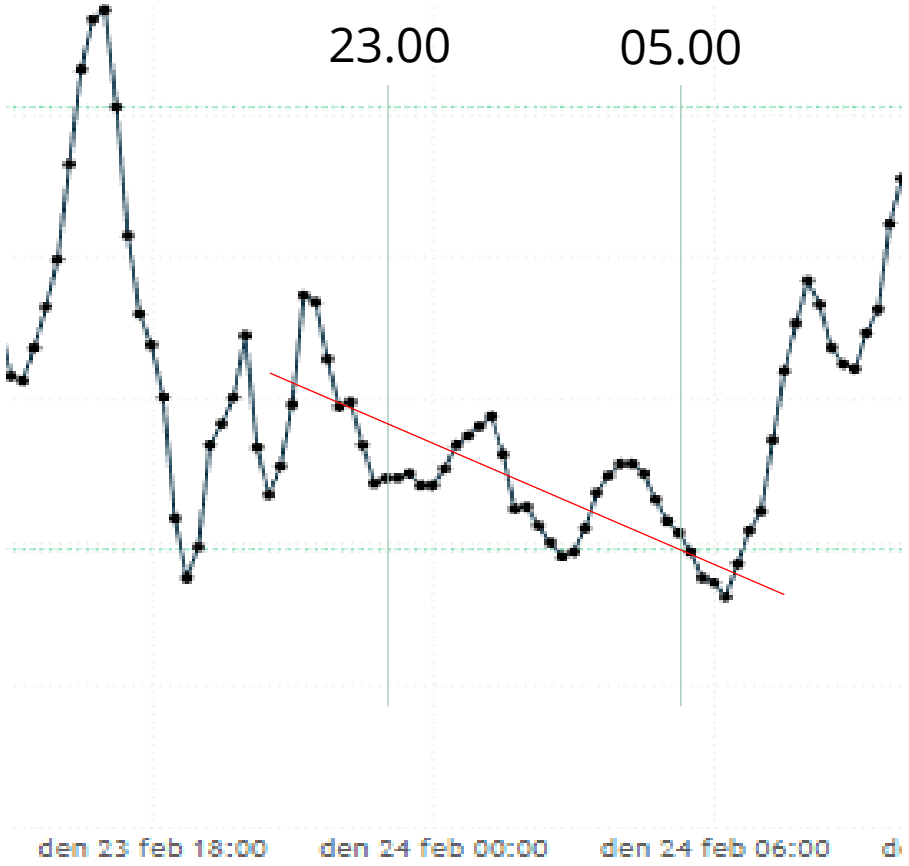


- No registration in CGM is needed
- Time of Meal identified by ML trained to identify meal patterns
- Given Time of Meal; Pre-prandial, Post-prandial, Delta and Peak values are calculated

OneTwo Analytics

Night time insulin effect analysis

- Identification of night trend as a linear regression averaging over e.g. 14 days
- Automatically exclude nights with episodes like meals, hypos (not caused by basal pressure) and hypers
- Present trend together with fasting glucose level



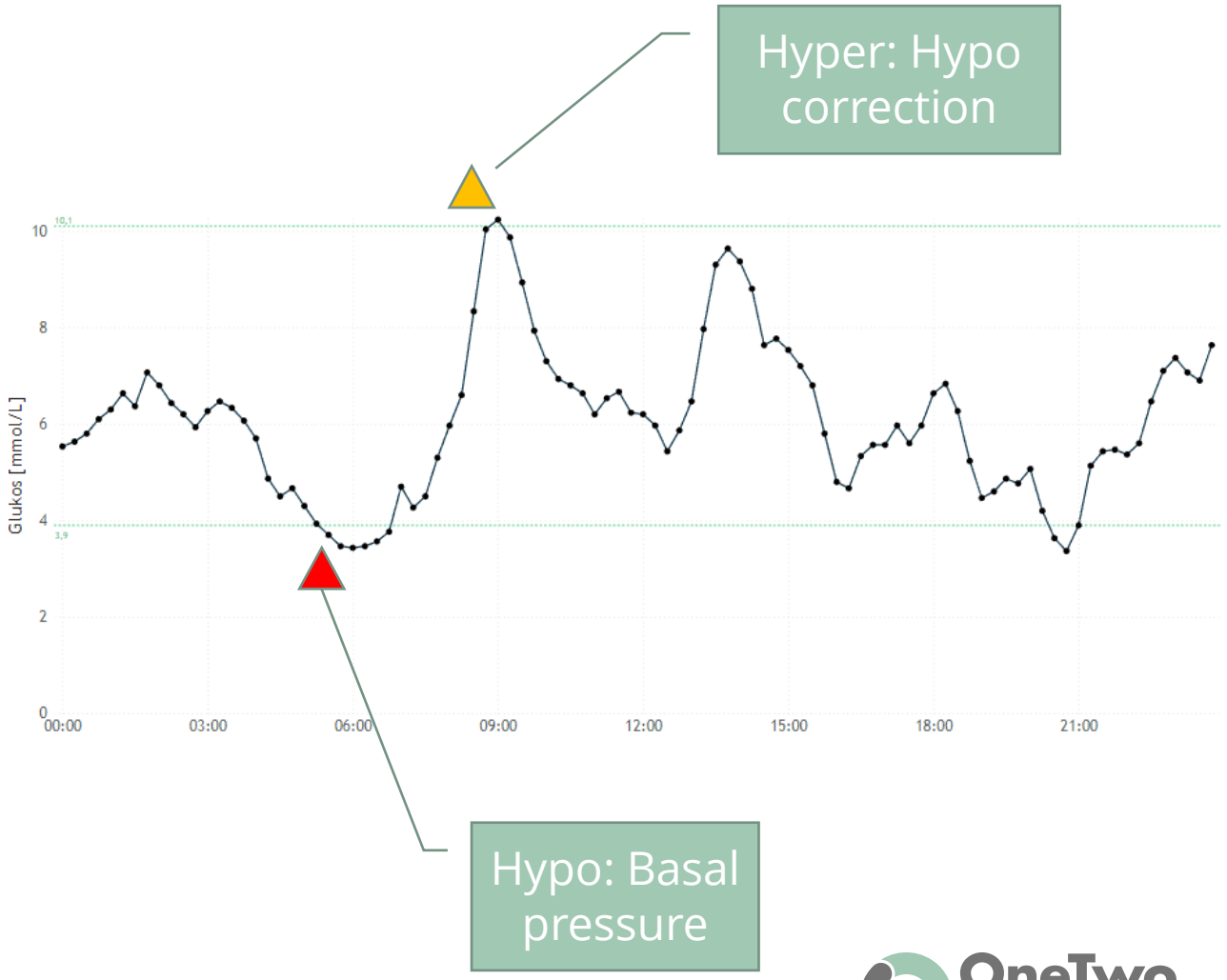
Nightly glucose trend
Change in glucose during the night

Average nightly trend (mmol/l per h)	0.09
Average fasting glucose (mmol/l)	7.7

OneTwo Analytics

Hypo and hyper identification and root cause analysis

- ML modules are trained in identification of root causes behind hypo and hyper episodes
- Hypo causes:
  - High basal pressure
  - Hyper correction
  - High meal bolus
- Hyper causes:
  - Lack of basal
  - Hypo correction
  - Lack of bolus at meal



OneTwo Analytics

Ruanda

Digital Biomarker

Using digital Biomarker to diagnose diseases

- Tracking digital biomarker on the smartphone of the patient
- Analysing these biomarker in the context of the lifestyle and environment using AI
- Diagnosing diseases and starting this autonom treatment or transfer the patient
- follow up treatment progress and adjust therapy

Digital Biomarker – Chance mit Perspective

Wearable devices and smartphones

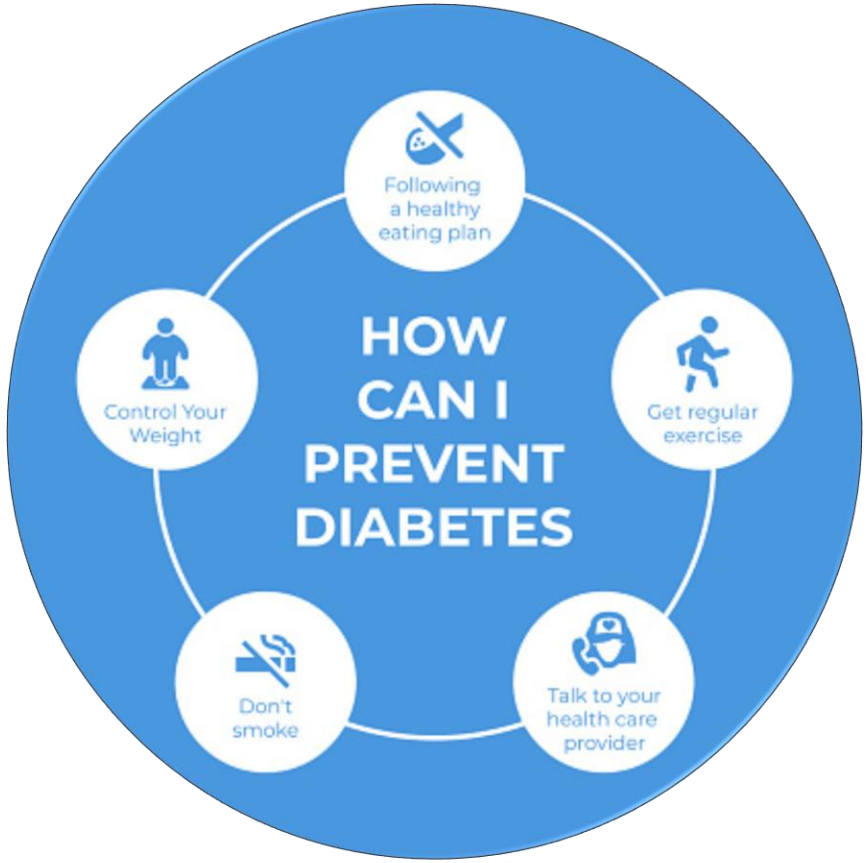
Data acquisition and analysis

Visualizing patient outcomes
Proving drug values
Understanding diseases

Smart Health - the Future of Diabetes Care

Providing intervention and therapy

Digital diabetes education 24/7/365



Preventing Diabetes

Digital Biomarker – Chance with Perspective

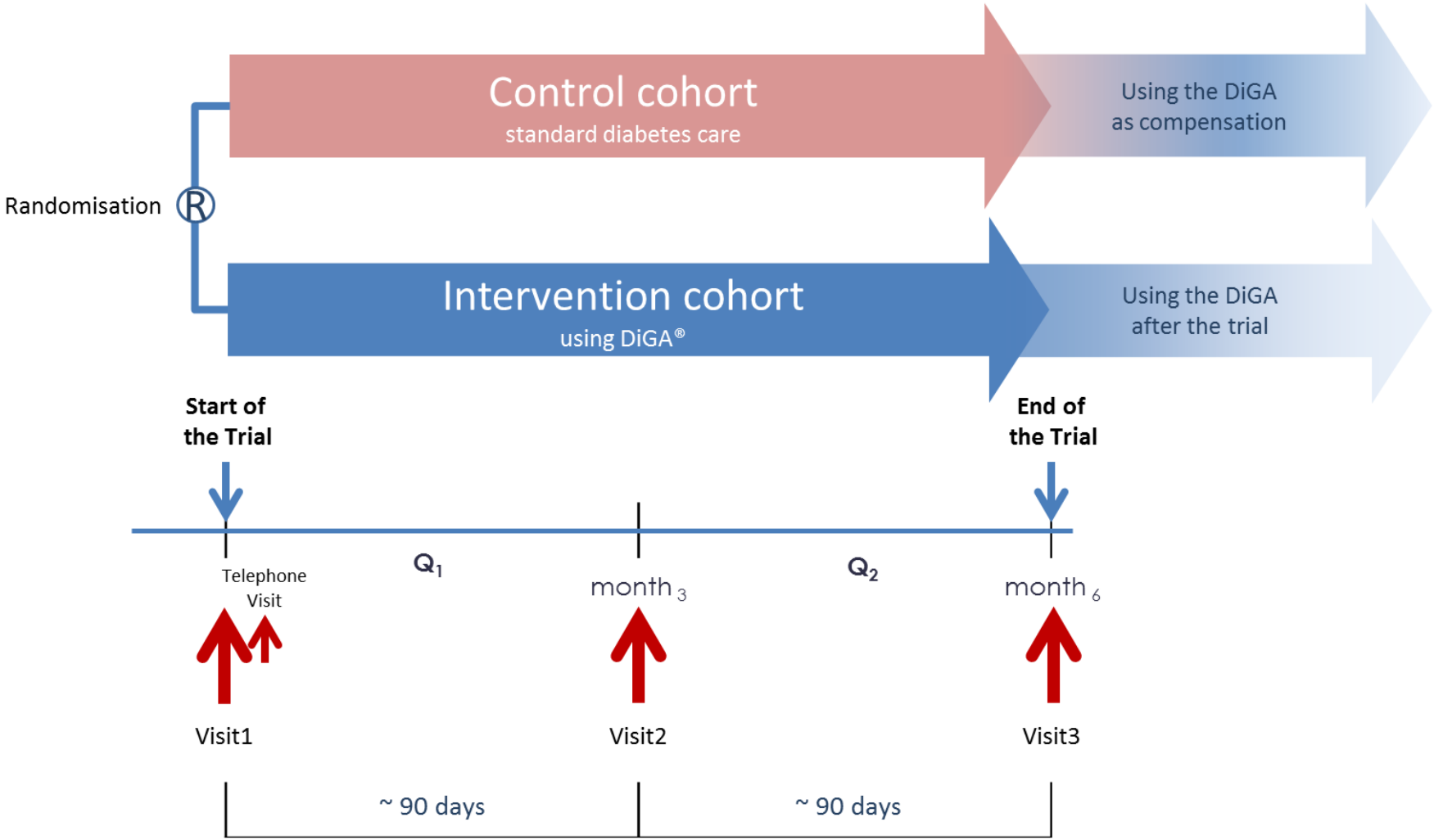
- ✓ Using digital biomarker to diagnose Diabetes
- ✓ Digital Diabetes Education using glucose sensor for 50 ct ✗
- ✓ Digital Diabetes therapy (digital Diabetologicum) ✗

YES

Walk away from Diabetes

Evidence for Diabetes DiGA`s

Evaluation mit DiGA - RCT



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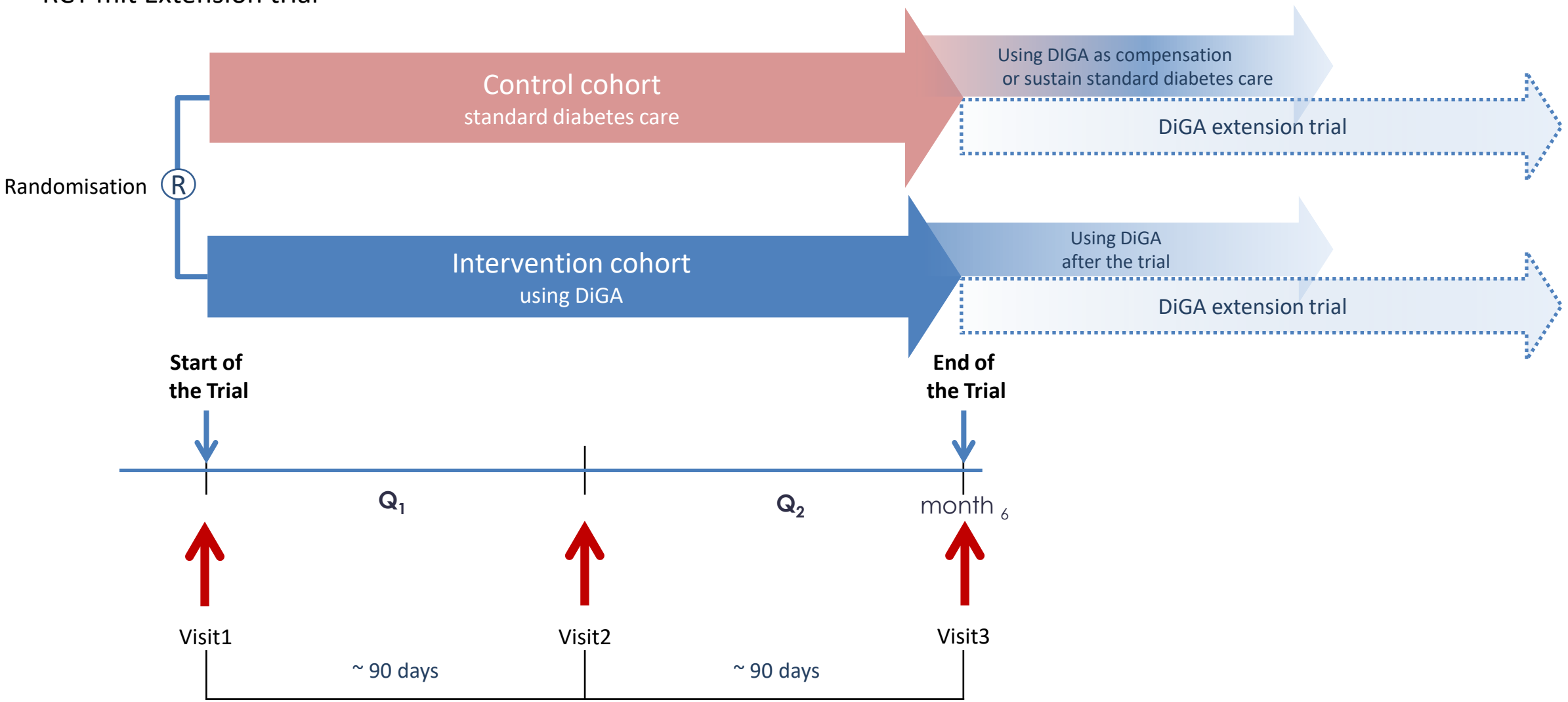
RCT mit Extension trial



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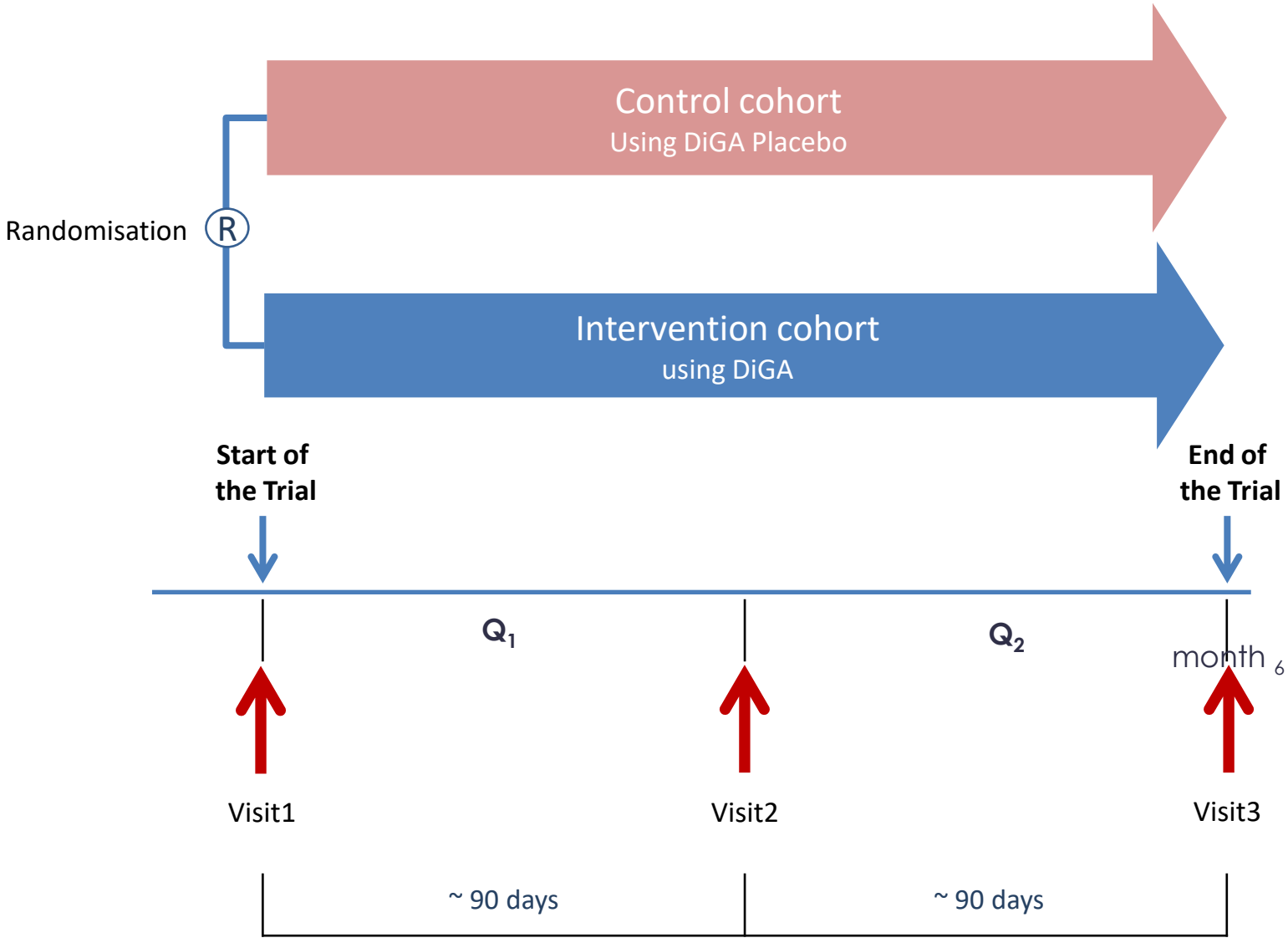
Verblindete RCT mit Extension trial



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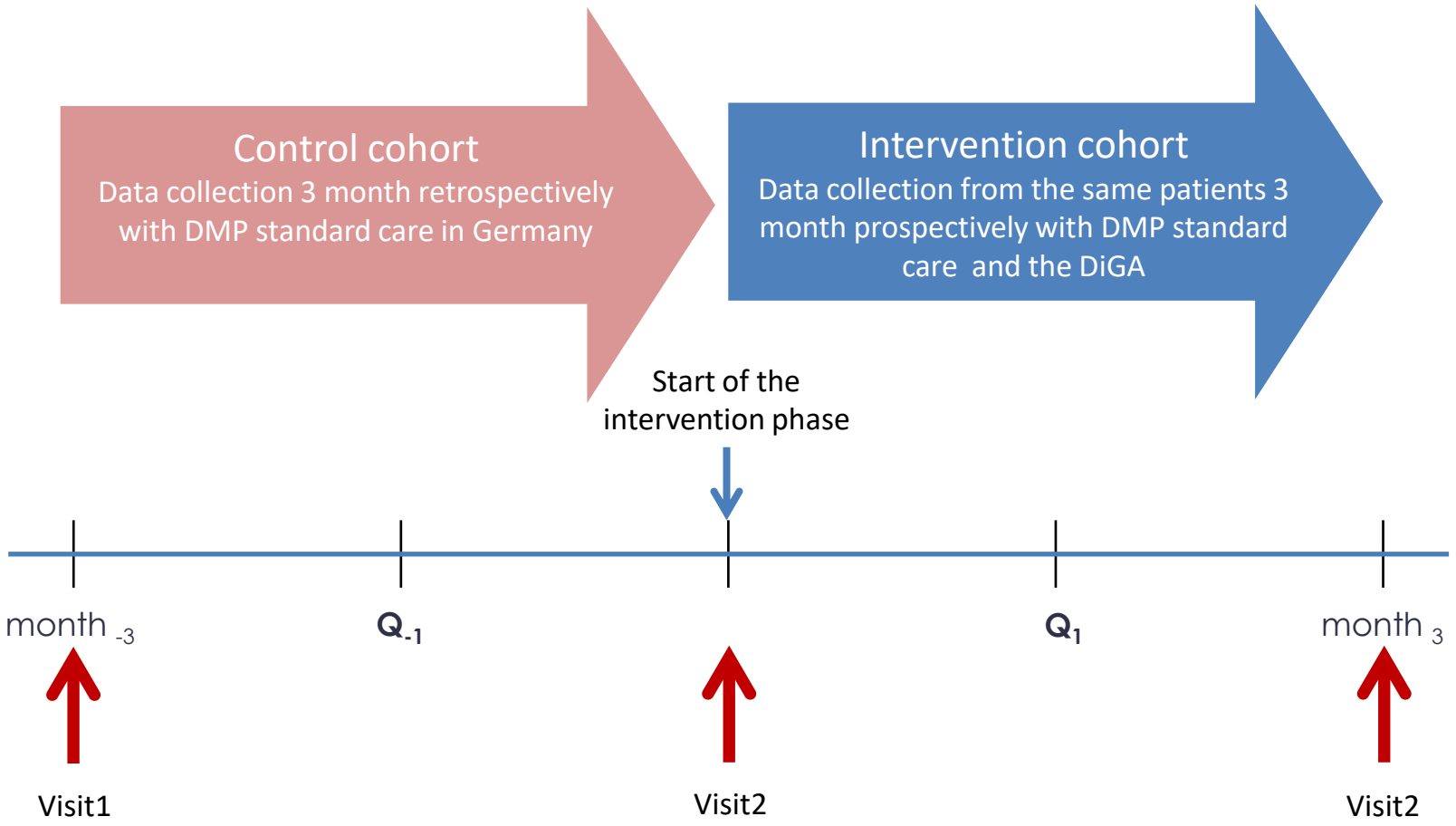
EDDY Design



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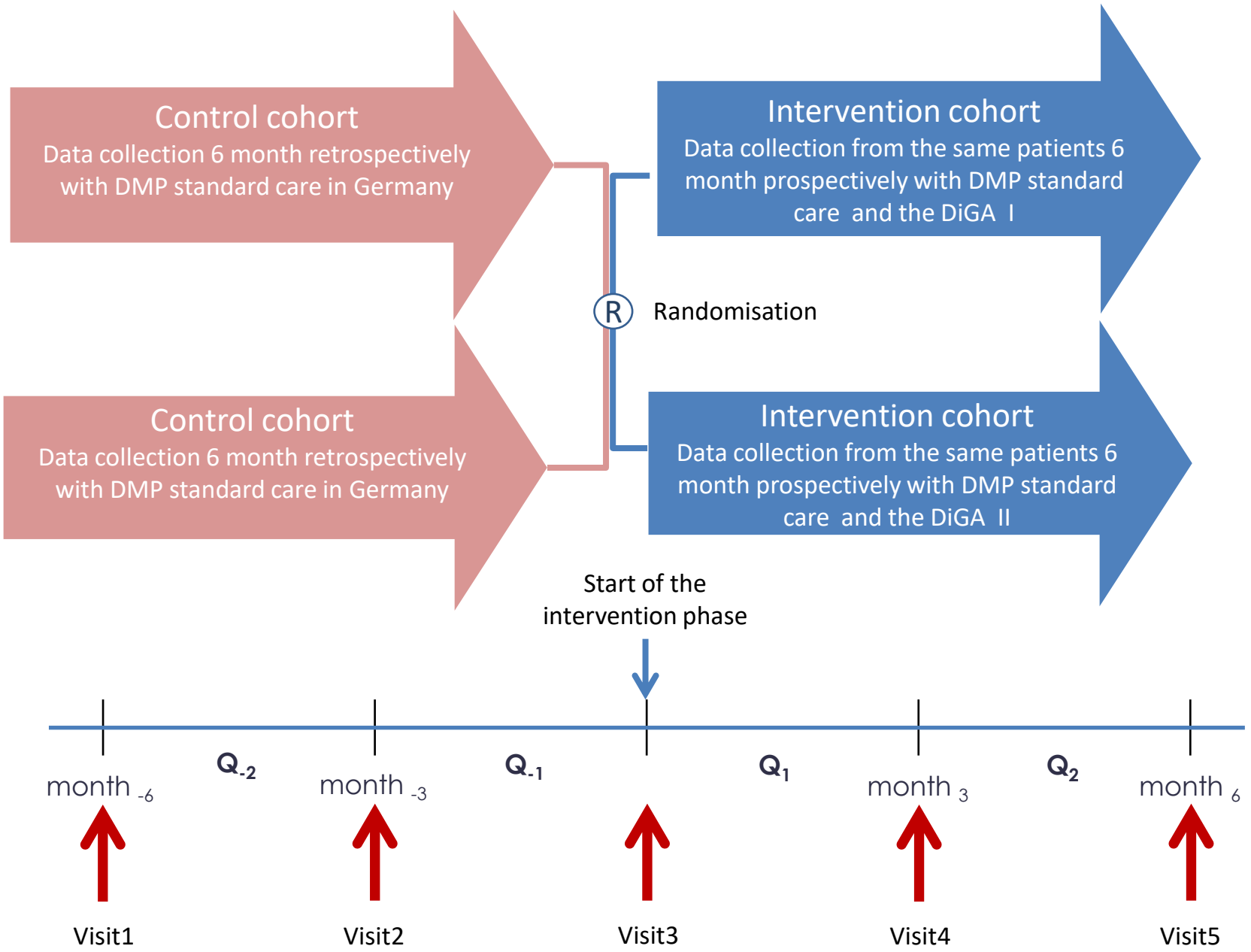
Verblindete RCT mit 2 Interventionen mit intraindividueller Kontrollgruppe



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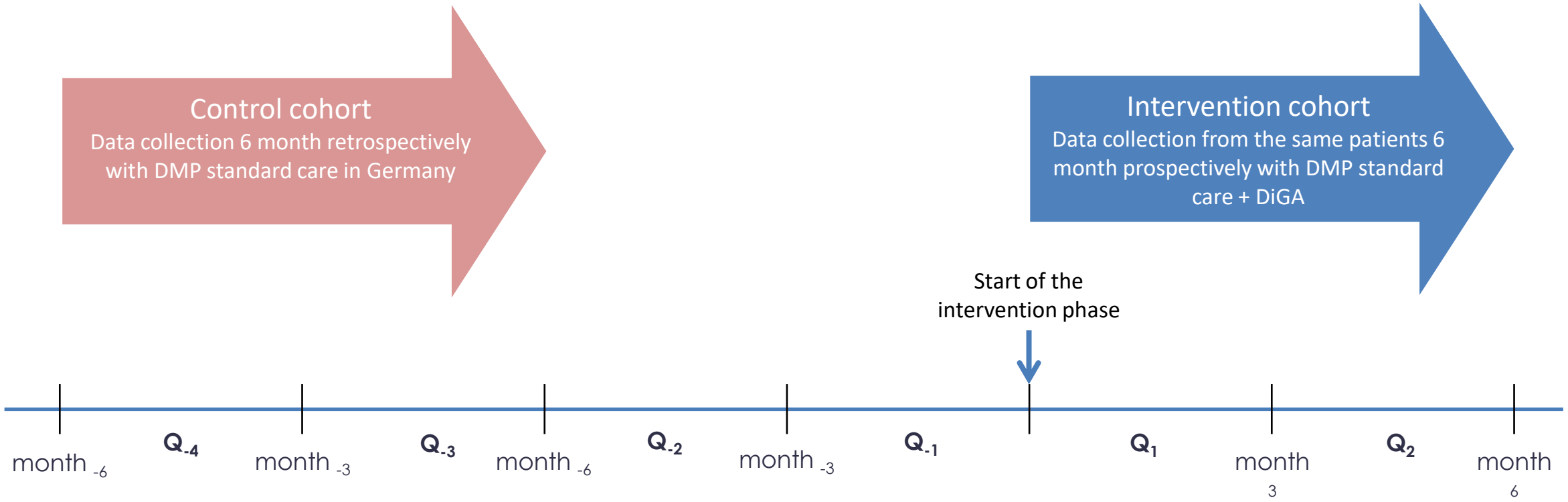
EDDY 6 Monate Design



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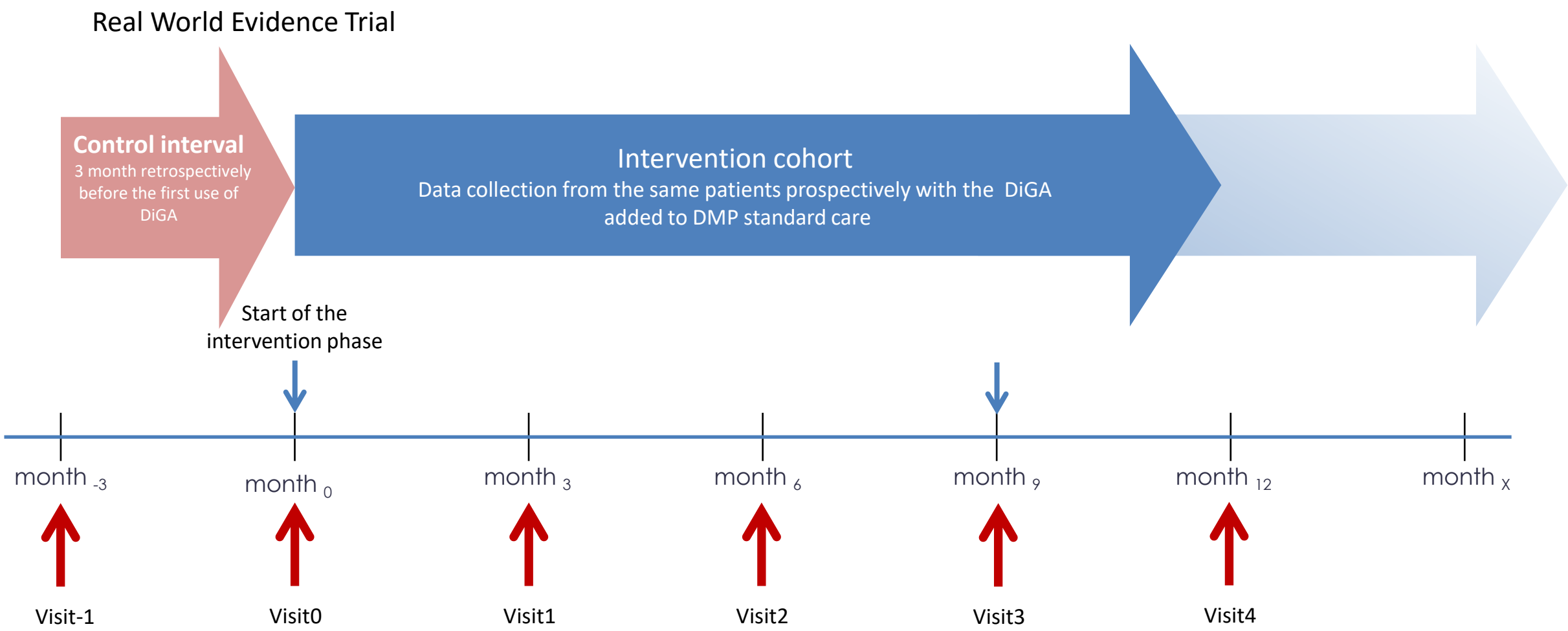

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