Financing and making available of digital health applications in Europe

End report

For: Integral Care Agreement task force Digital and Hybrid Health, Care and Wellness
Represented by: The Ministry of Health, Welfare and Sport of the Netherlands
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Opdracht

De bedoeling van dit onderzoek was met een combinatie van deskresearch en interviews een concreet, tastbaar en bruikbaar antwoord te vinden op de volgende 6 vragen:
1. Op welke wijze is/of gaat er invulling gegeven (worden) aan de financiering en/of beschikbaarheid van digitale toepassingen (zoals gezondheids-apps ((zelf)zorg en zelfmanagement-apps)) voor burgers, cliënten en patiënten in andere landen dan Nederland?
2. Welke verantwoordelijkheid neemt de overheid/gaat de overheid van de andere landen (nemen) in het financieren en/of beschikbaar maken van voorzieningen en toepassingen benoemd bij 1?
3. Welke bevorderende factoren in andere landen zijn aan te wijzen ten aanzien van het initiëren, organiseren en inbedden van de gekozen (financiële) aanvliegroute aldaar?
4. (Op welke manier) hebben initiatieven in andere landen bij financieringsvraagstukken ook het (toekomstig) businessmodel van de leveranciers van de toepassingen (zoals gezondheidsapps) meegenomen?
5. Welke geleerde lessen en/of ‘succesverhalen/mislukkingen’ zijn bekend uit andere landen en waardoor hebben ze tot die effecten geleid?
6. Tot welke graad/mate van adoptie van digitale toepassingen (zie definitie bij 1) heeft de gekozen (financiële) aanvliegroute anno 2025 geleid bij burgers, cliënten en patiënten en professionals en is het initiatief onderdeel van de cultuur geworden/aan het worden?

Samenvatting

Passende zorg, arbeidsbesparing, betaalbaarheid, duurzame toegankelijkheid en verduurzaming van de zorgsector vragen om een versnelling van de digitalisering in Nederland. Passende zorg betekent steeds vaker (digitale en) hybride zorg. Onder hybride zorg wordt verstaan de waar mogelijk gepersonaliseerde maatwerk / mix van digitaal en fysiek aangeboden zorg en ondersteuning van gezondheid. Uitgangspunten hierbij zijn, gebaseerd op gezamenlijke besluitvorming: zelf als het kan, thuis als het kan en digitaal als het kan. Eén van de ambities die zijn overeengekomen in het Integraal Zorgakkoord (IZA, 2022), ondertekend door een groot aantal partijen in de zorg en het Ministerie van Volksgezondheid, Welzijn en Sport, was om te onderzoeken welke zorgpaden geschikt zijn voor digitale en/of hybride zorg. Van deze geschikte zorg komt 70% digitaal of hybride beschikbaar. Bedoeling is dat tegen eind 2026 minimaal 50% van de patiëntenpopulatie voor wie de hybride zorgpaden geschikt zijn, hiervan gebruikmaakt.

Het doel van dit rapport is om te leren van ervaringen in andere Europese landen om deze ontwikkelingen te bevorderen. Daartoe heeft het Ministerie van Volksgezondheid, Welzijn en Sport opdracht gegeven tot een analyse van zes belangrijke vragen met betrekking tot de financiering en beschikbaarheid van digitale gezondheidstoepassingen buiten Nederland. Dit rapport beschrijft de gebruikte methoden, een combinatie van deskresearch en interviews, de antwoorden op de zes vragen en aanbevelingen voor de Nederlandse context. Om de zes vragen te beantwoorden, zijn elf landenprofielen opgesteld (zie Appendix 1). De elf landen, België, Denemarken, Engeland, Estland, Finland, Frankrijk, Duitsland, Italië, Nederland, Noorwegen en Spanje (c.q. de regio Catalonië), zijn gekozen op basis van de literatuur over koplopers op het gebied van financiering van digitale gezondheidstoepassingen. De categorieën binnen de landenprofielen zijn gekozen op basis van de zes vragen en de relevante literatuur. De categorieën betreffen Beleid, Scope, wat als Waarde wordt beschouwd en daarmee reden is voor financiering, Maatregelen om die waarde te oogsten, Impactramingen, Vergoedingsregelingen, Prijsstelling, Uitvoering, Adoptie en Geleerde lessen.

Het geconsolideerde antwoord op de zes vragen met betrekking tot de financiering en beschikbaarheid van digitale gezondheidstoepassingen is:

1. Op welke wijze is/of gaat er invulling gegeven (worden) aan de financiering en/of beschikbaarheid van digitale toepassingen (zoals gezondheids-apps ((zelf)zorg en zelfmanagement-apps)) voor burgers, cliënten en patiënten in andere landen dan Nederland?
Alle 11 landen bieden of streven naar financiering en/of beschikbaarheid van digitale gezondheidstoepassingen. De Scope van producten, de Waarde die wordt toegekend aan deze producten, Maatregelen om die waarde te oogsten, waaronder toetsingskaders, Vergoedingsregelingen en Prijsstelling verschillen en overlappen. Iedereen is nog bezig uit te zoeken wat werkt, maar de dominante richting lijkt een combinatie van vergoeding van digitale gezondheidstoepassingen, waar van toepassing aangevuld met vergoedingen voor zorgprofessionals, of betaling voor hybride zorgpaden. Verschillende landen maken, al dan niet op het nationale gezondheidsportaal, een overzicht met vergoede of aanbevolen digitale gezondheidstoepassingen beschikbaar. De toepassingen kunnen worden voorgeschreven of aanbevolen door zorgprofessionals. In sommige landen kunnen inwoners de verzekeraar rechtstreeks om vergoeding vragen of toepassingen zelf downloaden. Doorgaans zijn hier geen kosten aan verbonden. Prognoses op bijvoorbeeld jaarbasis van de overall impact voor het zorgstelsel van het gebruik van deze toepassingen zijn er vooralsnog nauwelijks.

2. Welke verantwoordelijkheid neemt de overheid/gaat de overheid van de andere landen (nemen) in het financieren en/of beschikbaar maken van voorzieningen en toepassingen benoemd bij 1?
Over het algemeen zijn de rollen vergelijkbaar met die voor gezondheidszorg, geneesmiddelen en medische hulpmiddelen. Het Ministerie van Volksgezondheid stelt beleid vast en ondersteunt, ook financieel, onderzoek, innovatie en transformatie. De betaler van gezondheidszorg, geneesmiddelen en medische hulpmiddelen betaalt of vergoedt de digitale gezondheidstoepassingen of hybride zorgpaden. Als er een autoriteit of binnen een autoriteit een afdeling verantwoordelijk is voor digitale gezondheid, speelt deze doorgaans een rol in toetsen van de toepassingen. Naast de overheid zijn vaak ook stakeholders zoals beroepsverenigingen, zorgprofessionals en experts bij deze inspanningen betrokken.

3. Welke bevorderende factoren in andere landen zijn aan te wijzen ten aanzien van het initiëren, organiseren en inbedden van de gekozen (financiële) aanvliegroute aldaar?
Leiderschap, economische ambities, een gevoel van urgentie of een positie onderaan een ranglijst van landen naar mate van digitalisering, lijken een rol te hebben gespeeld. Daarnaast worden digitale gezondheidstoepassingen steeds beter en daarmee een optie als gezondheidsinterventie. Ook is er in het kader van toegankelijk houden van zorgstelsels behoefte aan het bevorderen van zelfzorg, omdat er in de zorg grenzen aan mankracht en middelen zijn en de vraag blijft groeien. Budgetten die de overheid alloceert of het zorgstelsel vraagt te alloceren, lijken over het algemeen een stimulans voor het initiëren, organiseren en inbedden van de aanpak. Hoewel initiëren met een wisselend detailniveau is vastgelegd in beleid van het Ministerie van Volksgezondheid, wordt het organiseren en inbedden, het plannen van de financiering, kiezen van de financiële aanpak en betalen waarschijnlijk overgelaten aan de betaler van de gezondheidszorg. In de huidige situatie lijken beschikbare budgetten in plaats van waarde bepalend voor de prijsstelling. Dat maakt dat fabrikanten, bij gebrek aan onderhandelingspositie, min of meer een “take it or leave it”-aanbod krijgen.

4. (Op welke manier) hebben initiatieven in andere landen bij financieringsvraagstukken ook het (toekomstig) businessmodel van de leveranciers van de toepassingen (zoals gezondheidsapps) meegenomen?
Tot nu toe bevinden de meeste landen zich nog in een soort pilot fase, waarin ze niet of slechts beperkt rekening houden met (toekomstige) businessmodels van leveranciers. Uit de geleerde lessen blijkt de noodzaak van geharmoniseerde proportionele toetsingskaders of erkennen van toetsingen van andere landen. Daarnaast zijn veranderingen in prijsstelling van digitale gezondheidstoepassingen nodig om fabrikanten in staat te stellen hun producten door te ontwikkelen naar de kwalitatieve betaalbare oplossingen die de digitale transformatie voor de diverse gezondheidsproblemen en zorgstelsels mogelijk maken.

5. Welke geleerde lessen en/of ‘succesverhalen/mislukkingen’ zijn bekend uit andere landen en waardoor hebben ze tot die effecten geleid?
Kort samengevat zijn de geleerde lessen: innovatie bevorderen, een proportioneel, geharmoniseerd duidelijk toetsingskader dat geschikt is voor digitale zorgtoepassingen, en transformatie ondersteunen.

6. Tot welke graad/mate van adoptie van digitale toepassingen (zie definitie bij 1) heeft de gekozen (financiële) aanvliegroute anno 2025 geleid bij burgers, cliënten en patiënten en professionals en is het initiatief onderdeel van de cultuur geworden/aan het worden?
Op basis van de beschikbare informatie lopen Duitsland en Noorwegen voorop wat betreft aantal gebruikers. In Duitsland kunnen artsen medische apps (‘DiGA’) voorschrijven en kunnen patiënten deze rechtstreeks aanvragen bij de zorgverzekeraar. Een overzicht van de vergoede apps, waarvan sommige een combinatie met hardware zijn, is beschikbaar op een website. In Noorwegen kunnen artsen wellness apps aanbevelen en kunnen patiënten deze

zelf downloaden van het nationale portaal Helsenorge. In beide landen wordt het onderdeel van de cultuur, hoewel de adoptie in Noorwegen afhankelijk blijkt van marketinginspanningen.

Bij het komen tot aanbevelingen hebben we rekening gehouden met de doelstellingen van IZA en AZWA, de antwoorden op de zes vragen, de landenprofielen en de literatuur. We hebben ons gericht op de financiering en beschikbaarheid van digitale gezondheidstoepassingen en mogelijkheden in Nederland.

Om fabrikanten in staat te stellen en te stimuleren om producten met toegevoegde waarde voor gebruik in zorgpaden te maken (70/50-doelstelling) en zorgprofessionals om hun routines aan te passen, hun patiënten te ondersteunen en gebruik te maken van kwalitatieve digitale gezondheidstoepassingen, en om de beoogde uitkomsten, zoals duurzame toegankelijkheid van het zorgstelsel mogelijk te maken, raden we het volgende aan:

> AANBEVELING 1: **Doe nader onderzoek naar 'value-based pricing', waardegedreven prijsstelling, zoals voorgesteld door Groene & Schneck (2023)[1] en Gensorowsky et al. (2022)[2].** Maak daarbij gebruik van de 'keuzekaarten'[1] van Thuisarts en neem hierin zowel de digitale gezondheidstoepassingen als het werk van zorgprofessionals mee.
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> AANBEVELING 2: **Realiseer op korte termijn een voorlopig vergoedings- en onderzoeksinitiatief als aanloop naar structurele vergoeding als volgende stap voor het diga.nl-initiatief.** Overweeg hierbij de vele andere wetenschappelijk bewezen en veelbelovende digitale toepassingen die met publieke financiering en anderszins zijn gerealiseerd. Onderzoek hun impact in de praktijk en hoe die nog verder uit te breiden.
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> AANBEVELING 3: **Investeer in onderzoek naar de soort ontwerpen van en interventies in digitale zorgtoepassingen en maatregelen daaromheen die waarde toevoegen, therapietrouw bevorderen en duurdere zorg voorkomen of verminderen**. Met als doel de waarde en uiteindelijk het aantal digitale en hybride zorgpaden voor een breed scala aan gebruikers te vergroten.

Om burgers en zorgprofessionals te ondersteunen bij hun gezamenlijke besluitvorming en om 'zelf als het kan, thuis als het kan, digitaal als het kan' te implementeren, lerend van andere landen (vraag 1) en hun mate van adoptie (vraag 6), raden we aan:

> AANBEVELING 4: **Overweeg om de digitale en hybride zorgpaden beschikbaar te maken in Thuisarts met de aangepaste 'keuzekaarten' uit aanbeveling 1 en bijbehorende begrijpelijke teksten.** Maak gebruik van de lijst met wetenschappelijk bewezen en veelbelovende producten uit aanbeveling 2 en de bestaande mogelijkheden van Thuisarts om de relevante medische richtlijnen, trainingsmaterialen voor zorgprofessionals, websites van zorgaanbieders en informatie in wachtkamers te actualiseren.
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> AANBEVELING 5: **Zorg voor budgetten die passen bij het toenemende en vitale belang dat wordt toegekend aan digitale gezondheidstoepassingen en hybride zorgpaden in IZA en ander beleid.**

[1] De nu 70 Thuisarts-keuzekaarten zijn overzichtelijke weergaves van de behandelopties voor een specifiek gezondheidsissue volgens de medische richtlijnen, met in begrijpelijke taal per optie de doelgroep, voor- en nadelen en eventueel aanvullende informatie die gezamenlijke besluitvorming ondersteunt, zoals vergoeding van de weergegeven opties. De keuzekaarten bieden al een deel van de informatie die nodig is voor de door Groene & Schneck voorgestelde methode, zijn al gekoppeld aan medische richtlijnen en bieden de mogelijkheid om 'zelf als het kan, thuis als het kan, digitaal als het kan' weer te geven.

Gezien de geleerde lessen (vraag 5), de noodzaak rekening te houden met businessmodels (vraag 4) om fabrikanten, waaronder veel startups, in staat te stellen te overleven, om onnodige obstakels weg te nemen en voortgang te boeken naar een interne markt met betaalbare digitale kwaliteitsproducten in de vele Europese talen, waaronder Nederlands, die wereldwijd kan concurreren, raden wij aan:

> AANBEVELING 6: **Bevorder internationale harmonisatie van geaccepteerde onderzoekdesigns, waaronder real world evidence benaderingen**, om te komen tot toetsingen die passen bij digitale gezondheidstoepassingen en hybride zorgpaden, die in heel Europa worden geaccepteerd.
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> AANBEVELING 7: **Harmoniseer toetsingskaders door standaardisatie of wederzijdse internationale erkenning van bewijs en certificering**, om dubbel werk, onnodige kosten en per land aanzienlijk verschillende producteisen die markttoetreding en schaalvoordelen ontmoedigen te voorkomen.
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> AANBEVELING 8: **Heroverweeg een rol voor de industrie in relevante commissies**, om te zorgen dat ook het perspectief van fabrikanten, wier producten digitale en hybride zorgpaden mogelijk maken, kan worden meegewogen.
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> AANBEVELING 9: **Overweeg de noodzaak om bij prijsstellingen rekening te houden met (aanvankelijk) lage aantallen door zorgprofessionals aangeraden / gedownloade digitale gezondheidstoepassingen**, gezien de afhankelijkheid van succesvolle verandermanagementactiviteiten, vooral in de vroege stadia van de transformatie, en de noodzaak van kostendekking.

De algemene conclusie is dat alle landen steeds meer het potentieel en cruciale belang inzien van digitale gezondheidstoepassingen om de problemen van hun zorgsystemen aan te pakken, zoals een tekort aan personeel, een vergrijzende bevolking met chronische ziekten en oplopende zorgkosten. Iedereen leert al doende. Duitsland loopt voorop met verstrekken van medische apps op recept, Noorwegen met beschikbaar maken van wellness apps via het nationale portaal Helsenorge en marketingcampagnes, en Nederland heeft de meeste hybride zorgpaden in ontwikkeling. Zinvol gebruik en integratie van kwalitatieve digitale gezondheidstoepassingen in zelfzorg en zorg kunnen veiligheid, kwaliteit, toegankelijkheid en efficiëntie van de zorg verbeteren en gepersonaliseerde, participatieve, predictieve, preventieve en palliatieve zorg ondersteunen. Bovenstaande aanbevelingen zijn belangrijke stappen om te profiteren van de waarde die digitale en hybride zorgpaden kunnen bieden, en de doelstellingen van IZA en aanverwante overeenkomsten te realiseren.

Relevant beleid - fragmenten

Passende zorg, arbeidsbesparing, betaalbaarheid, duurzame toegankelijkheid en verduurzaming van de zorgsector vragen om een **versnelling in digitalisering**.

Passende zorg betekent steeds vaker [digitale of] hybride zorg. In het integraal zorgakkoord verstaan we onder hybride zorg: de waar mogelijk gepersonaliseerde maatwerk/mix van digitaal en fysiek aangeboden zorg en ondersteuning van gezondheid. Uitgangspunten hierbij zijn: **zelf als het kan, thuis als het kan en digitaal als het kan.** Voor zowel de zorgverleners als de patiënt is dit in veel gevallen een efficiëntere manier van zorg verlenen die de kwaliteit van leven, de kwaliteit van zorg kan vergroten en bijdraagt aan het verduurzamen van de zorg.

Om de zorg toegankelijk, kwalitatief en betaalbaar te houden is transformatie nodig naar hybride zorg.
a. In 2026 leidt de inzet van hybride zorg tot aantoonbaar anders werken en het **verlagen van de werkdruk** van de zorgverleners met toegankelijkheids- en kwaliteitsbehoud.
b. Veldpartijen **(her)ontwerpen de zorgpaden en -processen** en zorgen voor afschaling en aanpassing van bestaande traditionele werkwijze en processen. Overheidspartijen faciliteren waar nodig deze transformatie ook bij implementatie.
c. Sectoren **onderzoeken welke zorgpaden geschikt zijn** voor digitale en/of hybride zorg. Van deze geschikte zorg komt 70% digitaal of hybride beschikbaar. Van alle zorg die hybride wordt aangeboden, streven we naar een inclusie van c.q. het gebruik door minimaal 50% van de patiëntenpopulatie waarvoor de [digitale of] hybride zorgpaden geschikt zijn. Hiertoe worden sectorale afspraken gemaakt.
d. Veldpartijen **zorgen dat de [digitale of] hybride zorg toegankelijk is** voor mensen en bevorderen inclusiviteit van deze zorg. Overheidspartijen faciliteren deze ontwikkeling.

Bekostiging/financiering van [digitale of] hybride zorg
a. Het leveren van [digitale of] **hybride zorg vraagt** (voor)investeringen en daarnaast **een passende financieringssystematiek** doorvertaald in de contracten met zorgaanbieders, waarbij de prikkels gericht zijn op een zo efficiënt mogelijke zorgverlening.
d. Partijen zorgen ervoor dat de vraag wordt opgelost hoe om te gaan met toepassingen die gezondheid bevorderen maar die geen directe link met de Zvw hebben, bijvoorbeeld in het kader van preventie. Dit geldt ook voor PGO's.

Integraal Zorgakkoord (IZA, 2022)

Steeds meer zorg gaat digitaal. Digitale zorg moet voor zoveel mogelijk mensen bereikbaar zijn. Er komt daarom een landelijke helpdesk voor vragen over digitale zorg. Deze helpdesk werkt samen met lokale steunpunten voor zorg. De website thuisarts.nl is en blijft de plek waar mensen terecht kunnen voor betrouwbare informatie over gezondheid en zorg. De website krijgt een verbetering en er komt meer informatie bij. Zo hoeven mensen een zorgverlener minder vaak om hulp te vragen.

Aanvullend Zorg en Welzijnsakkoord – Samenvatting (AZWA, 2025)

Assignment

The aim of this research was to find concrete, tangible, and useful answers to the following 6 questions through a combination of desk research and interviews:

1. How is/will the financing and/or availability of digital applications (such as health apps ((self)care and self-management apps)) for citizens, clients and patients in countries other than the Netherlands be implemented?
2. What responsibility does/will the government of other countries take in financing and/or making available the facilities and applications mentioned in 1?
3. What facilitating factors in other countries can be identified with regard to initiating, organizing and embedding the chosen (financial) approach there?
4. (In what way) have initiatives in other countries also taken into account the (future) business model of the suppliers of the applications (such as health apps) in financing issues?
5. What lessons learned and/or “success stories/failures” are known from other countries and why did they lead to those effects?
6. To what degree/extent has the chosen (financial) approach led to the adoption of digital applications (see definition in 1) among citizens, clients, patients and professionals in 2025, and has the initiative become/is it becoming part of the culture?

Executive summary

Appropriate care, staff shortages, affordability, sustainable accessibility, and making the healthcare sector more sustainable require an acceleration in digitization in the Netherlands. Appropriate care increasingly means (digital and) hybrid care. Hybrid care is described as wherever possible, personalized, tailor-made/mixed digital and physical care and health support. The basic principles are, based in shared decision-making, **by yourself if feasible, at home if feasible, and digitally if feasible**. One of the ambitions agreed in the Integrated Care Agreement (IZA, 2022), signed by organizations in the field and the Ministry of Health, the stakeholders including medical societies relevant to healthcare sectors (e.g., primary care, medical specialist care), was to investigate which care pathways are suitable for digital and/or hybrid care. Of these suitable care pathways, 70% will be made available digitally or hybrid, aiming for inclusion of or use by at least 50% of the patient population for whom the hybrid care pathways are suitable by the end of 2026.

The goal of this report is to learn from experiences in other European countries in order to advance these efforts. To this end, the Dutch Ministry of Health commissioned an analysis of 6 key questions related to the financing and making available of digital health applications outside the Netherlands. This report details the methods used, a combination of desk research and interviews, the answers to the 6 questions and recommendations for the Dutch context. To answer the 6 questions, 11 country profiles, see Appendix 1, were compiled. The 11 countries, Belgium, Denmark, England, Estonia, Finland, France, Germany, Italy, The Netherlands, Norway, and Spain (Catalonia region), were chosen based on the literature on front running countries in financing digital health applications. The categories within the country profiles were chosen based on the 6 questions and related literature. The categories range from Policy, Scope, what is considered Value and as such a rationale for financing and/or reimbursement, Measures to capture that value, Impact estimates, Reimbursement schemes, Pricing models, Execution, Adoption and Lessons learned.

The consolidated answer to the 6 questions related to the financing and making available of digital health applications are as follows:

1. How is/will the financing and/or availability of digital applications (such as health apps ((self)care and self-management apps)) for citizens, clients and patients in countries other than the Netherlands be implemented?
All 11 countries currently offer or aim for financing and/or availability of digital health applications. Scope of products, perceived Value of these products, Measures to capture the value including evaluation frameworks, Reimbursement schemes and Pricing models, differ and overlap. Everyone is still figuring things out, yet a combination of reimbursement of digital health applications, supplemented where applicable with fees for health professionals or payment for hybrid care pathways seem the dominant direction of travel. Several countries have a directory, either or not in the national health portal, in which reimbursed or recommended digital health applications are made available. The applications can be prescribed or recommended by health professionals. In some countries citizens can also directly request reimbursement or download applications, generally at no cost. The overall impact of use of these applications for the health system is thus far scarcely estimated.

2. What responsibility does/will the government of other countries take in financing and/or making available the facilities and applications mentioned in 1?
In general, it is safe to say that the roles are comparable to those for healthcare services, drugs and medical appliances. The Ministry of Health makes policies, and supports also financially research, innovation and transformation. While the payer of healthcare services, drugs and medical appliances pays for or reimburses the digital health applications or related hybrid pathways. If there is an authority or department within an authority responsible for digital

health, they generally have a role in assessments. Next to the government, stakeholders such as professional societies, health professionals and experts are often part of these efforts.

3. What facilitating factors in other countries can be identified with regard to initiating, organizing and embedding the chosen (financial) approach there?
Leadership, economic aspirations, a sense of urgency, or rear position, for instance in a list of countries' digitalization level, seem to have played a role. Also, digital health applications are getting mature enough to be considered as a health intervention and there's a need to advance selfcare for sustainability of health systems, as resources are limited and demand is unlimited and growing. Significant budgets allocated or required by the government seem generally an enabler for initiating, organizing and embedding the approach. While initiating the approach to a varying level of detail is settled in policies by the Ministry of Health, organizing and embedding, planning the funding, choosing in more detail the financial approach and paying, is likely left to the payer of healthcare services. In the current situation allocated budgets instead of value seem to determine pricing, making it more or less a "take it or leave it" offer for manufacturers, who lack a negotiating position.

4. (In what way) have initiatives in other countries also taken into account the (future) business model of the suppliers of the applications (such as health apps) in financing issues?
So far, most countries are still in some kind of piloting stage, where they are not or to a limited extent considering (future) business models of suppliers. The lessons learned signal a need for harmonized proportional assessment frameworks or cross-country recognition, and changes to pricing models to achieve the innovations that can enable the desired digital transformation at an affordable rate across health issues and healthcare systems.

5. What lessons learned and/or "success stories/failures" are known from other countries and why did they lead to those effects?
In short, the lessons learned are promote innovation, employ a proportional harmonized clear fit for purpose assessment framework and support transformation.

6. To what degree/extent has the chosen (financial) approach led to the adoption of digital applications (see definition in 1) among citizens, clients, patients and professionals in 2025, and has the initiative become/is it becoming part of the culture?
Based on the information available, Germany and Norway are the most advanced in the number of users. In Germany, doctors can prescribe, and patients can directly request medical apps (DiGA), some of which are a combination with hardware. A list of these apps with information is available in a website. In Norway doctors can recommend and patients can directly download wellness apps from the national portal Helsenorge. In both countries it is becoming part of the culture, although without marketing the numbers in Norway are flat.

In determining our recommendations, we haven taken into account the IZA and AZWA aims, the answers to the 6 questions, the country profiles, and the literature. We have focused on financing and making available of digital health applications and opportunities in the Netherlands.

To enable and incentivize manufacturers to make the value-adding products for uptake in care pathways (70/50 aim) and health professionals to adjust their routines, support their patients and make good use of quality digital health applications, and ultimately to achieve the intended outcomes including health system sustainability, we recommend:

> RECOMMENDATION 1: **Further explore value-based pricing as suggested by Groene & Schneck (2023)[1] and Gensorowsky et al. (2022)[2] using Thuisarts**

'choice cards'[2], taking into account both digital health applications and related work of health professionals.

RECOMMENDATION 2: **Realize in the short term a provisional reimbursement and research initiative working towards structural reimbursement as a next step for the diga.nl initiative,** considering the many other examples of scientifically proven and promising digital applications realized with public funding and otherwise, researching and enhancing their impact in practice.

RECOMMENDATION 3: **Invest in research to uncover the digital health application design features and type of novel interventions and contextual measures that deliver value, promote adherence, and prevent or reduce the need for in person / more expensive care**, to evolve the value and ultimately the number of digital and hybrid pathways for a wide range of users.

To support citizens and health professionals in their shared decision-making, and implement 'by yourself if feasible, at home if feasible, digitally if feasible', while learning from other countries' approaches (question 1) and their adoption levels (question 6), we recommend:

RECOMMENDATION 4: **Consider making digital and hybrid pathways available in Thuisarts with the updated 'choice cards' from recommendation 1 and related understandable content.** Utilize the list of validated and promising products from recommendation 2, and the potential to update the relevant medical guidelines and professional training materials and embed the content in provider websites and waiting room information systems.

RECOMMENDATION 5: **Ensure budgets that fit the increasing and vital importance ascribed to digital health applications and hybrid pathways in IZA and other policies.**

Following the lessons learned (question 5), and the need to take into account business models (question 4) to enable manufacturers including the many small companies to survive, removing hurdles, progressing towards a digital single globally competitive European market with affordable quality digital products in the many European languages including Dutch, we recommend:

RECOMMENDATION 6: **Advance cross-border harmonization of accepted study designs including real world evidence approaches**, to achieve fit for purpose evaluations of digital health applications and hybrid care pathways that are accepted across Europe.

RECOMMENDATION 7: **Harmonize assessment frameworks through standardization or mutual cross-country recognition of evidence and certification**, to avoid duplication of efforts, unnecessary costs and product requirements that differ significantly from country to country, discouraging market entry and economies of scale.

[2] The now 70 Thuisarts choice cards include for a specific health issue the established health interventions according to the medical guidelines, and in lay language per intervention the related patient population, pros and cons and potentially further information that supports informed shared decision-making such as reimbursement levels of the choice options on display. The choice cards provide already part of the information needed for the pricing method suggested by Groene & Schneck, are already linked with medical guidelines and provide potential to understandably display the choice options reflecting 'by yourself if feasible, at home if feasible, digitally if feasible'.

RECOMMENDATION 8: **Reconsider a role for industry in relevant committees**, to ensure the perspective of manufacturers, whose products enable digital and hybrid care pathways, is considered.

RECOMMENDATION 9: **Consider the need to take the (initially) low number of prescribed / downloaded digital health applications into account in pricing**, given the dependence on successful change management activities, especially in the early stages of the transformation, and the necessity to cover costs.

General conclusion is that all countries increasingly see the potential and vital importance of digital health applications to address the issues their healthcare systems deal with, such as a shortage of healthcare staff, an ageing population with chronic diseases, and an overall budget that is strained. Everyone is learning by doing. Germany is most advanced in providing medical apps on prescription, Norway in providing wellness apps via the national portal Helsenorge and marketing campaigns, and the Netherlands has the most hybrid care pathways under construction. Meaningful use and integration of digital health applications in health and care processes have the potential to improve safety, quality, accessibility, and efficient healthcare delivery, and support personalized, participatory, predictive, preventive and palliative aims. The provided recommendations are important steps to benefit from the value digital and hybrid care pathways can provide, supporting the aims detailed in IZA and related agreements.

Relevant policy - excerpts

Appropriate care, staff shortages, affordability, sustainable accessibility, and making the healthcare sector more sustainable require an **acceleration in digitization**.

Appropriate care increasingly means [digital or] hybrid care. In the Integrated Care Agreement, we define hybrid care as: wherever possible, personalized, tailor-made/mixed digital and physical care and health support. The basic principles are **by yourself if feasible, at home if feasible, and digitally if feasible**. For both healthcare providers and patients, this is often a more efficient way of providing care that can improve quality of life and quality of care and contributes to making healthcare more sustainable.

To keep healthcare accessible, high-quality, and affordable, a transformation to hybrid healthcare is needed.
a. By 2026, the use of hybrid care will lead to **demonstrably different working methods** and a **reduction in the workload** of healthcare providers, while maintaining accessibility and quality.
b. Parties in the field will **(re)design care pathways and processes** and ensure the downscaling and adaptation of existing traditional working methods and processes. Government parties will facilitate this transformation, including during implementation, where necessary.
c. Sectors will **investigate which care pathways are suitable** for digital and/or hybrid care. Of this suitable care, **70% will be made available digitally or hybrid**. Of all care offered hybrid, we **aim** for **inclusion of or use by at least 50% of the patient population** for whom the [digital or] hybrid care pathways are suitable. Sectoral agreements will be made to this end.
d. Field parties will **ensure that [digital or] hybrid care is accessible** to people and promote the inclusivity of this care. Government parties will facilitate this development.

Funding/financing of [digital or] hybrid care:
a. Providing [digital or] **hybrid care requires** (upfront) investments and **an appropriate financing system** that is reflected in the contracts with healthcare providers, with incentives focused on providing care as efficiently as possible.
d. Parties will ensure that the question of how to deal with applications that promote health but have no direct link to the Health Insurance Act (Zvw) is resolved, for example in the context of prevention. This also applies to Personal Health Environments (PGOs).

Integrated Care Agreement (IZA, 2022)

More and more healthcare is going digital. Digital healthcare must be accessible to as many people as possible. That is why a **national helpdesk** for questions about digital healthcare is being set up. This helpdesk will work together with local healthcare support centers. The website **thuisarts.nl** is and will remain the place where people can go for reliable information about health and healthcare. The website will be improved, and more information will be added. This will mean that people will need to ask a healthcare provider for help less often.

Supplementary Care and Welfare Agreement - Summary (AZWA, 2025)

Methods

To provide concrete, tangible and useful answers to the 6 questions, a combination of desk research and semi-structured interviews was used to create country profiles, see Appendix 1, for Belgium, Denmark, England, Estonia, Finland, France, Germany, Italy, the Netherlands, Norway, and Spain (Catalonia). The countries were chosen based on the work by Tarricone et al. (2024)[3] who used a comparative policy analysis and key informant interviews to present the current status of formal reimbursement policies for digital medical devices (DMDs) across the 27 EU Member States. Tarricone identifies five clusters of approaches, see Figure 1. The first cluster consists of frontrunners Belgium, France and especially Germany, which have national assessment frameworks based in regulations which include reimbursement. The Netherlands is in the second cluster (assessment frameworks either not directly linked to reimbursed, centralized or consolidated) together with Estonia, Finland and Spain. Denmark, Poland, Portugal and Sweden are in the third (institutional certification processes), and Austria, Greece, Ireland, Italy and Luxembourg (preparatory processes for the launch of national assessment frameworks) in the fourth cluster. The remaining 11 countries, mostly from Eastern Europe, are in the fifth cluster (nothing yet in place yet nor concretely planned).

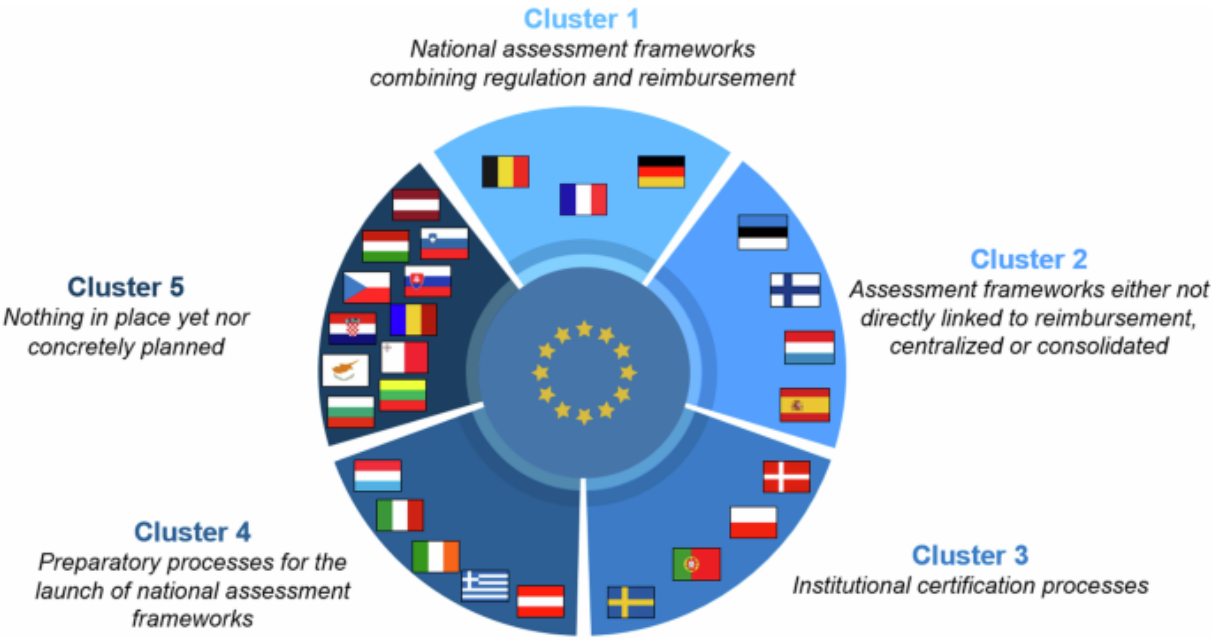


Figure 1 Classification of EU Member States' approaches to DMD assessment into five clusters based on the status of the frameworks (active, under development, or missing) and their primary purposes (Tarricone et al., 2024)[3]

The findings by Tarricone et al. largely overlap with previous work by Research2Guidance (2022)[4], see Figure 2, which also included Iceland, Norway, Switzerland, and the United Kingdom and visualized addressable market (population) for all countries.

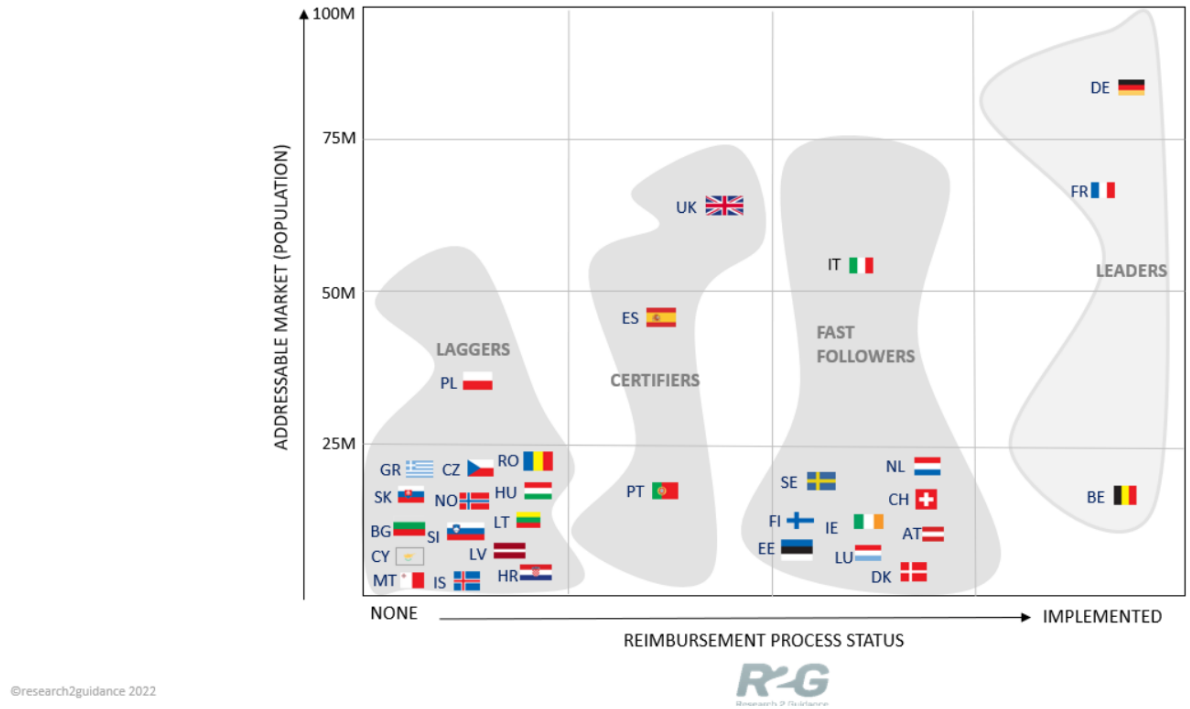


Figure 2 EU country digital health application implementation status and addressable market (Research2Guidance, 2022)[4]

Existing contacts in ministries of health, insurer organizations, contact persons listed in publicly available information and given the type of questions or type of missing data some manufacturer representatives and an assessment organization were invited for an interview. Draft country profiles were shared to enable interviewees to provide feedback. The country profiles include, based on the 6 questions and findings by Van Kessel et al. (2023)[5] and Prenda Trupec and Hoogendoorn in the Label2Enable project (2024)[6][3], see Figure 3, details on Policy, Scope, what is considered Value and as such a rationale for reimbursement, Measures to capture value (how to measure the value of the digital health application and create the environment in which that value can be captured), how Impact is estimated, Reimbursement scheme, Pricing model, who are responsible for Execution of the policy, Adoption achieved thus far and Lessons learned.

[3] For transparency reasons: also the authors of this report.

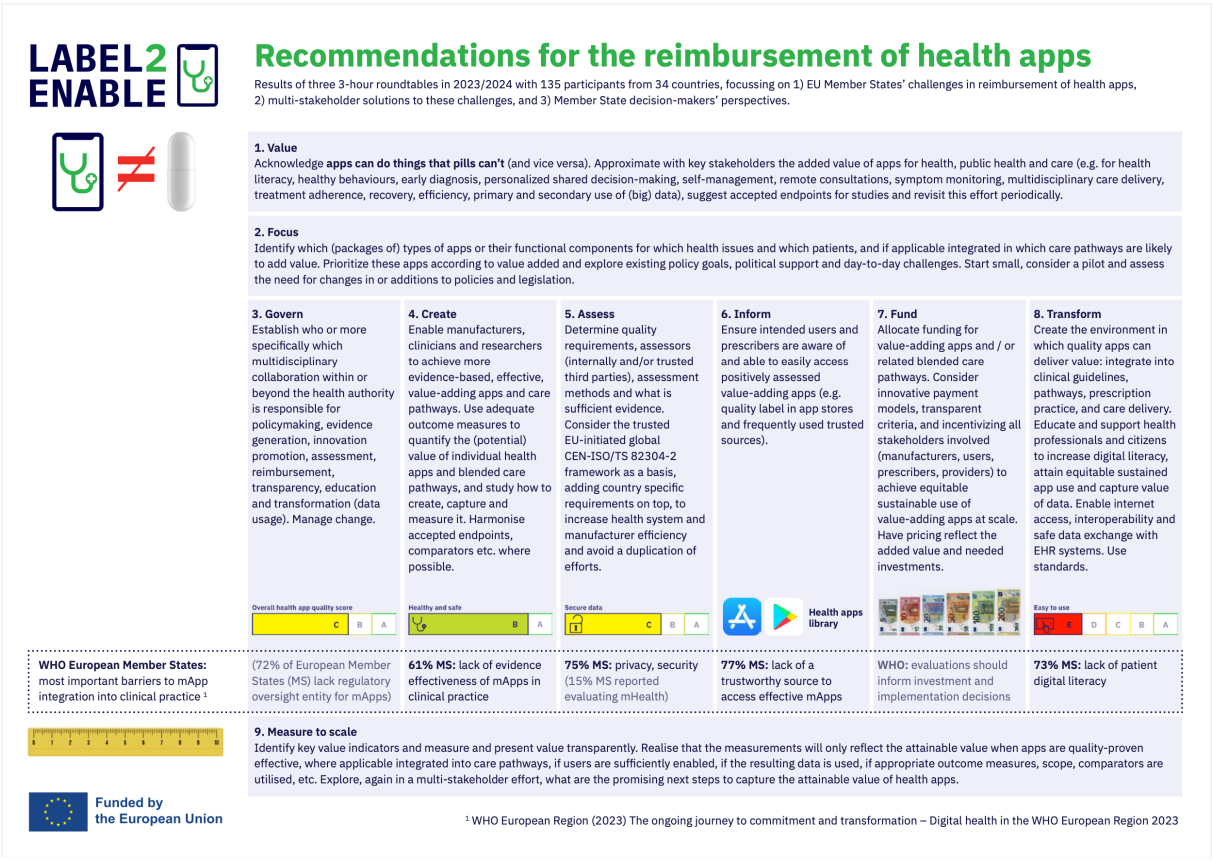


Figure 3 Label2Enable recommendations for the reimbursement of health apps (Label2Enable, 2024)[6]

To contribute to the usefulness of the recommendations, within the possibilities of the timelines given (September – November 2025), additional interviews aimed to gather a multi-stakeholder understanding of the situation in the Netherlands and to include the perspectives of two experts on the particular value of digital health applications and such assessments. A full list of interviewees is included as Appendix 2.

Results

1. How is/will the financing and/or availability of digital applications (such as health apps ((self)care and self-management apps)) for citizens, clients and patients in countries other than the Netherlands be implemented?

As the country profiles prove, all countries interviewed have a digital health policy or health policy which includes a digital health section or are in the process of creating one. A short description has been added to provide initial understandings while references enable further explorations. The scope and terminology used for digital health applications differ per country, although there are clear overlaps. Beyond software, combinations with hardware, e.g. wearables, sensors or virtual reality, and AI increasingly get recognized.

Reimbursement in Belgium, France and Germany's DiGA focuses on (digital) medical devices, although the article by Lievevrouw et al. (2024)[7], shows the possibly accidental nature of this decision. Value doesn't necessarily equal being a medical device or not. Of note, nearly all German DiGA (54/57, 95%) and all French PECAN (4/4, 100%) applications are class I medical devices, and thus not assessed by notified bodies.[8] As recognized by Lievevrouw et al. (2024)[7] and Essén et al. (2022)[9] the result of a focus on medical devices is that apps intended for self-care remain of unknown quality, leaving citizens and health professionals in the dark as to whether they are in fact picking a product that delivers on its promise or one that may do more harm than good due to a lack of safety and/or security.[10, 11] The Organisation for the Review of Care and Health Apps (ORCHA) finds that only around 20% of the many thousands of apps they review meet their quality standards, demonstrating they are clinically backed and safe with patient data.[12] Given the aim of the Netherlands 'by yourself if feasible, at home if feasible, digitally if feasible', and remarks in IZA that parties will ensure that the question of how to deal with applications that promote health but have no direct link to the Health Insurance Act (Zvw) is resolved, for example in the context of prevention, a **scope wider than medical devices** seems applicable. Germany's DiPA initiative, Denmark, England, Finland, The Netherlands, Norway and Spain (Catalonia) focus on or include wellness applications and/or applications that do not directly impact health but rather support the delivery of healthcare. Not all already provide reimbursement or other types of funding for these applications.

Digital health applications can provide a **different type of value** than other health interventions, which **may require different types of implementation measures** to make these products available and capture the value. **Germany is front runner**, and has been from the start, **in specifying value of digital health applications**, with beyond 4 medical benefits:

- improvement of the state of health
- reduction of the duration of a disease
- prolongation of survival
- improvement in the quality of life

9 patient-relevant improvement of structures or processes:

- coordination of treatment procedures
- alignment of treatment with guidelines and recognized standards
- adherence
- facilitating access to care
- patient safety
- health literacy
- patient autonomy
- coping with illness-related difficulties in everyday life
- reduction of therapy-related efforts and strains for patients and their relatives[13]

and 8 care benefits:

- mobility

- cognitive and communicative abilities
- behavioral patterns and psychological problems
- self-care
- coping with and independently dealing with illness- or therapy-related requirements and stresses
- organizing everyday life and social contacts
- household management
- stabilization of home care.[14]

Other countries indicate types of value without further specifications, see the country profiles and Figure 4.

VALUE / BENEFIT	VALUE / BENEFIT CATEGORIES		
	BELGIUM	GERMANY	FRANCE
Traditionally, HTA evaluations have focused on reducing mortality/morbidity and improving quality of life, as well as health economic impact. These outcomes are still essential for assessing value.			
Mortality, Morbidity, Quality of Life	X	X	X
New ways of assessing the value of DHS exist, but there is limited experience of translating them into reimbursement decisions.			
Organisational improvements	(X)	(X)	X
Health Economics	X		
(The comparison and categorization are simplified and do not cover all aspects.)			
Novel patient centric outcomes		X	

Figure 4 Comparing value and benefit utilized in Belgium, Germany and France (COCIR, 2023)[15]

Prodan et al. (2022)[16] who researched Belgium, Catalonia, England, France, and Germany, link digital therapeutics to the successful scale up of "P5 medicine"; medicine that is **personalized, participatory, predictive, preventive and palliative**. They consider **digital, organizational and workflow transformation essential** to realizing this vision. Pravettoni & Triberti (2019)[17] refer to psychocognitive instead of palliative as the 5th P and public (making health data available) as a proposed 6th P, arguing that the use of **new technologies** in healthcare contexts, represents an **extraordinary opportunity to achieve these values**. France echoes 3 of the 5 Ps (preventive, predictive and personalized). Additionally, aim is to make a major digital healthcare ecosystem in France, capable of being a competitor in the global market, **reducing** the current **dependence on a few players** (big tech?) **subject to regulations less protective of personal data**.[18] This is amplified by the European Commission in their 'Futures of big tech in Europe' report (2024) which advocates for the development of leading tech actors in Europe instead of solely relying on those headquartered in other geographies, for "big bet" investments in Europe, coupled with more serendipity-inducing experimental approaches, and for benchmarking EU and national Research & Innovation budgets not only against their past performance but also against spending and strategies of big tech, see Table 1.[19] Other countries, including Belgium, Denmark, Estonia, the Netherlands and Norway, focus on **organizational and health economic benefits**, such as reduced staff shortages, hospitalizations, readmissions, length of stay and consultations.

Table 1 Public sector R&D budget allocations in 2022 (top EU countries) vs big tech (European Commission, 2024)[19]

Rank	Entity	€m
1	**Amazon**	69,625.56
2	Germany	43,085.30
3	**Alphabet**	37,564.50
4	**Meta**	33,606.44
5	**Apple**	24,964.70
6	**Microsoft**	23,310.91
7	France	17,899.71
8	Italy	12,654.46
9	Spain	7,956.80
10	Netherlands	7,751.55

Source: Eurostat; https://www.macrotrends.net
Note: Country data refers to government budget allocations for R&D (GBARD)

Beyond the wide variety in value and in most countries lack of specification of value, the interviews and resulting country profiles indicate that contextual **measures to capture value** (e.g., increasing digital health literacy, uptake in care pathways, in prescription practice, in clinical guidelines, in repositories, interoperability, internet access, etc.) and **how to measure impact** (value) are also **in the discovery phase**. Combined with the evolving knowledge which interventions and designs within the digital health applications create value[20], this suggests **research, development and learning by doing are needed to discover, capture and measure the attainable value** of digital health applications, to repeat the EC's vocabulary "more serendipity-inducing experimental approaches". 'If you judge a fish by its ability to climb a tree, it will believe its whole life it is stupid.' If we judge an app as we would a pill, we will likely miss out on value particular to these technologies. Digital health applications have different active substances (data, health information, behavior change techniques, algorithms, ..), evolve frequently and may affect medical outcomes indirectly, via e.g. health literacy, behavior change or data-driven decision-making. Italy introduces the term **digital active ingredients** (primarily responsible for the clinical outcome and attributable to a therapeutic algorithm) and **digital excipients** (value-added services necessary to ensure the best patient experience and to enable long-term use of the therapy). **Increasingly countries acknowledge** the **importance of hybrid care pathways**.

Even though more study designs are permitted, clinical trials for German DiGA so far adhere closely to the established **methodologies common in the pharmaceutical sector**.[21] Nearly all DiGA manufacturers pursue, similar to medication, medical outcomes in a randomized controlled trial.[22, 23] **Despite the need for more relevant and timely evaluations**, keeping pace with the level of innovation of mHealth and contributing to meaningful impact in informing payers, providers, policy makers and patients as advocated years ago already by Pham et al. (2016).[24] **Real world evidence and real world data may be and are already considered**.[23, 25] Beyond study designs other elements that may differ compared to medication trials are for instance:

- evidence requirements (perhaps more focus on literacy and equity and less on studies in every country for every indication if the effect is not biochemical and physiologic?)
- accepted interventions (can evidence for one digital health application be used for another and results of types of applications be compared in a systematic review, if design and contextual measures matter, and interventions with the same name (e.g. cognitive behavioral therapy[26]) can take very different forms and shapes, currently largely lacking guidance from medical societies?)
- comparators (a placebo app is more difficult to achieve than a placebo pill and if the role of an app is stepped care or reducing the chances of decline while waiting for access to health care, perhaps non-treatment is an acceptable comparator),

- outcome measures (reflecting the particular value and capability of digital health applications), and
- follow-up[27]

Guidance by medical societies and harmonization in what is accepted evidence would benefit investor interest, manufacturers' decision-making and ultimately **help** achieve an innovative, sustainable and globally competitive industry.[28-31] The first DiGA are in the meantime included in medical guidelines.[32]

Denmark, Finland, Germany, the Netherlands, Norway and Spain (Catalonia) have a **public directory with digital applications** that are positively assessed, detailing their characteristics and if applicable level of approval, i.e. reimbursement (provisional, permanent). These directories include **foremost local manufacturers**, which entails missing out on economies of scale and on contributing to an innovative, sustainable and globally competitive European industry. France and Estonia don't have a public library, Belgium not anymore, England currently not, and Italy not yet, making it harder to find this type of information. Desk research shows that being accepted as a DiGA in Germany, does not mean getting accepted in France's PECAN.[33]

Having an adequate enough idea of costs (investments) and benefits (**attainable impact**) may significantly influence the efforts to pursue it. According to the latest report by the World Health Organization, "Going Digital for Non-Communicable Diseases"[34], investing today an additional US$0.24 per patient per year in telemedicine, mobile messaging and chatbots could have a significant impact over the next 10 years, including **saving** 2 million **lives**, **averting** 7 million **acute events and hospitalizations**, **gaining** 5 million **life years**, generating in addition US$ 199 billion in **economic benefits**, and achieving a **return on investment** of US$19 for every US$1 invested. The European Health Data Space impact assessment (2022)[35] references with regard to telemedicine an OECD study (2017) which estimates that 12% to 56% of **emergency department visits** are inappropriate, and a consultancy report (2013) which calculated that by using mHealth solutions to their potential, healthcare systems in the EU could save €99 billion in **total annual healthcare spend** in 2017 after the cost of extra workforce to support mHealth. How much value in health, costs, staff efficiency, citizen productivity, EU compliant supply of applications, jobs, or otherwise is estimated to be achieved **on a country level** in for instance the upcoming year was **not yet found**.

Powell et al. (2020) recognized the **need** for a **specific reimbursement channel**.[36] MedTech Europe (2021) also concluded that Digital health technologies (DHTs) do not fit easily into existing reimbursement pathways in European countries and regions, which tend to focus on services, medicines, and medical devices.[37] Indeed, all countries interviewed developed or are developing specific reimbursement initiatives for digital solutions or their hybrid pathway, as did the Netherlands with its diga.nl initiative. Judging by interviews in the Dutch context, **transformation funds and grants provide temporary funding to prepare transformation**. This generally includes redesigning pathways, developing or procuring the technology, incorporating it from a technical and functional perspective, training health professionals new habits and supporting them in abandoning old ones. To achieve **actual transformation**, **changes in financing** schemes are **often needed**, especially if deployment of a digital health application includes a change in tasks across organizations or new activities for which payment titles do not yet exist. Changes needed may differ from pathway to pathway. All three front runners have **provisional reimbursement**, as suggested by Prodan et al. (2022)[16], lowering the threshold for qualifying and achieving returns, although conditions for evidence differ, see Appendix 1. While in these front runners the manufacturer is tasked with acquiring the missing evidence, in the Netherlands Digizo.nu takes charge of this role, given the focus on pathways instead of products.

The scope of reimbursement and pricing models vary per country and are dependent on to what extent health professionals are already paid. **England, France, Germany, Netherlands**

(diga.nl) **and Norway reimburse or license digital health applications**. Germany pays manufacturers in general €200-250 for use of the DiGA by an individual patient, mostly for 90 days, although some are a one-off payment for unlimited use by an individual patient. In Norway citizens can download several wellness applications from the national portal. Norway advises against their current set-up, a lump sum license to a manufacturer for use of in total 6 wellness apps by an unlimited number of citizens, as it does not enable the manufacturers to thrive. France pays manufacturers a predefined fixed compensation for therapeutic DMDs under PECAN with an initial flat rate of €435 including tax per patient, invoiced for a period not exceeding 3 months, followed by a monthly tariff of €38,30, resulting in a maximum financial compensation of €780, including tax, per year per patient. The prices are negotiated after the National Commission for the Evaluation of Medical Devices and Health Technologies (CNEDiMTS) has finalized its clinical benefit evaluation. France's predefined monthly flat rates for telemonitoring device providers depend on the type of value (organizational, quality of life, morbidity, mortality) and start currently (for organizational benefit) at €50 per patient per month for up to 4999 patients in the indications, decreasing thereafter (5000-7999: €45,83, etc.). Additionally, France has an 'operator **tariff**' **for health professionals** performing telemonitoring set at €11 to €70 per patient per month depending on the health professional's expertise level, while Germany currently pays physicians €7.93, if applicable, for their follow-up for the use of a DiGA by a patient. The prescription of the application is part of the basic and insured person's flat rate and is therefore not reimbursed separately in Germany. Germany has no compensation for additional services related to education and therapy support.[32] In some countries (England, Italy, Norway, Spain (Catalonia)) healthcare professional costs are already covered by the health system.

Belgium, Estonia, the Netherlands (Digizo.nu) **and Spain (Catalonia) focus on hybrid care pathways**. Belgium abandoned in 2023 their validation pyramid approach, which focused on individual digital health applications, and now reimburses one care pathway (heart failure) for hospitals that sign the related agreement. The now 48 participating hospitals receive in the first month €200 per patient, in the second to sixth month €95 and €45 as of the sixth month. The hospitals in turn decide how much to pay to which supplier for the digital health application that meets the requirements as per the hospital assessment. The GP can charge €24.92 per calendar year to cover time spent at communication with the telemonitoring team in the hospital. The Dutch initiative Digizo.nu was officially launched in March 2024, although according to the repository the earliest assessment dates back to December 2020. [38, 39] It is not directly linked with reimbursement. Currently 31 processes spanning different care sectors are included, aiming for researching and approving at least 2 applications per process. For 20/31 processes this has been achieved, for 2 processes 1 application has been listed, totaling 82 products (status November 17, 2025) which healthcare providers can choose from relieving them of the burden of assessments. Providers may choose to use other products with similar characteristics. Whereas Digizo.nu can apply a minimum sales volume and number of customers to make the number of products that need to be assessed manageable, Belgium decided to have hospitals do the assessments themselves, Spain (Catalonia) used a tender and Estonia innovation grants.

In short, all countries implement or aim to implement financing and/or availability of digital health applications. Scope, perceived value, measures to capture value including evaluation frameworks, reimbursement schemes and pricing models, differ and overlap. Everyone is figuring things out. Impact for the healthcare system as a whole seems thus far scarcely estimated. Given the importance increasingly given in policies to digital health for healthcare system sustainability, more research focused on the topics where knowledge is lacking seems of the essence to efficiently and effectively attain the desired outcomes.

2. What responsibility does/will the government of other countries take in financing and/or making available the facilities and applications mentioned in 1?

The **Ministry** or Department **of Health** is **generally responsible for** the **policy** which includes decision-making on **scope of products**, e.g. in France and Germany medical devices, in France telemonitoring and therapeutics, in Germany therapeutics only. Governments generally provide **budgets for implementation of the digital transformation**. How exactly these budgets are spent and to what extent the budgets cover all of the costs would require research beyond this report. See 'policy' and 'execution' in the country profiles for available details. Who is responsible for its execution ('problem owner'), operationalizing, driving and monitoring its progress and having the means and staff to do so was in several countries more challenging to pinpoint. **Several countries have or will have a digital health authority** or department within an authority focused on digital health or HTA body that usually decides on assessment criteria **and** assesses the digital health applications. In Germany a law specified the assessment. Several countries **have set up a committee** with health professionals or more stakeholders to assist in the assessment, contribute to guidance on integration and potentially decide on reimbursement. Who decides on reimbursement rates and is to measure impact varies. The **insurers generally pay** for either the product and if applicable the health professional or for the hybrid care pathway in health systems with insurers.

In general, it is safe to say that the **roles are comparable to those for healthcare services, drugs and medical appliances**. The Ministry or Department of Health makes policies, and supports also financially, e.g. via grants, research, and innovation by manufacturers, and creates budgets for implementation of the transformation. To what extent these budgets cover the costs is not (yet) clear. The payer of healthcare services, drugs and medical appliances pays for or reimburses the digital health applications. If there is an authority or department within an authority responsible for digital health, they generally have a role in assessments. Stakeholders and experts are often part of these efforts. England plans to substantially expand the NHS app. Norway has taken on a role as manufacturer for several apps but recommends otherwise.

3. What facilitating factors in other countries can be identified with regard to initiating, organizing and embedding the chosen (financial) approach there?

In several countries **leadership**, be it political (Belgium[7] and Germany[40]: ministers of Health De Block and Spahn, France[41, 42]: president Macron, Netherlands: parliament[43] following an article in a popular healthcare professional magazine[44]) or otherwise (Norway: project manager), **economic aspirations** (Belgium[45], France), a **sense of urgency** e.g. due to an ageing population and increasing shortage of staff (The Netherlands, Estonia), or a rear or substandard position in digital health (Germany[46]), innovation (France[47]) or healthcare system performance (England[48]) seem to have played a role. Significant **budgets** allocated or required by the government (e.g. 3% of annual spend in NHS organizations for one-time investments in service transformation (England), 718 million to accelerate digital health (France)) seem **an enabler** for initiating, organizing and embedding the approach. Budget breakdowns were not found in this effort and would require more research. What may have contributed in Germany is the fact that with some 300 private and statutory health insurers, 2000 hospitals, 72000 doctors' offices and 400000 health professionals, scaling was and would remain almost impossible for small and medium-sized manufacturers.[49] Several countries use or used **pilot projects** to inform their approaches. Simple **no brainers** such as 'by yourself if feasible, at home if feasible, digitally if feasible', '70/50' (The Netherlands) and from 'diagnose and treat' to 'predict and prevent' and 'hospital to community, analogue to digital, sickness to prevention' (England) likely help as a guiding principle and if wisely applied and explained, in building acceptance and next steps. Reimbursement of the applications is easier than also redesigning pathways, although the latter is increasingly acknowledged as the adequate direction. In the end, while initiating to a varying level of detail is settled in policies by the Ministry of Health, organizing and embedding, planning the funding, choosing in more detail

the financial approach and paying, is likely left to the payer of healthcare services. For now**,** often **allocated budgets instead of value seem to determine pricing**, making it more or less a “take it or leave it” offer for manufacturers who lack a negotiating position.

4. (In what way) have initiatives in other countries also taken into account the (future) business model of the suppliers of the applications (such as health apps) in financing issues?

Schmidt et al. (2024)[50] evaluated the three-year evolution of the DiGA reimbursement program and its path forward and consider the **collaboration between payers and manufacturers essential for success,** particularly as this nascent market and emerging field continues to develop its processes and priorities. Although all countries increasingly see digital transformation as fundamental to the sustainability of their health system, this does not yet seem to translate to seeing manufacturers, many of whom are start-ups or small companies dependent on investors, as equals or fundamental to achieve their end goal. Although many of the transformation programs launch **multistakeholder partnerships**, **manufacturers seem generally not a member or full member of these efforts**. It may have taken years, considerable (public) capital, and particular not widely available or easy to acquire expertise to develop their product and achieve the required evidence and compliance. Achievements that may take years to copy. Yet, rather than being cherished, they seem to be considered somewhat exchangeable. The current value proposition for manufacturers is not particularly tempting. Norway reported initiatives to be dependent for survival on research grants. A partnership perspective may be more appropriate at least for now than a supplier perspective in a more established market. The **three apps in the diga.nl initiative currently funded** with a lump sum license **to save them from drowning are part of a much larger group of products** developed and / or scientifically proven in the Netherlands with public funding **that scarcely manage to reach their target audience**, providing nowhere near the return on investment of public money that is feasible.

It also appears that these manufacturers’ **products are treated as mature end products** instead of innovative front runners in an entirely new business. To enable the desired digital transformation, significant investments may be recommendable to optimize:

- effectiveness of the novel interventions these products incorporate and knowledge in which cases which intervention is likely to be most effective
- usability and accessibility to achieve the goal of 50% of the target audience and more to decrease the chances of a digital divide increasing health differences
- the sustained adequate use of digital health applications necessary to achieve the intended outcomes
- the availability of useful actionable data deriving from digital health applications in electronic health records to adequately support data-driven decision-making in management of health issues
- the novel types of measures in the many relevant healthcare provider organizations which these manufacturers may not easily have access to
- marketing of this novel type of product that most medical societies have not yet provided guidance for and health professionals may not have received training in

Freitag et al. (2024)[51] interviewed 16 experts, representatives of DiGA manufacturers and statutory health insurances in Germany, about negotiating prices and payment terms for DiGA. Each expert was asked to rank their top 3 pricing model from a list of 7: a cost based, a reference based, an external reference based, a value-based care, a usage based, a user experience based and a managed entry agreement-based pricing model. The **value-based care pricing model** was considered the **fairest risk sharing model** by both Statutory Health Insurances (SHIs) and DIGA manufacturers. All experts agreed that a value-based care pricing model would **cause the “right” incentives for DiGA manufacturers** since this model motivates DiGA manufacturers to maximize outcomes, and investors to invest. Van Kessel et

al. (2023)[5] examined the digital health reimbursement strategies in 8 European countries (Belgium, France, Germany, Italy, the Netherlands, Poland, Sweden, and the United Kingdom) and Israel. Value based pricing (i.e., the price is based on the value that an intervention adds to the healthcare process, such as improved health outcomes or reduced costs) was concluded to be **fundamental for the sustainable integration of digital health**. **Yet** these frameworks were found to range from **embryonic to nonexistent**. Pricing was mostly determined through discussions between national or regional committees and the manufacturers of digital health solutions. In Germany the pricing of DiGA that are permanently listed and as such have been through price negotiations is generally €200-€250 for 90 days - 90 days aligns with the quarterly billing cycle in German medical practices[50] - a bandwidth that seems indicative of a lack of value-based pricing.[8] Intent is to make 20% of the pricing dependent on real world impact.[3] France has fixed pricing for PECAN (provisional reimbursement of digital therapeutics and monitoring devices) and for permanent reimbursement of monitoring devices.

Jürgens et al. (2024)[52] reviewed market access regulations for mHealth applications in Germany, Austria and Switzerland and remark the adaptation to additional legal, regulatory, technological and operational adjustments globally can make it particularly **difficult for mid-sized companies to establish their growth potential**. These companies often find themselves restricted to limited markets, despite having products that could benefit patients globally. This highlights the need for greater harmonization and standardization of market access regulations across borders, to enable MedTech companies of all sizes to compete in a global marketplace. The interviews for this report confirm manufacturers are confronted with **many new legislations, local standardization and lack of harmonization in assessment frameworks and their evidence requirements**. In Germany a new (German) data security certification costs manufacturers reportedly €160.000-€270.000.[32] Investments that may be beyond the means of a startup or small and medium-sized company, especially if for one country only. At an average price of €200-€250 per DiGA per patient this requires 1000 prescriptions to compensate only for this investment. Moreover, as this concerns a German standard, and other countries, e.g. England, may employ their own standards, investments benefit only a limited consumer base, which comes at a price to at least one stakeholder group, as someone will have to pay the bill. The Label2Enable recommendations for the reimbursement of health apps[6] propose to **have pricing reflect** the **added value** and **needed investments**, mindful of the considerable costs associated with gathering the required evidence, achieving compliance, development, support and maintenance of a digital health application. Taking investments into account in pricing might incentivize proportional rigor and a reduction in overlaps in assessment requirements.

The toll increases as in the equation p (price) x q (quantity), q (**the number of prescriptions**) **is in the current stage of the digital transformation low**. This means that returns on the significant investments are low, and even fixed costs may be hard to cover, making manufacturers dependent on investors, who in turn will need an appealing financial perspective over a reasonable period of time. Goeldner & Gehder (2024)[21] report that by the end of September 2023, 15 DiGA had surpassed the threshold of 5000 prescriptions over their lifetime, Nelson Advisors (2025)[53] that the top 15 DiGA, which account for 82% of total prescriptions receive between 8 and 77 prescriptions a day. Raising q by means of **exports** seems **thus far near impossible**. Only one app (Untire) was found to be reimbursed / licensed in more than one country (Germany and the Netherlands). Norway reported their manufacturers had tried several other markets and failed everywhere. A DiGA that tried to get reimbursed in France failed to meet PECAN's requirements.[33] **Harmonization and cross-country recognition are needed** to enable economies of scale that can provide returns on investments, enable further innovations, and ultimately contribute to sustainability of manufacturers and affordability of their products in a European market and beyond. The need for harmonization is recognized by manufacturers, medical professionals, authorities, and researchers, however not yet achieved.[54-58] Ataiy et al. (2024)[59] found from a survey with

10 DiGA manufacturers **doubts about profitability and pricing structures**, stressing fair reimbursement mechanisms while providing incentives for innovation and affordability. If improvements to the app require significant investments beyond coding, if significant changes entail a risk of not getting accepted, and if pricing levels do not reflect these costs and risks, then the improvements needed to achieve or speed up the desired digital transformation are effectively discouraged.

Other potential signs of not yet considering business models which can affect the performance or survival of current manufacturers and the perspective that others may need to choose to enter the market **may include**:

- a **lack of manufacturer interest or approvals** in some frameworks (e.g. DiPA)
- pricing for several DiGA requiring **arbitration**
- **lump sum funding** to stay afloat (Netherlands, Norway)
- **bankruptcies** of DiGA manufacturers[60]

The cost of DiGA in general and the cost of delisted DiGA in particular constituted only a minor fraction of the total 2022 SHI benefit expenditures of €274.2 billion, of which €10.4 billion are expenditures for medical devices. Hence, expenditures for **DiGA** amounted to approximately **0.01% of total expenditures**.[1] If digital transformation is as important to countries as their policies suggest, this percentage should be expected to increase.

Groene & Schneck (2023)[1] discuss the approach suggested by Gensorowsky et al. (2022)[2] for deriving the **appropriate cost** of DiGA. Their approach required for each DiGA to **first determine an established therapy in the same indication area eligible for reimbursement** within the SHI system. For example, cognitive behavioral therapy can be personally delivered for the treatment of depression. Then, **calculate** the SHI's **willingness to pay for a specific improvement in health by dividing the cost of the existing therapy by the average effect achieved** by this therapy option. In the example above, this could be the cost of 15 CBT sessions (approximately €1,500) divided by the average reduction in depressive symptoms (Cohen's d of approximately 0.56). **Apply**ing **this cost-effectiveness ratio to the average health improvement of a particular DiGA** yields an appropriate price that reflects the SHI's willingness to pay to treat a condition. For a DiGA that improves depressive symptoms by a Cohen's d of 0.25, this would be €1,500 /0.56 × 0.25 = €669.64. While the approach presented by Gensorowsky et al. is considered a tangible step toward value-based pricing of DiGA in Germany, there are aspects the framework does not address. For example, it does not **consider** the possibility of **a minimum effect size** required for a patient to experience any noticeable positive impact, leading to the question of whether a DiGA with negligible absolute effect should be covered or how to determine a minimum effectiveness threshold. Furthermore, their cost-effectiveness framework does not consider any patient benefits outside of medical benefits. For example, the **use of DiGA might have** the same health benefits as pharmacological therapy, but with **fewer side effects or** entail **procedural and structural benefits only**. Finally, **research is required to evaluate** and detail **how value-based prices** should **reflect the level and quality of underlying scientific evidence.**

All in all, investments, research, harmonized proportional assessment frameworks or cross-country recognition, changes to pricing models and likely to funding programs are needed to achieve the innovations that can deliver the desired transformation at an affordable rate across health issues and healthcare systems. Testing of value-based pricing models such as discussed by Groene & Schneck (2023) provides potential. Transformation requires beyond the innovations, efforts by medical societies and healthcare providers to ensure the necessary digital literacy among their members and staff. Furthermore, a seat for manufacturers at the relevant tables and proactivity instead of reactivity (waiting for a manufacturer to file an application) could be considered, especially for high-need areas in the healthcare system.

5. What lessons learned and/or “success stories/failures” are known from other countries and why did they lead to those effects?

As apparent from the country profiles, which in turn were built on (multi-stakeholder) desk research and interviews and their clear remarks, everyone is still learning. The learnings could be clustered in three categories, being innovation, evaluation and transformation.

With regard to **innovation**, Norway seems to have the most experience in developing digital health applications as an authority and is at the same time very specific that building apps as an authority is not a good model. It effectively kills market potential and authorities are by nature not manufacturers. A fear of paying too much, perhaps related to examples of "big tech", resulted in a "big mistake" with deals that are not good for developers (instead of the "big bet" that the European Commission proposes in their 'Futures of big tech in Europe' report). Sort of killing these developers softly, while agreement with room for innovation where developers can thrive should have been achieved. The need for a pricing model that promotes innovation, the value of and one could argue need for provisional reimbursement, for example looking at the number of originally provisional listings in Germany, and a policy for significant changes in the product and their assessment that doesn't kill innovation is apparent.

Most learnings relate to **evaluation**. The assessments, their criteria, evidence requirements and what constitutes a 'significant change' are not clear or pragmatic, and can be volatile, creating uncertainties as to attainability of a successful outcome. They are considered not proportionate to risk levels, unworkably long, can take years to complete or only be applicable for 1 product. Forms are not accurately filled out, feedback is inconsistent. The frameworks are not harmonized across borders, not aligned with other requirements within countries, duplicative, and not specific to digital health applications and the value these products can deliver. They present a disproportionate burden especially for young and innovative companies, effectively discourage innovation and negatively impact manufacturer growth. New study designs and acceptance of real-world data are needed. Proving direct clinical effects is difficult and operationalization of novel outcomes should be simplified (and their acceptance across borders assured to become attractive). Spain (Catalonia), who recently adopted the Label2Enable handbook for CEN-ISO/TS 82304-2 as a basis, appears unique in reporting the (new) requirements are positively received.

Transformation efforts are found to be significant, confirming the remarks of Prodan et al. (2022)[16] on digital, organization and workflow transformation being essential. This has an effect on needed implementation budgets. Working towards more hybrid care pathways within and across organizations and the patient's home situation involves discovering and growing into new roles, undoing routines, adjusting guidelines and IT infrastructures. The potential applicability to all care pathways across several partner organizations who may employ their own solutions (e.g. a GP practice may work with several hospitals) can add further complexity. Funding pathways and (national) platforms have to be adjusted, e-prescription and interoperability with electronic health record systems arranged, and standardization (e.g. HL7 FHIR and SNOMED CT) across stakeholders achieved. Patients, practitioners and providers have to be informed, educated and potentially trained. Eligible users, their benefits and business cases have to be estimated and scaling beyond front runners, pilot projects and grant funding achieved, presenting uncertainties. The front running countries employ a reactive approach, where manufacturers apply for reimbursement. A combination of including vetted digital health applications in a trusted national platform with many visitors and a role of healthcare professionals to introduce these applications to patients and citizens seems to be perceived as an optimal strategy for this stage of the transformation.

In short, promote innovation, employ a proportional harmonized clear fit for purpose assessment framework and support transformation.

6. To what degree/extent has the chosen (financial) approach led to adoption of digital applications (see definition in 1) among citizens, clients, patients and professionals in 2025, and has the initiative become/is it becoming part of the culture?

Based on the available data, **Germany** is the **undisputed leader in** number of digital health **applications** (in German: DiGA) **reimbursed** (57 on Sept 10, 2025), number of **prescriptions** made (over 1 million between Sept 2020 and December 2024), **practices who prescribe** (33.2% in 2024) and **number of articles and reports that detail adoption**. England may be bigger, but procurement is not national, making uptake more difficult to establish, and figures as to adoption were not found. **Awareness** of DiGA **continues to grow** towards becoming part of everyday care for more and more people – both professionals and patients. Nevertheless, the **number of those who still know little or nothing about DiGA remains significant**.[32] Groene & Schneck (2023)[1] remark the **number of prescriptions** are **low relative to the** size of the German SHI population of approximately 74 million and the **prevalence of the conditions** in the adult population that DiGA address. For example, approximately 20% of the adult population suffers from 3-month back pain, approximately 7.2% from diabetes and approximately 19% from adiposities. In contrast, by September 2022, the two approved DiGA for adiposities [Zanadio (AidHere, Germany) or Oviva Direct (Oviva AG, Switzerland)] had 'only' been activated 30 thousand times. This indicates that the prescription rate was at the time below 0.5% for this condition. Interestingly **Norway scores remarkably high with wellness applications. Driven by marketing and trust in the national health portal** Helsenorge, the downloads of the 6 apps Norway licenses approach 300.000 on a population of 5.6 million.[61] The smoking / vaping / snus cessation app Slutta (daily motivational messages, advice and tips, and an overview of the time since smoking cessation), created by Helsedirektoratet, available for free, is most popular with some 2 million downloads.[62] Without marketing (in all kinds of media including social media[63-66]) the numbers are flat. Recommendations for apps by health professionals, which can be sent directly from the national health portal, are expected to enhance results and reduce the reliance on marketing.

Uncovska et al. (2023)[67] found in a survey (n=1051) from a broad cross-section of the German population, with both users and non-users of mHealth apps and DiGA general **willingness to use mHealth apps / DiGA** to be **high at 76%,** especially if they are governmentally certified. However, **only 27% of respondents** were **willing to pay out of pocket**. Quality certification by a government or other entity is important to patients, **53% of patients** would **only** be **willing to use mHealth apps/ DiGA when their quality is certified by the government**. This might be due to the fact that multiple applications for the same indication are available, and **patients lack the specialized knowledge to identify the appropriate app with proven medical benefit**. A Label2Enable survey (article in peer review) found that 86,3% of the 1228 respondents thought the government should review and rate health apps to help them choose or pay another organization to do so.

Uncovska et al. (2023)[67] also found **perceived self-efficacy and performance expectancy** are **significant predictors of willingness to use digital health interventions**; with age, attitude, and e-literacy being key demographic predictors. A key takeaway for regulators, providers of mHealth apps / DiGA, and other stakeholders involved in mHealth adoption mentioned, is the **importance of addressing negative beliefs early on**, targeted communication around effortless usage of mHealth services across age groups and demographics and focus on **highlighting expected benefits of mHealth app / DiGA usage**. The most frequently mentioned reasons to stop using mHealth apps / DiGA included "I do not need it anymore" (33%), "I do not find it helpful to use" (31%), and "I do not have time to use it" (24%). When comparing responses for DiGA users to non-prescription mHealth app users, Uncovska et al note that "I do not find it helpful to use" was only mentioned by 14% of DiGA-experienced users (vs. 34% mHealth app users), while "the usage is too complicated" was not

mentioned at all (vs. 8% mHealth app users). It would be interesting to further **investigate methods to increase patient adherence**. The correlation between patient adherence and app design remains relatively unexplored.[67] Increasingly, more recent studies have focused on self-efficacy as a significant predictor of intention to use. **Improving electronic literacy and health education**, which have been identified as determinants of self-efficacy are thus considered **key to boosting mHealth / DiGA adoption rates**. This could be done by traditional methods (training, demonstrations, free trials), but also through targeted marketing communication showcasing effortless usage of mHealth services across age groups and demographics. Further attention may also be due to ensure the needs of the population as a whole are met. For example, a notable fact for which no explanation was found in the desk research seems to be that **most DiGA users are female**.[50] Causio et al. (preprint)[68] highlight the **complex** nature of digital health applications designed **to enhance health literacy and engagement**, underscoring the importance of incorporating theoretical frameworks, user-centered design, cultural sensitivity, and ongoing support to boost engagement and promote behavior change, maximize effectiveness and advance the global transition to digital-first healthcare, important for the '70/50' aim.

Dahlhausen et al. (2022)[69] interviewed 19 DiGA developers and distributors and found that **health professionals in outpatient settings** are seen as **most important in promoting patient access and adherence** to DiGA (both median 10 out of 10). This is considered due to their:

- central gatekeeping role in the prescription process
- trust from and influence on patients, which especially in the outpatient sector is characterized by longer-lasting patient–doctor relationships with frequent touchpoints
- their ability to onboard patients and monitor DiGA use

For some indications where inpatient treatment plays a central role in the patient journey, for example, rare or oncological diseases, inpatient HCPs are considered highly relevant as well to promote patient access. In most other cases, however, their potential is regarded as lower as they are restricted to prescribing DiGA as part of release management. A Label2Enable survey (n=1228) (article in peer review) confirms that **health professional advice on health apps is trusted most** (80.4%), followed by pharmacists (61.1%), government or health authorities (59.9%), health professional organizations (56.0%) and family and friends (41.7%). Family and friends' and app stores' advice were in the current situation used considerably more often than their trust levels suggested. Uncovska et al. (2023)[67] found that users experienced with DiGA report the highest need for prescription by physicians: **45%** state they **would use mHealth only if prescribed**.

Wangler & Jansky (2024)[70] found in a large-scale survey with German General Practitioners (GPs) (n=5,868) between spring and summer 2022 that **24% of GPs** (urban 42%, rural 9%) expressed **confidence in their ability to give patients capable advice on DiGA**, **14% had prescribed DiGA** (21% urban, 5% rural), and 13% planned to prescribe them in the near future. Groene & Schneck (2023)[1] discuss several measures to **increase prescription rates** by healthcare professionals derived from studies discussed. First, a **higher compensation for prescribing** DiGA might increase prescription rates. Second, an **integration** of DiGA **into evidence-based treatment guidelines** might improve adoption. While the relevant societies are responsible for creating these guidelines, **the Ministry of Health is planning to support this process by drafting exemplary digitally supported care processes** as part of its digital transformation strategy. Third, it is important to **educate physicians** about DiGA and to ensure that information on their efficacy is easily accessible and comparable. This comprises a revision of the **format in which information within the** DiGA **directory is presented**. In particular, the efficacy of different DiGA to treat specific conditions should be clearly compared in tabular format. To create transparency on the methodology of evidence creation, a **simple, intuitive score** should be added to the table which indicates the underlying level and quality of scientific evidence. This score should be derived from existing hierarchical systems of classifying evidence. Another avenue to improve the health of the population is by **increasing**

the **self-prescription** volume of proven DiGA. For some disease areas such as urogenital conditions, more than a third of all DiGA are accessed via the self-prescription route.

Biliunaite et al. (2023)[71] found in an experimental vignette study (Label2Enable project) that **health professionals who were presented** the CEN-ISO/TS 82304-2 label that indicates with **simple intuitive** green A to dark orange E **scores** if an app is of high-quality were **more willing to recommend a health app** (prevention, self-management and healthcare apps) to both patients with low and high social economic status. A follow-up study (Biliunaite et al. (2025)[72] in Spain (Catalonia) found that beyond the label, **health professionals need**ed **more knowledge, confidence and habit in recommending apps**. In a participative design study (article in peer review) the CEN-ISO/TS 82304-2 health app quality report, the more detailed version of the CEN-ISO/TS 82304-2 label, was designed to efficiently satisfy health professionals' information needs in recommending an individual app to an individual patient. Powell et al. (2020)[36] consider that **even those capable of prescribing apps may have difficulty recommending them**. Lack of guidance on standards for app quality and app-related liability may cause healthcare providers to hesitate in recommending apps.

Kendziorra et al. (2025)[73] used semi-structured interviews with 46 physicians across Germany to explore the challenges physicians face when integrating DiGA into their treatment options and the changes this integration entails for their medical workflows. Participants, sampled for diversity in specialty, experience, and region, were interviewed between June 2022 and August 2024. The findings reveal that DiGA influence multiple aspects of medical practice, including information acquisition, patient assessment, physician–patient relationships, and treatment pathways. While DiGA offer new **opportunities for bridging gaps in care and enhancing patient autonomy**, they also present **challenges** that require and lead to adjustments **in physicians' workflows**, **decision-making processes**, and **professional roles**. Physicians highlighted barriers such as the **lack of trusted, accessible information, time constraints, and concerns about liability**, all of which contribute to varying levels of acceptance and adoption. Furthermore, the **need to assess additional patient factors**, **such as digital literacy and motivation**, adds complexity to patient consultations and decision-making. Particularly in the early stages of DiGA adoption, when physicians have little experience with how patients engage with these tools, the lack of standardized processes—such as monitoring usage, assessing treatment success, and determining appropriate follow-up actions—can create additional pressure and uncertainty.

In short, based on the information available, Germany and Norway are the most advanced in number of users. In Germany doctors can prescribe and patients can request DiGA directly with information being available in a separate directory, in Norway doctors can recommend and patients can directly download wellness applications from the national portal Helsenorge. In both countries the applications are available free of charge. Certification from the government, recommendations from health professionals, perceived self-efficacy, boosting health / digital literacy and performance expectancy matter. The body of research on support measures for health professionals is increasing, while the correlation between app design and patient adherence and how to tackle e.g. gender- or health literacy-specific differences in uptake remain relatively unexplored.

Recommendations

In determining our recommendations, we haven taken into account the IZA and AZWA aims, the answers to the 6 questions, the country profiles, and the literature. We have focused on financing and making available of digital health applications and opportunities in the Netherlands. Our recommendations are:

1. **Further explore value-based pricing as suggested by Groene & Schneck (2023)[1] and Gensorowsky et al. (2022)[2] using Thuisarts 'choice cards'.**
   The (now 70) Thuisarts 'choice cards' already include, for the purpose of shared decision-making, the established health interventions for a particular health issue. With the support of insurers, reimbursement structures and pricing for these established interventions can be identified, while medical societies can provide evidence of their effectiveness based on the clinical guidelines with which Thuisarts information is already aligned. The pricing method suggested by Groene & Schneck and Gensorowsky et al. could help determine price levels for the related digital and/or hybrid pathway, accounting both for the product and work for health professionals. Utilize available sources, including digital health applications that have previously been evaluated with public funding (e.g., ZonMw), see Recommendation 2, as well as those that have been positively assessed in other European contexts, see Appendix 1. See Figure 5 for the choice card for smoking cessation. In this example of a choice card apps are already included, yet the link currently guides to 4 apps that are neither assessed nor reimbursed.[74] One of these 4 is a permanently listed DiGA in Germany. The Trimbos institute seems to consider a hybrid care pathway promising for this health issue, especially for persons with a low social economic position.[75]

KEUZEKAART Ik wil stoppen met roken.
Hoe kan ik dat het beste doen?

2024

In deze tabel staan manieren om te stoppen met roken. Bespreek met je arts, praktijkondersteuner of coach welke manier het beste bij jou past.

Behandelmogelijkheden →	Zelfhulp	Hulp van iemand die veel weet over stoppen met roken	Middelen met nicotine en hulp van iemand die veel weet over stoppen met roken	Medicijnen en hulp van iemand die veel weet over stoppen met roken
Wat is het?	Je volgt een online cursus, luistert podcasts, gebruikt een boek of een app op je telefoon om te stoppen. Zie: ikstopnu.nl	Je hebt 4 of meer gesprekken met een stoppen-met-roken-coach, de praktijkondersteuner (POH) of de huisarts. Je hebt de gesprekken alleen of in een groep. Dit duurt een paar maanden. Soms krijg je er ook online hulp bij.	Je gebruikt middelen met nicotine. En je krijgt hulp van een stoppen-met-roken-coach, de praktijkondersteuner (POH) of de huisarts. Middelen met nicotine zijn bijvoorbeeld: kauwgom, pleisters, zuigtabletten of kauwtabletten. Als je 2 middelen tegelijk gebruikt, wordt de kans groter dat het stoppen lukt.	Je slikt medicijnen. En je krijgt hulp van een stoppen-met-roken-coach, de praktijkondersteuner (POH) of de huisarts. Door de medicijnen krijg je minder zin om te roken. Je krijgt soms ook minder klachten tijdens het stoppen. Meestal krijg je nortriptyline, bupropion of varenicline en soms cytisinicline.
Voor wie?	Voor alle rokers.	Voor alle rokers.	Overleg met je huisarts of je deze middelen kunt gebruiken.	Deze medicijnen zijn niet geschikt voor jongeren onder de 18 en voor zwangeren. Ook bij psychische klachten kun je ze niet altijd gebruiken.
Welke bijwerkingen of problemen kun je krijgen?	Geen.	Geen.	Lichte klachten zoals jeuk door de pleisters of een droge mond door de zuigtabletten.	Bijwerkingen hangen af van het soort medicijn. Dit zijn voorbeelden van bijwerkingen die je kunt krijgen: droge mond, slaperig zijn, niet goed kunnen poepen, slecht slapen, misselijk zijn, vreemde dromen, overgeven, veranderde smaak, spierpijn.
Vergoeding	Als je 1 van deze manieren kiest om te stoppen, kun je vaak een vergoeding krijgen van de zorgverzekeraar. Vraag hiernaar bij je eigen zorgverzekeraar.			
Andere aandachtspunten	• Eerst minder gaan roken helpt niet om makkelijker te stoppen. En het blijft slecht voor je gezondheid. • E-sigaretten roken (vapen) is geen goede manier om te stoppen. Je houdt de gewoonte om te roken, je kunt eraan verslaafd raken en je krijgt ook schadelijke stoffen binnen. • Als je gestopt bent met roken, moet je in het begin soms meer hoesten. Dit kan 3 maanden duren. • Maak je je zorgen over je gewicht? Bewegen kan helpen om te stoppen met roken. Het kan er ook voor zorgen dat je niet te zwaar wordt. Wil je advies? Maak dan een afspraak met je diëtist, praktijkondersteuner of huisarts.			

Deze keuzekaart is te vinden op THUISARTS.NL

Figure 5 Thuisarts choice card for smoking cessation[76]

2. **Realize in the short term a provisional reimbursement and research initiative as a next step for the diga.nl initiative**.
   Consider the many other examples of scientifically proven and promising digital applications realized with public funding (e.g. ZonMw) and otherwise. Measure and enhance their impact, working towards access to structural reimbursement based on proportional fit for purpose requirements as a next step.

3. **Invest in research to uncover the digital health application design features, type of novel interventions and contextual measures that deliver value, promote adherence and effectively contribute to stepped care.**
   Take into account the diversity within the intended user group and what else is needed to enhance and capture the value. Gather the experiences, improvement potential and recommendations from the national helpdesk once available. Actively disseminate the findings and make good use of them in assessment frameworks, recommendation 2, future innovation grant requirements, and where applicable pricing.

4. **Consider making digital and hybrid pathways available in Thuisarts with the updated choice cards from recommendation 1 and related understandable content.**
   If digital / hybrid care pathways and potentially also 'wait and see' as a choice option would be added to the choice cards, and if pricing issues would be solved as intended in recommendation 1, these cards would reflect 'by yourself if feasible, at home if feasible, digitally if feasible'. To enhance effectiveness, the related understandable content should include information on the digital / hybrid care pathways on equal footing. Also, these pathways should be structurally incorporated into updates of relevant medical guidelines and professional training materials and embedded within provider websites and waiting room information systems, linkages that Thuisarts already provides for. This integration would support the IZA objectives of self-management, self-reliance, achieving a minimum adoption rate of 50%, informed shared decision-making and safe care substitution. A check with or research by experts on behavior change, shared decision-making and health inequalities could establish if the design of these choice cards can be further optimized. Choice cards could also support informed decision-making on non-reimbursed apps, e.g. the heavily downloaded fertility tracking apps[77, 78], reducing the dependence on possibly harmful information from Google searches and influencers. Finally, if choice cards would include a click to more information, app stores (digital care pathways) or possibly also providers (hybrid care pathways), they could potentially also serve to monitor interest in or adoption of digital / hybrid pathways.

5. **Ensure a budget allocation that fits the increasing and vital importance ascribed to digital health applications and hybrid pathways in IZA and other policies.**
   Consider if policies employed in transformation for other sectors would be worth replicating to promote uptake of hybrid care, as an alternative to lump sum transformation funding. E.g. to achieve the energy transition (temporary) subsidies or other financial incentives are used to achieve uptake of the intended products (in the example e.g. solar panels, heat pump, solar boiler or hybrid or electric cars).

6. **Advance cross-border harmonization of accepted study designs including real world evidence approaches.**
   This includes outcome measures appropriate for digital health applications that uncover and quantify the value of meaningful use of these applications and the contextual measures to capture that value for a specified intended user group.

7. **Harmonize assessment frameworks through standardization or mutual cross-country recognition of evidence and certification.**

Ensure the proportional rigor needed for both impact and innovation, while avoiding duplication of efforts. Ensure transparency and predictability of assessment processes, and lower administrative and evaluation-related costs.

8. **Reconsider a role for industry in relevant committees, to ensure the perspective of manufacturers, whose products enable digital and hybrid care pathways, is considered.**
   Learning from Belgium, France and Germany, and given the particular knowledge manufacturers have gained over the years with their product, a role for manufacturers should also be considered in acquiring the missing (real world) evidence (Digizo.nu method step 5). Especially given the current status quo in which products, and notions about optimizing use context as well as evaluation methods are still evolving.

9. **Consider, especially in the early stages of the transformation, the need to take the (initially) low number of prescribed / downloaded apps into account in pricing.**
   Transformation, education and marketing efforts (change management activities) are needed to increase the numbers of prescribed / downloaded digital health applications. Equal consideration should be given to the investments required to generate scientific / real world evidence - which matters in all countries for applications which intent to positively affect health -, for regulatory compliance, innovation, and marketing alongside running costs such as maintenance, and support. Especially if investors are still hesitant to step in.

In short,

- enable manufacturers to make value-adding digital health applications and to innovate and thrive instead of barely survive
- enable and incentivize health professionals to adjust their routines, support their patients and make good use of useful data originating from quality digital health applications in their shared decision-making and management of patients' care
- use the potential of Thuisarts, research and the many validated or promising apps with similar profiles as those part of diga.nl that are barely alive / struggle to survive

to enable the digital transformation, delivering the intended outcomes including potential long term cost savings and health system sustainability.

Appendix 1 – Country profiles

This appendix includes country profiles for Belgium, Denmark, England, Estonia, Finland, France, Germany, Italy, the Netherlands, Norway and Spain (Catalonia). Their content was compiled using desk research and semi-structured interviews. The categories within these profiles derive from the 6 questions that needed to be answered for this report and the literature.

Semi-structured interview questions used for the different categories include:

Policy:

- Does your health system (intend to) promote or support use of digital health applications?
- Is there a law or other document that details the policy?
- If so, could you provide a link / name?
  These documents and documents referred to in these documents or otherwise found were also used to provide answers in the following categories.

Scope:

- What scope of digital health applications is of interest within your health system?
- Is there an official definition / description of this scope?
- Can you provide a link?
- Does the scope include both medical devices and wellness applications?
- Does the scope include software, combinations of hardware and software, more, e.g. platforms?

Value:

- What does your health system consider the added value of these applications?
  As an example, Germany's 4 medical benefits and 9 patient-relevant improvement of structures or processes and 8 care benefits were referenced.

Measures to capture value:

- What is done to ensure capturing the attainable value? (e.g. uptake applications in guidelines, interoperability, enhance digital literacy, knowledge, etc.)
- To what extent is the assessment for this reimbursement specific to digital health applications? (e.g., research designs, outcome measures, comparators, RWE)
- Could you provide a link to the assessment framework?
- Is there is a directory of positively assessed / vetted / reimbursed applications / hybrid care pathways?
- Why / why not?
- If so, could you provide a link?

Impact:

- Is the overall expected impact of use of these applications in your health system for the next year (or years) estimated?
- If so, what are the categories of impact?
- Do you measure actual impact?
- If so, how? (outcome measures)

Reimbursement:

- Does the policy include reimbursement?
- If so, has (or is) a reimbursement channel specific to digital health applications been (being) developed?
- Do you have a flowchart of this process?
- What is covered in the reimbursement? (e.g. the application, the health professionals that prescribe / onboard / analyze / use data, the hybrid care pathway, the intervention regardless of whether it is hybrid or in-person care / the implementation)

Pricing:

- What type of pricing model is used?

- What does the price level take into account? (e.g. the (future) business model of the suppliers / level of evidence provided / investments needed / alternative health interventions with the same health claim / number of prescriptions / sustained use / intended use period)
- Do you charge manufacturers for an assessment?
- If so, how much?

Execution:

- Which organization(s):
    - is (are) tasked with implementation of your policy / law?
    - decide(s) which application gets reimbursed?
    - decide(s) on the assessment criteria / framework?
    - assess(es) the applications? (also without prospect of reimbursement)
    - determine(s) the reimbursement rates?
    - pay(s) / reimburse(s)?
    - provide(s) guidance on integration of the app in care pathways and eligibility
    - measure(s) impact?

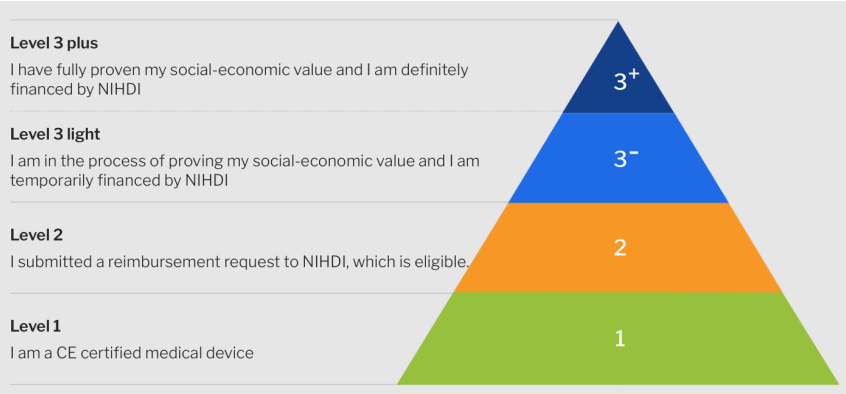
Adoption:

- To what extent has the chosen (financial) approach led to the adoption of digital applications among citizens, clients, patients and professionals in 2025
- Has (is) the initiative become (becoming) part of the culture?
- Who can prescribe? (professionals / patients?)
- What is measured with regard to uptake? (e.g., willingness to prescribe / confidence in prescribing / number of prescriptions / number of downloads / perceived self-efficacy / diversity in such? / barriers in such?)
- Are these figures public?

Lessons learned:

- What would you consider lessons learned and/or “success stories/failures” and why did they lead to those effects?

Belgium

Policy	The first eHealth Action plan (2015-2018), in which mobile medical applications is only one of several topics, instigated 24 projects (2 stroke, 3 diabetes, 2 chronic pain, 3 mental health, 8 cardiovascular diseases, 1 oncology, 1 sleep apnea and 1 COPD). Each project selected 1 app to examine how mHealth tools could fit in the healthcare model. Intended use was mostly monitoring (with or without teleconsultation), 16/23 were used in combination with accessories or wearables, 20/23 were for direct use by the patient. Particular attention was paid to the clinical case, mobile health quality criteria (privacy, security, semantic interoperability, scientific evidence, conviviality) and the budget model. Based on the results a validation pyramid was created (2018). The highest level of the pyramid entailed reimbursement of these tools.[79]  *mHealth Validation pyramid (mHealth Belgium, 2025)[80]* As of October 2023 a new reimbursement procedure for mobile medical applications has been introduced by NIHDI, replacing the Validation pyramid.[81] The current eHealth Action Plan spans 2025-2028.[82]
Scope	Mobile medical applications are software applications that: - have been CE-marked as a medical device and FAGG (Federal Agency for Medicines and Health Products)-registered - enable a patient to share health related information (potentially via sensors) with a health care provider - enable a healthcare provider to diagnose, treat or monitor a patient at a distance, via a medical device that is intended for use by the patient in their own context - provide a patient user interface in the 3 official languages[83] Remote care is the provision of medical services as referred to in Article 34 of the Act on Compulsory Insurance for Medical Care and Coordinated Benefits of 14 July 1994, by means of information and communication technologies in situations where the healthcare provider or multiple healthcare providers and the beneficiary are not at the same location.[84]
Value	Action point 19 of the first eHealth Action plan (2015-2018) identified with regard to value: Improve the health and comfort of citizens (patients and users) by supporting care incorporating effective mHealth apps.[79] A current understanding of value is clinical and organizational benefits, e.g. mortality, morbidity, quality of life, less hospitalizations or more efficiency for care staff.[83] Further distinction is pending.
Measures to capture value	The first care process that is definitely reimbursed concerns telemonitoring and therapy guidance in chronic heart failure.[85] Ambulant follow-up of cancer patients is investigated.[83] The currently reimbursed pathway design is: The hospital decides on the telemonitoring

	technologies, which have to comply with a short list of technical and functional requirements. The care pathways and role of the cardiologist, nurse specialist and GP are described in detail: The cardiologist prescribes and determines thresholds. The patient measures daily on a fixed time weight, heart rate, and blood pressure. The telemonitoring team in the hospital assesses the health data and generated alarms every working day during office hours and contacts the patient at the latest the next day if thresholds are exceeded. Based on the clinical condition and symptoms of the patient follow-up is determined, which could also entail changes to the threshold. Validated alarms, patient contacts and follow up are registered in the electronic health record. The GP / home care is informed of changes within 48 hours to ensure continuity of care. Education to enhance health literacy and promote self-management and adherence is part of the hospital and GP service. On a national level, Belgium has invested in a transmural (previously called telemonitoring prescription) platform to support seamless data exchange.[86] BeMedTech maintains the mHealth Belgium website.[80] The list of apps included is since the new procedure an overview of providers who *claim* to comply with levels of the pyramid and is not endorsed by NIHDI (National Institute for Health and Disability Insurance).[85] NIHDI for the time being does not envision a new directory with applications due to related workload to assess all applications that may be in scope and the potential of significant changes over time in these applications requiring reassessments on top.
Impact	Goal of the agreement is to assess if the follow-up via telemonitoring after hospitalization for heart failure results in a decrease of hospital (re)admissions, length of stay and an improvement in quality of life. About 200.000 to 250.000 (2 to 3%) of Belgian citizens suffer from heart failure. The disease has a significant effect on quality of life and hospitalizations. An initial evaluation is planned 2 years and a final evaluation 4 years after January 1, 2025. KPIs are yet to be determined (numerical, budgetary and qualitatively with patients and hospitals, e.g. who gets prescribed, who refuses, why, who stops, geographical differences etc.).[85]
Reimbursement	In the current procedure, a reimbursement proposal by a manufacturer / supplier, medical / scientific society / hospital / multidisciplinary work group according to a template triggers an assessment of the care pathway potential by a multidisciplinary work group. The reimbursement entails bundled payment (instead of fee for service) for a hospital, as achieving value requires beyond use of the technology by the patient, monitoring of the data it produces by health professionals. BeMedTech (industry) proposes a split forfeit instead. Temporary reimbursement for applications with an incomplete evidence base is available. Standard duration is three years, with an interim report after 18 months.[3] Alternatives to the new procedure to get reimbursed are possible. E.g. the first care process definitely reimbursed (telemonitoring and therapy guidance in chronic heart failure) started before the current procedure. Additionally innovation projects are funded by Public Services department Public Health for hospitals to implement digital tools in practice that may over time become available for the entire sector.[87]
Pricing	Specific for the care pathway currently reimbursed: According to the agreement, the hospital gets in the first month €200, in the second to sixth month €90 and as of the seventh month €45 a month. This includes both the technologies and hospital services. No fee is to be charged to the patient. The GP can charge €24.92 per calendar year to cover time spent at communication with the telemonitoring team. The price levels have been determined with input from experts, taking into account the overall

	budget for telemonitoring heart failure, number of patients, price levels abroad, and a role for the nurse specialist.
Execution	The federal public service is tasked with implementation of the eHealth plan. The eHealth platform decides on the technical requirements. NIHDI supports the multidisciplinary working group in the evaluation of the reimbursement request and the potential elaboration of the reimbursement [88], decides on the rates for hospitals and GPs and measures impact based on agreed KPIs. The insurances / mutualities pay the hospitals and GPs. A multidisciplinary working group consisting of 3 medical doctors assigned by the medical societies, 3 paramedics assigned by the insurance committee (NIHDI), 2 experts in health economics on behalf of universities, and 2 representatives of the hospitals, 8 of the insurances / mutualities, 1 of beMedTech, 1 of Agoria (both industry), 1 of the federal public service (FPS) Health, Food chain safety and Environment, 1 of the eHealth platform[89], 1 of the Federal Agency for Medicines and Health products (FAGG) and 13 ad hoc members evaluates the proposals, provides guidance on the care pathway and prepares a proposal for temporary or indefinite reimbursement.[90] The hospital assesses the technologies at least on the provided technical and functional requirements, decides which technologies to use (if own devices) or purchase, negotiates the rate and pays the manufacturer. Reportedly the amounts the manufacturers tend to receive are less than half of what the hospitals get.
Adoption	Nov 11, 2025: 48 hospitals have signed the agreement for heart failure telemonitoring and integrated telemonitoring in their care processes.[85, 91] In total, Belgium currently has 103 hospitals.[92] Per calendar year every hospital commits to including at least 50 patients. This is checked annually as of 2 years after the agreement was signed. Hospitals are requested to provide status updates every 4 months.
Lessons learned	- As all other countries, Belgium is still learning. - These technologies are not stand alone plug and play interventions but can require significant transformation efforts impacting organizational outcomes working towards more integrated transversal care. - Creation / renewal of care pathways and related financing takes very long (+1.5 year). - The process is currently reactive (an application of a manufacturer triggers the assessment of the potential of a care pathway) instead of proactive.

Denmark

Policy	Health apps are referred to in a number of strategies, among other the 2023 Digitization strategy, in which the establishment of a committee to recommend health apps, giving citizens and healthcare professionals a better overview and guidance on apps of high healthcare quality on sundhed.dk was announced to navigate the now jungle of apps.[93] Following the conclusion of political negotiations on the digitization strategy, the government, together with all parties in the Danish Parliament, decided to allocate funds to finance a Danish Board for Health Apps for the period 2024-27.[94]
Scope	Health apps are broadly understood as applications with a health-related function in the form of software that run on, for example, a mobile phone, tablet, computer or smartwatch.[95] The scope includes both medical devices, wellness apps, and more administrative apps that e.g. enable communication with the health system. Recommendations of the Board focus on the software, if a hardware is needed, the recommendations would only concern the software.
Value	The use of digital solutions is crucial in overcoming the challenges facing the healthcare system in the form of labor shortages and an increase in the number of people with chronic diseases. The healthcare system must be able to make greater use of the many health apps that can help to improve the quality of treatment, prevent disease through early detection and ensure better use of healthcare professionals' time.[93] Health apps can provide citizens and healthcare professionals with new opportunities in relation to prevention, treatment, and rehabilitation. At the same time, health apps provide healthcare professionals with new opportunities to support patient treatment, as apps can be a supplement and support tool for patients undergoing treatment.[94]
Measures to capture value	Manufacturers can apply by filling out a template on the Danish Medicines Agency website and providing documents. The assessment spans General information, Clinical evidence, User-friendliness, Price, Social value, Security and access, and a Declaration of good faith.[96] Clinical evidence is the most important requirement. The assessment is free of charge. Apps that are evaluated and recommended by the Danish Board for Health Apps are in a directory on the national health portal sundhed.dk.[97] What further measures are needed is currently discussed a lot in what are still the early stages of implementation.
Impact	Impact is not yet measured. However, the Board did decide on success criteria for their task: 1. Visibility to citizens (awareness of the recommended apps), 2. Relevance (apps spanning a broad range of health and disease areas), 3. Health inequality (recommending apps that are accessible to the general population), 4. Ease work force pressures in the healthcare system (e.g. reduce visits), 5. Coherence (recommend health apps that can be used nation-wide and that fit in patient pathways).
Reimbursement	Not available currently. A budget for analysis of how to do different types of evaluations and how to finance was agreed in the last life science strategy as a first step in the direction of a reimbursement model.
Pricing	Not yet decided.
Execution	The Minister of the Interior and Health was given in the Health Act the authority to appoint a Board for Health Apps. In September 2024 the

	Minister of the Interior and Health appointed eight members to the Board, representing the regions, municipalities, patients, the Danish Medical Association, the Danish Association of General Practitioners, the Association of Senior Citizens, the Chamber of Commerce, and the medical industry.[98] The Board decides on the assessment criteria, and assesses with input provided by the secretariat (the Danish Medicines Agency[94]) and external experts provided by relevant medical societies. These medical doctors fill out a template with their findings, which carry weight in the assessment as clinical evidence matters most. Further tasks are yet to be decided upon. A new organization called Digital Health Denmark, owned in part by the state, in part by the regions and in part by the municipalities, will be established in 2027 and will have the overall responsibility for coordinating tasks related to the digitalization of the healthcare system.
Adoption	The first 5 health apps were recommended in June 2025 as a valuable supplement to the existing offerings in the health sector, strengthening the healthcare sector and citizens' ability to manage their own illness and health.[99] In the meantime the number has grown to 10 recommended apps. From the launch date of June 27 to October 2025, 2229 visits, 1015 clicks to the Apple app store buttons and 619 to the Google play store buttons were recorded in Sundhed.dk.
Lessons learned	- A lot of health apps have **difficulties showing direct clinical effects**, although small effects can also be valuable. - It is quite difficult to reach citizens and patients just via sundhed.dk, a **role for healthcare professionals** (GPs, doctors) and further **communication** efforts are considered to increase the use of health apps by patients and in the health system and achieve the intended effects. - The **apps are quite diverse**, large and small health issues, administrative, more health specific, etc. and they change quite often. **Significant changes need to be reported** to trigger an assessment of the implication of the change or changes made. Every app is to undergo a **reassessment on an annual basis**.

Status December 8, 2025

https://www.sundhed.dk/borger/sygdom-og-behandling/om-sundhedsvaesenet/anbefalede-sundhedsapps

Displayed are product icon, (abbreviated) name of product, (abbreviated) name of manufacturer, country of manufacturer, cost, and medical device class. Text in gray indicates the app was listed in a previous category already.

Category	Recommended
General	  MinLæge Lægersor MinSund Sundhed.  no cost no cost
Hormones and metabolism	  

	Hedia Di Hedia Ap no cost MDR - IIb Kulhydra Diabetesf no cost MinSpiral Bayer no cost MDR - IIa
Lifestyle and wellbeing	Mit liv - m Det digita no cost
Muscles, joints and bones	Mine Kno OSAIA H no cost / dkk29/m dkk199/m SelfBack SelfBack no cost / dkk249/m MDR - I
Pain and injuries	SelfBack SelfBack no cost / dkk249/m MD.. - I
Psyche	Meta Lea Meta Lea dkk99/m Stress Au GGZ Cen no cost
Social	Stress Au GGZ Cen no cost

England

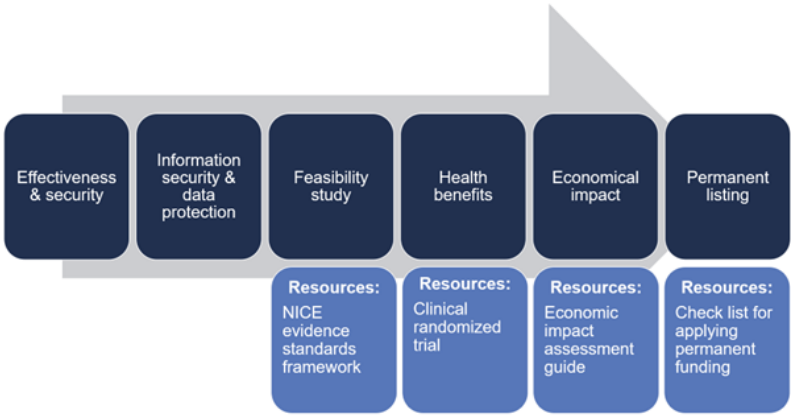
Policy	In 2024 Lord Darzi published the results of a rapid (9-week) investigation of the state of the National Health Service (NHS), assessing patient access, quality of care and the overall performance of the health system. He concluded the NHS is in serious trouble, and regarding digital that while many sectors of the economy have been radically reshaped by digital technologies, the NHS is in the foothills of digital transformation. The last decade was a missed opportunity to prepare the NHS for the future and to embrace the technologies that would enable a shift from 'diagnose and treat' to 'predict and prevent'.[100] Subsequent conversations with thousands of employees and members of the public, and some 250.000 ideas submitted to the Change NHS website, confirmed no one defends the current status quo and that staff and patients are crying out for change. As a result, the 10 Year Health plan for England (2025) aims at transformational change that will guarantee sustainability for generations to come instead of continuing down the current path, making tweaks to an increasingly unsustainable model. The plan aims to make the NHS fit for the future through 3 radical shifts: - hospital to community - analogue to digital - sickness to prevention Science and technology will be key to this reinvention. Multi-year budgets will be introduced, and NHS organisations will be required to reserve at least 3% of annual spend for one-time investments in service transformation, to help translate innovations into practice more rapidly. The role of life sciences and technology companies can play in service delivery will be expanded and procurement of technology streamlined.[101]
Scope	Currently, both the Evidence Standards Framework (ESF) and the Digital Technology Assessment Criteria (DTAC) refer to Digital Health Technologies (DHTs). A technology is likely covered by the ESF if it: - is an app, software or online platform that is intended to benefit people's health or care or the wider health and social care system - has a medical, wellness or system efficiency purpose - offers value to the health and social care system - is available and likely to be commissioned in the UK health and social care system DTAC operationalizes DHTs as apps, wearables, software as a service and other.[102] The 10 Year Health plan for England identifies Data, AI, genomics, wearables and robotics as transformative. Intent is to make wearables standard in preventative, chronic and post-acute NHS treatment by 2035. All NHS patients will have access to these technologies, which will be part of routine care. The NHS will provide devices for free in areas where health need and deprivation are highest. NICE's technology appraisal process is to expand and cover devices, diagnostics and digital products. NICE will also be given a new role to identify which outdated technologies and therapies can be removed from the NHS to free up resources for investment in more effective ones.[48]
Value	The transformative capacity of data, AI, genomics, wearables and robotics is explained as personalizing care, improving outcomes, increasing productivity and boosting economic growth. By harnessing the digital revolution, the NHS will be able to: - ensure rapid access for those in generally good health - free up physical access for those with the most complex needs - help ensure the NHS's financial sustainability for future generations

	- transform the NHS App into a world-leading tool for patient access, empowerment and care planning[48]
Measures to capture value	The National Institute for Health and Care Excellence (NICE) introduced in 2019 the ESF, a set of evidence standards for a wide range of DHTs, to promote more consistency in their evaluation across the NHS. Intended users are commissioners and evaluators in the health and care system making purchasing decisions and companies developing DHTs for use in the system. The framework was updated in 2021 and 2022.[103] NICE uses the Early Value Assessment (EVA), a rapid assessment of digital products, devices and diagnostics for clinical effectiveness and value for money, to provide the NHS with clear guidance about which digital or other health technology will make a real difference to patients and what further evidence is needed.[104] NHSX, since 2022 part of the NHS England Transformation Directorate, introduced in 2021 the Digital Technology Assessment Criteria (DTAC). Aim was to enable innovators to build what the NHS is looking for into their DHT 'by design', and to provide those buying DHTs for the NHS and social care a proportionate simple set of criteria to assess these technologies against to realize the benefits DHTs can bring.[102] On the request of NHS England, the DTAC is currently mapped against CEN-ISO/TS 82304-2 to consider acceptance and possibly adoption of the technical specification. All of these measures are not directly linked to reimbursement nor formally mandated but highly recommended before buying a product. In practice reimbursement without DTAC is unlikely. The 10 Year Health plan for England aims to make the NHS app by 2028 a full front door to the entire NHS. Patients will be able to: - get instant advice for non-urgent care, and help finding the most appropriate service first time through My NHS GP - choose their preferred provider through My Choices - book directly tests where clinically appropriate through My Specialist - hold consultations through My Consult - manage their medicines through My Medicines - book vaccines through My Vaccines - manage a long-term condition through My Care - access and upload health data through My Health - get extra care support through My Companion - manage their children's healthcare through My Children - co-ordinate the care of a loved one or relative through My Carer - leave feedback on the care they received in easy-to-action formats - use continuous monitoring to help make proactive management the new normal, allowing clinicians to reach out at the first signs of deterioration to prevent an emergency admission to hospital - access 'HealthStore' and its approved digital tools through the NHS app to manage or treat their conditions[48] A single sign on will be introduced and the use of technology like AI scribes scaled to liberate staff from their current bureaucratic and administrative burden, freeing up time to care and focus on the patient.[48]
Impact	The EVA process intends to support impact measurement but is sporadically and access to be processed is not clear. Suppliers have to supply data on the impact of their product, which is different from impact on the system as a whole.
Reimbursement	The UK employs a range of different reimbursement mechanisms to respond to the needs of different settings, technological maturity as well as clinical and financial risk. In reviewing these mechanisms, it appears

	that most have been developed to support innovation and address inadequacies in the National payment system.[105] The 10 Year Health plan for England and its 'HealthStore' seek to enable innovative businesses to work more collaboratively with the NHS and regulators. Further details are not yet available.[101]
Pricing	Healthcare providers or NHS trusts negotiate rates locally. To be bought you have to be in 'the framework', a type of catalogue of which there are several.[106] Price is mentioned there but can be negotiated down. In practice, several parties may be involved in the DHT assessments, some of which charge a fee.
Execution	The 10 Year Health plan for England will result in a new operating model and as such several organizational changes.[101] Currently NHS England decides on the DTAC assessment criteria. Several organizations provide DHT assessments. The NHS trusts or healthcare providers negotiate rates and pay.
Adoption	In a recent study 178/204 NHS organizations (such as NHS provider trusts) reported combined a total of 14.747 DHT deployments, with the number of deployments ranging from 0 to 1115 per NHS organization with an average of 107. This count does not represent unique products. The same product could theoretically be represented in all NHS organizations that deploy a product.[107] An indication of the total number of downloads is not available.
Lessons learned	The Association of British HealthTech Industries (ABHI) echoes that **DHTs do not fit easily into existing funding pathways**. While some technology-level reimbursement exists (e.g. the MedTech Funding mandate[108]) there is a long process to get awarded and it is only applicable for one technology / company, which limits digital transformation at pace and scale and decreases the attractiveness of the market for investors. **Specifics of DHTs must be considered when developing instruments for assessing and rewarding the value they provide** for patients, healthcare actors, health systems' sustainability and society: - Timelines should be appropriate, engagement with the manufacturer early and consistent and feedback clear. - Criteria and evidence requirements should be transparent and specific, appropriate based on risk profiles, supportive of innovation and development of a dynamic market, aligned and non-duplicative with base processes such as UKCA and DTAC and have direct links to funding. - Financial criteria should be based on value/cost effectiveness, not on affordability (to be determined at local adoption level). - There should be no cap on products eligible / awarded for reimbursement, provided the products meet criteria.[105] A provisional review with industry and NHS providers has highlighted for several areas a lack of clarity on how DTAC should be applied, and a need to reduce the burden on industry and suppliers and to improve the effectiveness of DTAC in the system.[102] In total 26% of all deployed DHTs were reported as being compliant to DCB 0129 (UK clinical risk management standard, part of DTAC), 4.6% were DCB 0160 compliant, 70.1% had no documented evidence of safety assurance.[107] DTAC does not have a system to assess, deploy and reimburse.

Estonia

Policy	The new e-health strategy 2025–2030 focuses on data-driven management, improving the quality and accessibility of health data, and introducing new technologies. Further development requires better managed data, a legal environment that supports innovation, and less fragmentation. The strategy highlights three priorities: people-centred healthcare, supporting healthcare professionals and valorizing data. The plan builds on national health and digital society development plans, that were prepared with experts, companies and state institutions, and stakeholder feedback.[109] The Tervisekassa (the Health Insurance Fund) innovation grant (2024) was introduced as a result of a telemedicine pilot project (2020-2024).[110] This permanent scheme supports the implementation of impact studies, to obtain reliable information about effectiveness, cost-efficiency and ease of use of services compared to current best practice, and compares to DiGA (Germany), PECAN (France) and Early Value Assessment (UK).[111]
Scope	Digital solutions, or digital health technologies, are mobile applications, programs and software used in the healthcare system, which can be used alone or in combination with other products or services. Such solutions are being used throughout the healthcare system, starting from supporting people's well-being and lifestyle and finishing with complex diagnostic and treatment devices.[112] The description is still evolving. Permanent listing is on a case-by-case basis. In practice the focus will likely be more on medical devices than wellness applications. Remote healthcare services or telemedicine are defined (by the European Commission) as the provision of healthcare services at a distance, through the use of ICT. It involves secure transmission of medical data and information, through text, sound, images or other forms needed for the prevention, diagnosis, treatment and follow-up of patients.[112]
Value	The new e-health strategy aims to make healthcare more human-centric by offering more accessible services to patients and new solutions to healthcare providers. High-quality and accessible data helps to adapt healthcare services to people's needs, reduce the workload of doctors and improve the efficiency of treatment.[109] The use of digital healthcare technologies in the healthcare and social system provides a way to ensure the sustainability of society in a situation of aging population, lack of health care professionals, and insufficient resources. Solutions can help people take more responsibility for their health, maintain and improve their health and quality of life, influence health-related behavior, make processes more efficient, and save healthcare professionals' time and healthcare costs.[112] Aim of the innovation grant is to expand the range of services that have been proven to: - increase the people-centeredness of the health care system - improve health outcomes - support the person in maintaining health and preventing diseases - improve the integrity of care pathways - ensure the quality and availability of the service in a condition of limited resources The projects to be supported must be based on national strategic goals and development trends described in development plans.[113]
Measures to capture value	During the pilot project it became clear that the route to permanent reimbursement is longer than assumed in the projects call[114]:

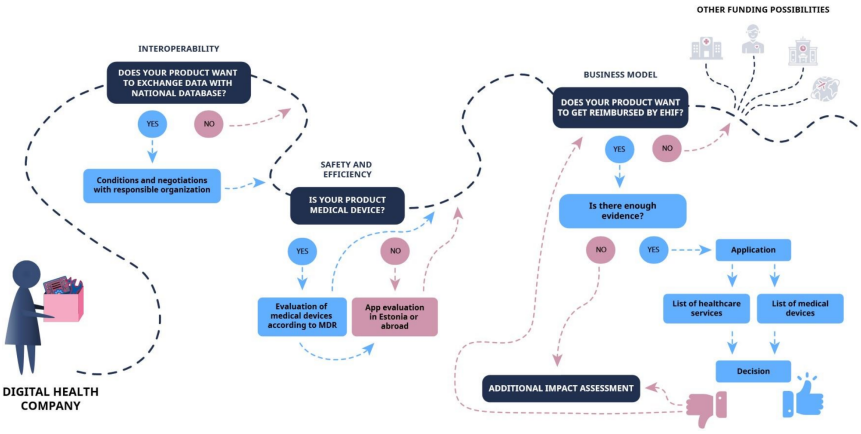


Route to permanent listing[114]

Investigating the impact of new (digital) service models is still an evolving field**. Digital solutions constantly evolve** and are **highly dependent on end-users**. This makes it very **difficult to measure their clinical impact and effectiveness**. The structure of a randomized controlled trial (RCT), the gold standard in healthcare, is challenging for service models containing digital solutions to demonstrate their full value. Still, awaiting agreements and better alternatives, Estonia relies on RCTs for research on digital solutions. The NICE evidence standards framework (ESF) was found a useful tool for conducting initial feasibility studies. To obtain permanent funding, one study alone is not sufficient.[114] The auditing process for another spin-off from the pilot project competition, the primary care digital service channels project, is similar to NHS's DTAC evaluation.[114]

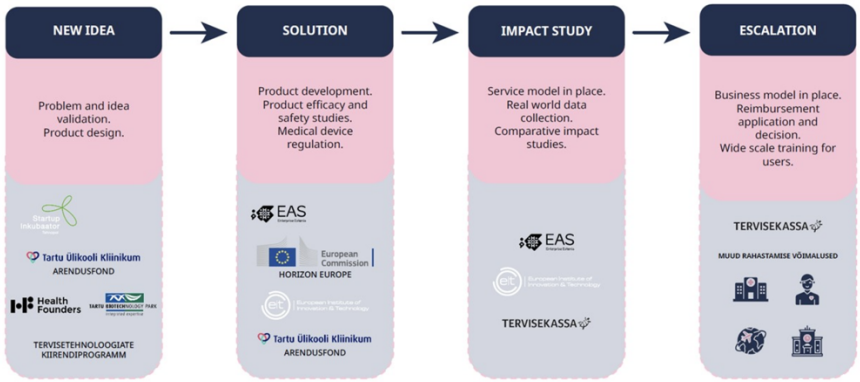
The digital solutions guide brings together important information that a digital solution manufacturer should consider in the different development stages of a solution. The guide focuses on three points of contact between the state and a digital solution manufacturer:

- interoperability, i.e., data exchange between the digital solution and national databases and/or those of healthcare providers
- security and efficiency
- permanent reimbursement by the Health Insurance Fund[115]



Digital solutions guide[115]

Interoperability is well-established. There is not a separate repository. If reimbursed, the services are included in the listing of all services provided in healthcare. Further measures depend on the product and are determined on a case-by-case basis.

Impact	Determined on a case-by-case basis. Impact is especially assessed in the first year, in later phases less so.
Reimbursement	 *Innovation stages and funding measures of digital solutions[112]* Estonia generally uses the fee-for-service model. Given its ill fit with integrated patient care, integrated payment models tying together the technological component and the healthcare worker's time were tested in the pilot projects. A bundled payment attached to the patient – if patients use the product - was adopted afterwards. The call also experimented with outcome-based performance pay related to patient health and experience indicators. This meant that payment was based on the final outcome and impact on the patient, rather than number of procedures performed. This work is still on-going. The payment models tested in the pilot projects included compensation for new roles and activities of healthcare workers. Some of which have been partially included in the permanent Health Care Services List, meaning they are funded for all healthcare service providers.[114]
Pricing	Determined on a case-by-case basis. It depends on the product and pricing is in a learning phase. Manufacturers are not charged for an assessment.
Execution	The Social Ministry is tasked with implementing the eHealth strategy. Tervisekassa decides on the assessment framework, assesses the applications, determines reimbursement rates, pays, provides guidance on integration in care pathways and measures impact. The Health Care Services Committee decides which applications get listed (reimbursed).
Adoption	In total now some 7 digital solutions are listed, 3 related to contacting GPs (coverage some 90% of GPs), 1 remote psoriasis and 1 remote cancer monitoring, 1 stroke rehabilitation, and 1 AI in radiology. For diagnosis-based solutions the healthcare professional needs to prescribe. Niche products have perhaps 100 users. Estonia is a really small market (1.3 mln inhabitants[61]). Foreign manufacturers might decide translating their product in Estonian is not worthwhile. The few local companies are in the early phase of development.
Lessons learned	- Successful innovation in healthcare can only occur through open collaboration with other stakeholders in the health system. Health insurers have traditionally been distant from innovation and entrepreneurship. Tervisekassa took on a new role with the call.[114] - For the call, Tervisekassa engaged from the outset various stakeholders – **healthcare providers, academia, entrepreneurs, health insurance, policymakers**. Better-integrated healthcare services are essential in the future. It is important, as new roles

	emerge and are assumed, to transparently and clearly communicate where investments are being made and what roles are taken on.[114] - Estonia doesn't have budgets comparable to those of bigger countries, so there's a need to be really smart and frugal. Public money needs to be well spent and result in returns on investments. In the initial project there is already a focus on team (healthcare provider, doctor, research partner and manufacturer), scalability, type of evidence needed, etc. - We need stronger evidence to fund a solution than ESF, a permanent scheme and innovation grants for companies / teams to gather evidence needed to reach the goal of reimbursement.

Finland

Policy	The Ministry of Social Affairs and Health has recently launched a digital care pilot project.[116] The project is part of the Ministry of Social Affairs and Health's national research, development and innovation programme in the health and welfare sector, which aims to strengthen Finland's position as a developer and user of digital health solutions. The project is divided into four main phases: planning, procurement, testing, and evaluation and will run from May 2025 to February 2027. Its aim is to create a basis for a national operating model in which digital care solutions can be effectively and equally implemented as part of public healthcare.
Scope	Digital care refers to evidence-based digital therapies and self-care programs that can support patient well-being and the success of treatment. These can both be medical devices and wellness applications, can include software, combinations of software and hardware, platforms or service solutions. A total of 10 different digital solutions (applications and possible devices that support them) that meet strict quality and safety criteria and are based on researched evidence were selected for the project through an open competition[117]: 1. KaikuHealth (Elekta Instruments AB) Symptom monitoring and participation model for cancer patients 2. AIRe Platform (Jyväskylä University of Applied Sciences) Rehabilitation of low back pain and mild & moderate cerebrovascular disorders 3. Orla INR remote measurement (Orla Dtx) Secondary prevention of previously diagnosed thromboembolic complications (e.g. cerebral infarction, pulmonary embolism) 4. Cardio Signal (Precordior) Early detection of atrial fibrillation in heart failure patients 5. Beat2Phone ECG (Promedical) 1-channel ECG for detecting arrhythmias in connection with previously diagnosed heart disease or cerebrovascular accident 6. Diabetes application ecosystem Sensotrend Connect: Diabetes (Sensotrend) Terve Päivä digital treatment pathways: Diabetes, obesity treatment & weight management (SaraWell) Balansio: Diabetes, other chronic lifestyle-related diseases (ProWellness Health Solutions) 7. Sensotrend Connect and Metabite Sensotrend Connect: Diabetes (Sensotrend) Metabite: Monitoring and enhancing the nutrition of diabetic patients (Metabite) 8. Sooma tDCS (Sooma) Transcranial direct current stimulation for the treatment of depression 9. Pregnabit (Steripolar) KTG monitoring for monitoring fetal growth disorders or pregnancy complications (not for normal pregnancy) 10. BitHabit (Wellpro Impact Solutions) Prevention of worsening of established lifestyle diseases (diabetes, metabolic syndrome)
Value	During the project, information will be collected on the benefits these applications provide to patients and professionals and how they can be integrated into public healthcare. The goal is making the utilization of digital treatments part of Finnish, information-led healthcare equally in all areas and taking into account the needs of patients.

Measures to capture value	The Digi-HTA assessment framework was developed in a collaboration of FinCCHTA (the Finnish Coordinating Center for Health Technology Assessment[118]) and the University of Oulu.[119-123] Assessment results can be found in the FinCCHTA Assessment library.[124] The planning phase of the project defined the objectives, outputs, and roles of the participants and included preliminary studies on international reimbursement models and domestic distribution models, preparation of procurement documents and description of the project's operating model. At the same time, communications, an evaluation plan and risk management were prepared. In the procurement phase, the digital solutions selected for the project were put out to tender, and the distribution model, data protection arrangements, and training and support practices were agreed upon. In the testing phase an Application Library will act as a centralized distribution channel. The implementation of the applications will be supported by training, information sessions and instructions.
Impact	There are some regional studies collecting data on impact of the applications.
Reimbursement	To be determined by Kela (the Social Insurance Institution of Finland[125]) as a result of the project.
Pricing	The project offers health professionals and their patients the opportunity to try the evidence-based digital treatments and self-care programs free of charge for the duration of the project. Manufacturers are not charged for an assessment.
Execution	The Ministry of Social Affairs and Health is responsible for steering the pilot project. Digi Finland, an organization that in cooperation with various stakeholders develops social and healthcare services that are accessible to everyone living in Finland[126], is responsible for its implementation and central procurement of the use of the applications. An evaluation group, which included the Ministry of Health, Social Affairs and Health, Digi Finland, Kela, Sitra (the Finnish Innovation Fund[127]) and FinCCHTA was responsible for evaluating and selecting the offers. FinCCHTA evaluates the applications using the Digi-HTA assessment framework. The completed Digi-HTA assessment reports are published on the FinCCHTA website. Kela, Sitra and FinCCHTA are the key expert partners. The pilot project will be implemented in close cooperation with the participating application providers, regional healthcare professionals and patients. Who decides on reimbursement and the reimbursement rate is yet to be determined.
Adoption	The applications in the pilot project are offered to patients by their health professional as part of their care. The doctors treating the patients assess who the digital care application is suitable for and determine its use. They will be asked to provide feedback on the usability of the applications and their impact on patient care, as well as feedback on the smoothness of the distribution model itself. The experiences collected from patients are another important part of the evaluation of the pilot project and help to understand the benefits and challenges of digital care from the user's perspective.
Lessons learned	Too early to tell. In the evaluation stage all the assessments, reports and experiences generated during the experiment are compiled. Based on the results, recommendations will be made on what kind of permanent distribution and operating model could be used to permanently integrate digital treatments into Finnish healthcare. The final report will be

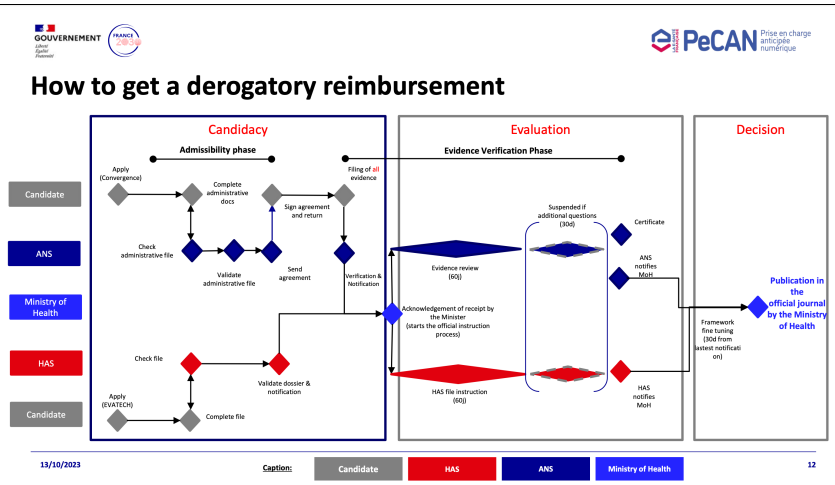
	completed in February 2027 and will include a summary of the experiments, the effectiveness, usability and benefits of the applications from the perspectives of both professionals and patients, recommendations for permanent operating models, scenarios for reimbursement models and prospects for further development.

France

N.B. Based on desk research and an expert check.

Policy	General law reimbursement for digital therapeutics (DTx) is LPPR ("Liste des Produits et Prestations Remboursable") and for telemonitoring LATM ("Liste des Activités de Télésurveillance Médicale").[3, 128] Introduced by the 2022 Social Security Financing Act (Article 58), early digital coverage ("Prise en charge anticipée numérique", PECAN[129]), launched in 2023, allows patients to quickly benefit from innovative digital medical advances. The initiative is part of the "Digital Health" acceleration strategy, announced by President Macron as part of France 2030, and allocated €718 million. It is consistent with various government digital health programs, including the ministerial roadmap for digital health.[130]
Scope	Innovative Digital Medical Devices (Dispositifs Médicaux Numériques, DMD, class I to III) that are intended for therapeutic use and eligible for LPPR, or for remote medical monitoring and eligible for LATM.[130] Candidate devices must: - have a valid CE medical marking for the indication in question, regardless of the risk class of the MD - be considered innovative, particularly in terms of clinical benefit or progress in the organization of care, based on the initial data available and considering any relevant comparators - be able to provide evidence of the benefits of the solution within the time frame set for the Haute Autorité de Santé (HAS, the French National Authority for Health) to decide on the merits of the solution before the end of the exemption period - comply with the DMD interoperability and security standards established by the Digital Health Agency (ANS) to ensure the exchange, sharing, security, and confidentiality of patient health data[130]
Value	PECAN**:** clinical and/or organizational benefits, LPPR: actual clinical benefit and clinical added value, LATM: clinical improvement, gains in organization of care, or public health interest.[3] The "Digital health" acceleration strategy is a strategy to prepare for the future and make France a **leader in digital healthcare**. As part of a mobilization of all players in the digital health industry, this proactive acceleration strategy aims to: - Foster the shift from curative, silo-based medicine to a **more preventive, predictive and personalized** approach, - Foster the emergence of a major **digital healthcare ecosystem** in France, **capable of asserting itself in a competitive global market**, - **Process healthcare data securely and ethically**, without depending entirely on a few players subject to regulations that are less protective of personal data.[18]
Measures to capture value	The PECAN decree of March 31, 2023, specifies the terms and conditions of application. Manufacturers can apply.[131] G_NIUS and recently published guides for LATM and PECAN can guide manufacturers.[132] France does not have a public repository. Further measures may exist or result from the Digital Health Acceleration Strategy aims: - Foster the conditions for the large-scale deployment of successful digital health projects - Sustain experimentations in real-life conditions and first industrial demonstrations

	- Support the development of structural projects to strengthen strategic territorial advantages - Prepare the future generation of key digital health technologies and facilitate rapid transfer mechanisms of research results - Develop stakeholder training, stakeholder trust and professional attractiveness of the sector[133] Within the framework of a cooperation agreement between France and Germany on the assessment of medical devices, signed in June 2025, exchanges are planned between the HAS and its German counterpart on their respective accelerated assessment processes (DiGA in Germany and PECAN in France). This cooperation aims to prepare for potential joint assessments of medical devices under the European regulation. Also, guides with the evaluation principles for LATM and PECAN were recently published. The importance of the quality of ongoing studies and the methodology of studies at all stages of the development to ensure their results are taken into account is emphasized.[134]
Impact	Information on this topic was not found in the current effort.
Reimbursement	The 1-year PECAN exemption period gives operators the opportunity to begin deployment of their DMD while finalizing their application for coverage under common law. Prescription by a doctor is required.[130]
Pricing	The predefined fixed compensation for therapeutic DMDs under PECAN is an initial flat rate of €435 including tax per patient, invoiced for a period not exceeding 3 months, followed by a monthly tariff of €38,30, resulting in a maximum financial compensation of €780, including tax, per year per patient.[135] For LPPR prices between manufacturer and CEPS are negotiated, primarily matching it with the clinical benefit evaluation issued by the National Commission for the Evaluation of Medical Devices and Health Technologies (CNEDiMTS).[136] LATM has predefined telemonitoring tariffs which include an operator tariff for the healthcare professional performing telemonitoring (set at €11 to €70 per month depending on the expertise level of the healthcare professional) and another for the retailer or distributor offering the technical solution. Monthly flat rates for the device provider are set at €50 (including VAT) per patient in case of organizational benefit for up to 4999 patients in the indications, at €73.33 (including VAT) per patient for clinical benefit related to quality of life, at €82.50 (including VAT) for clinical benefit related to morbidity, and at €91.67 (including VAT) for clinical benefit related to mortality. These fees may be adjusted based on the average monthly caseload of all patients who have benefitted from coverage for remote medical monitoring for the same indication (across all manufacturers), e.g. in case of 5000-7999 patients the rate decreases to €45,83, etc.[137] Payment by the French national health insurance is intended to be contingent on the actual use of the DMD under all reimbursement schemes.

Execution	 *The PECAN process[133]* To reduce delays in parallel two assessments are carried out within 60 days. The application must be submitted on the Convergence platform to enable the Digital Health Agency (ANS) to verify the solution's compliance based on the DMD interoperability and security reference framework[138], approved by the decree of February 22, 2023. The Haute Autorité de Santé (HAS) rules on the presumed innovation of the digital solution with a view to improving patient care through health insurance. Applications must be submitted on the EVATECH platform for evaluation by the National Commission for the Evaluation of Medical Devices and Health Technologies (CNEDiMTS)[139]. Based on these opinions, the decision on advance digital coverage is made within 30 days by the ministers responsible for health and social security.[130]
Adoption	Several sources report the number of PECAN candidates, which is to date 12 applications resulting in 4 favorable opinions. OECD (2025) reports 6 candidates for PECAN in 2023 and 2024, 1 digital therapeutic (Hellobetter®) and 5 remote telemonitoring, for LPPR 1 digital therapeutic (Deprexis®), while many other medical devices on the LPPR also included a software component (e.g. implantable cardiac prostheses, glucose monitoring devices), and 7 opinions for LATM (remote monitoring), mostly telemonitoring for patients taking systemic anticancer treatments.[140] MediTech Access (2025) reports at least 11 PECAN dossiers, 7 telemonitoring solutions and 4 DTx, resulting in 7 opinions of which 3 favorable, and at least 16 LATM applications, resulting in 9 decisions of which 6 favorable.[141] The CNEDiMTS annual report of 2023 reports 3 PECAN applications were processed, which resulted in 1 favorable opinion and 2 unfavorable opinions within timeframes of 37, 25 and 36 days.[142] The annual report for 2024 reports 5 PECAN applications were processed by the HAS, 1 was deemed inadmissible, the other 4 resulted in an opinion from the CNEDiMTS: 2 favorable and 2 unfavorable within timeframes of 41, 39, 21 and 26 days.[143] Information on uptake of the PECAN DMDs by health providers, health professionals and patients was not found in the current effort.
Lessons learned	Communication from the HAS allegedly highlights recurring challenges faced by applicants: - Inconsistencies between claims and supporting clinical evidence. - Incomplete or irrelevant administrative documentation. - Lack of relevance and clarity in argumentation. - Inaccurate identification of the target population and comparators.[141] CNEDiMTS reports that beyond renewals or "standard" applications, there was no increase in 2024 in applications related to innovation access

	mechanisms such as early support for digital medical devices (PECAN). This observation should undoubtedly prompt us to question the clarity of these exceptional mechanisms for companies and encourage them to request early meetings or pre-submission appointments. It would be useful, in light of the experiences of recent years, to assess these mechanisms, which would allow us to understand potential obstacles (eligibility criteria? duration? anticipation of studies? targeting of medical need? other?) in order to identify levers to strengthen the incentive for promoters of presumed innovative products to take action, in the interest of patients.[143]

Status PECAN November 27, 2025

A public repository is not available. Based on an overview previously shared and further desk research[32, 144-148] a focus on PECAN was applied.

Displayed: product icon if found on public website or app store, (abbreviated) name of product, (abbreviated) name of manufacturer, country of manufacturer, medical device class.

Category	PECAN
Cancer telemonitoring	 Continuu Continuu  Cureety Cureety MD.. - I MD.. - I
Chronic pain	 Axomove Axomove MD.. - I
Disorders of the retina	 Odysight Tilak Hea MDD - I

Germany

Policy	The Digital Health Care Act (“Digitale-Versorgung-Gesetz”, DVG)[149] introduced in 2019 Digital health applications (DiGA). Goal is for patients to benefit as quickly as possible from innovative approaches to care. In 2021 Digital nursing applications (DiPA)[150] were introduced for the approximately 4 million individuals in need of care. The 2024 Digital Health Act (“Digital-Gesetz”, DigiG)[151] aims to accelerate the digital transformation, better integrating DiGA into healthcare processes and enabling more complex treatments (class IIb medical devices).[21]
Scope	A DiGA is a CE-marked risk class I, IIa or IIb medical device, which is used by the patient alone or by patient and healthcare provider together to support the recognition, monitoring, treatment or alleviation of diseases or the recognition, treatment, alleviation or compensation of injuries or disabilities. Its main function is based on digital technologies and its medical purpose mainly achieved by way of its digital function.[13, 21] Primary prevention and “practice equipment”, telemedicine applications and video consultations are not DiGA.[152] Digital nursing applications (DiPA) aim to stabilize or improve the state of health of care recipients or to improve communication with their relatives and care professionals.[13] Nov 5, 2025: Of the 239 DiGA applications received, 185 concerned provisional listing (12 months with a possible extension of another 12 months, class I and IIa only), 54 permanent listing. In total 57 were positively assessed, 28 negatively, 127 were withdrawn, 11 are currently being processed, and 16 were deleted from the DiGA directory of which 7 on request of the manufacturer (reasons for which are not public). DiPA has no approved applications to date. The number of applications is not published.[13]
Value	For DiGA 4 types of medical benefits are recognized: - improvement of the state of health - reduction of the duration of a disease - prolongation of survival - improvement in the quality of life and 9 patient-relevant improvement of structures or processes (pSVV): - coordination of treatment procedures - alignment of treatment with guidelines and recognized standards - adherence - facilitating access to care - patient safety - health literacy - patient autonomy - coping with illness-related difficulties in everyday life - reduction of therapy-related efforts and strains for patients and their relatives.[13] Class IIb DMDs must have a medical benefit.[13] DiPA distinguishes 8 care benefits: - mobility - cognitive and communicative abilities - behavioral patterns and psychological problems - self-care - coping with and independently dealing with illness- or therapy-related requirements and stresses - organizing everyday life and social contacts - household management - stabilization of home care[14]

Measures to capture value	Provisional listing (1 year or - with extension - 2 years to gather sufficient further evidence for permanent listing) requires: - a systematic literature review (evidence synthesis of similar therapeutics) - a systematic data analysis (data on the use of the DiGA, justification of the improvement of healthcare) - a study concept for a quantitative comparative study (prospective preferred, retrospective and Real World Evidence possible) by an independent scientific institution.[152] Studies must be conducted in Germany, unless the comparability of the healthcare situation in another context can be proven. Based on the standard of care, the comparator can be: - non-treatment - treatment without use of a DiGA - treatment with a comparable DiGA Currently debated is treatment with a placebo DiGA.[3] Permanent listing requires a detailed study report of the as per the study protocol and analysis plan completed study.[152] **Resources** are available **for manufacturers** to get informed[153] and to apply[154]. The **directory**[8] provides health professionals and patients with detailed information on the DiGA. The setup of **e-prescription** for DiGA is part of the Digitalgesetz, and was previously recommended by researchers for its potential to further improve activation rates.[50, 69] **Interoperability with electronic patient records** is intended to enable providers to easily monitor patients' DiGA use and associated benefits, which may provide positive feedback driving further adoption.[69, 152] **Hybrid or blended care models** have been shown to increase patient adherence and patient access, yet introduce legal barriers, as DiGA are to be based primarily on digital technologies.[69] To promote acceptance e.g. **training** courses / documents for health professionals, targeted **marketing**, advertising and intensive **communication with health providers** are currently used and considered at least to some extent effective.[59] In a large survey (n=1297) with GPs, physicians, and psychotherapists from across Germany by Dahlhausen et al. (2021)[29] extended information campaigns (85.1%), recommendations from medical associations (80.3%) and medical colleagues (79.0%) were considered most effective to support professionals who are unsure of prescribing DiGA. Richter et al. (2021) found in a survey with 75 German rheumatologists [30] that 46% expected information on DiGA from the scientific societies / medical chambers (35%) but rarely from the manufacturer (10%) and the responsible ministry (4%). The respondents would like to be informed about DiGA via continuing education events (face2face 75%, online 84%), trade press (86%) and manufacturers' test-accounts (64%). DiGA can be **prescribed** by physicians and psychotherapists **or requested by insured individuals** with proof of the corresponding indication. Most are prescribed. The most directly requested DiGA (40% and 28%) are categorized under *genitals, kidneys, and urinary tract*.[21] In Germany and beyond, several DiGA have already been included **in evidence-based guidelines**.[32]
Impact	Plan is to make at least 20% of the remuneration of permanent listed DiGA depend on success factors to be agreed between GKV-SV and the manufacturers.[3] The measurement via different PROMs and further KPIs is still in draft phase[155]. After a second amendment no further consultation is expected for the second DiGAV change, that sets the base for Value Based Health Care (VBHC) in the future.
Reimbursement	A combination of provisional listing and permanent listing. Beyond the DiGA, required hardware is covered (currently VR headset (1 DiGA), and

	motion sensors (1 DiGA), 5 DiGA have optional hardware components). (TK, 2024).
Pricing	Gruppenspezifische Höchstbeträge gemäß § 3c der Rahmenvereinbarung nach § 134 Abs. 4 und 5 SGB V Geltungsstichtag: 01.10.2025

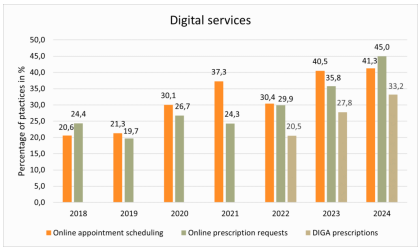
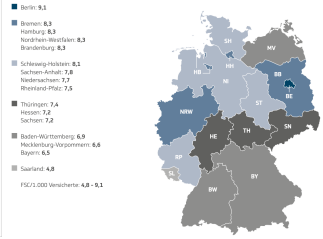
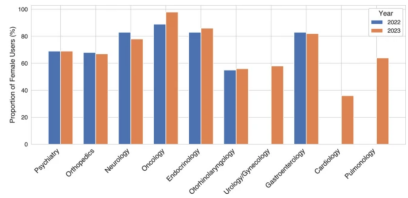
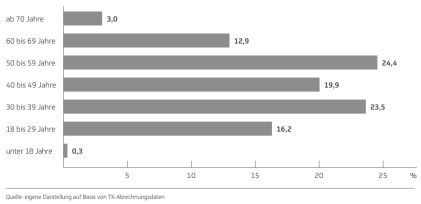
	Betrag pro Kalendertag inkl. USt.			
Höchstbetragsgruppe	Gruppenspezifischer Höchstbetrag	Höchstbetrag nach Einlösung von mehr als 10.000 Rezeptcodes / Freischaltcodes	Höchstbetrag für zur Erprobung in das DiGA-Verzeichnis aufgenommene DiGA	Höchstbetrag für zur Erprobung in das DiGA-Verzeichnis aufgenommene DiGA nach Einlösung von mehr als 10.000 Rezeptcodes / Freischaltcodes
Herz-Kreislauf-Erkrankungen | medizinischer Nutzen	5,02 €	3,77 €	4,02 €	3,01 €
Krankheiten des Urogenitalsystems | medizinischer Nutzen	7,63 €	5,72 €	6,10 €	4,58 €
Onkologische Erkrankungen | medizinischer Nutzen	7,51 €	5,63 €	6,01 €	4,51 €
Psychische Erkrankungen | medizinischer Nutzen	6,13 €	4,60 €	4,90 €	3,68 €
Stoffwechselkrankheiten | medizinischer Nutzen	8,84 €	6,63 €	7,07 €	5,30 €

Maximum pricing a day for permanently and provisionally listed DiGA targeting different health issues[156]

Maximum product-specific reimbursement prices for the first 12 months came into force on 1 October 2022. Price setting is primarily built on the number of DiGA in a group, their status (permanently / provisionally listed) and their utilization (number of DiGA activated by patients).[157] Upon permanent listing—or after 12 months for DiGA already permanently listed—price negotiations with the GKV-SV commence (3 meetings). If negotiations fail, an arbitration board decides.[21] If a manufacturer's price according to the "pricing table" is in the 1st quartile of average DiGA prices and annual revenues do not exceed €750.000, price negotiations can be bypassed.[158] Specific pricing mechanisms apply to DiGA considered pioneers in their indication group, those targeting rare diseases, or those with AI. [50] The regulatory framework makes the patient-relevant benefits of a DiGA a pricing criterion to be considered in particular, yet does not indicate how these should be translated into a reasonable price.[2] The vast majority of DiGA (51/57, 89%) have pricing for 90 days use of the DiGA, likely preferred due to its alignment with the quarterly billing cycle in German medical practices.[50] In total 5/57 DiGA (9%) offer a license, 1/57 (2%) 60 days use. Currently, physicians get €7.93 for the follow-up for the use of some DiGA, if there are any required services provided by contracted practitioners, which is currently the case for 13/57 (23%) DiGA.[159] Prescription of the DiGA is part of the basic and insured person's flat rate, and therefore not reimbursed separately. There is no compensation for additional services related to education and therapy support.[32]

While the DiGA model offers opportunities, manufacturers express **doubts about profitability and pricing structures**. A **balanced approach** that promotes **fair reimbursement mechanisms** and provides **incentives for innovation and affordability** is **needed**. A profitability evaluation highlights a **need for economies of scale** and **closer provider integration** to improve sustainability and long-term viability.[59]

Execution	The Digital Health Applications Ordinance (DiGAV, 2020) outlines the specifications for DiGA assessments.[160] The Federal Institute for Drugs and Medical Devices (BfArM) is tasked with implementation, assess(es) DiGA and decide(s) which ones get reimbursed. There is a defined framework for the calculation of maximum rates within the framework agreement.[158] The insurers negotiate the reimbursement rates. The medical society (if applicable) provide(s) guidance on integration in care pathways. DiGA: A health professional provides a paper prescription, the patient sends it to the health insurer, or the patient requests the insurer directly. Some DiGA manufacturers support patients in this effort to ease the burden. The insurer verifies the patient's entitlement (diagnosis) if a direct patient request, generates a prescription code, and reimburses. DiPA: The individual in need of care requests the insurer directly. The long-

	term care insurance fund (decides on the necessity of a DiPA and supplementary support services (up to in total €50 - in the new law €70 - a month).[13] Insurers are not allowed to change the prescription to another / own app. The patient manually enters the prescription code into the DiGA to activate it for the specified usage period.[73] Who measure(s) impact, and how, is not yet decided.
Adoption	Between September 2020 and December 2024 over 1 million DiGA were prescribed by physicians and approved by Statutory Health insurers (SHI). Of these, 861.000 DiGA were used by patients in that period. The number of redeemed activation codes continues to rise (as does the number of DiGA listed in the directory).[161] The majority of prescriptions are issued by general practitioners (60.943) and psychologists (10,246).[162] Although the figures vary slightly depending on the source, they demonstrate that awareness of DiGA continues to grow and that DiGA are becoming part of everyday care for professionals and patients. Nevertheless, the number who still know little or nothing about DiGA remains relevant.[32]  *Percentage of practices with DiGA prescriptions[161]*  *Activation codes (FSC) issued per 1,000 insured persons. Period: Oct 1, 2020, to Jun 30, 2023[162]*  *Percentage of female users DiGA [50]*  *Age distribution of DiGA users with at least one redeemed activation code (N = 59,956). Period: October 1, 2020, to June 30, 2023[162]*
Lessons learned	Lessons learned are plentiful and apparent from available figures (e.g. importance **provisional listing**), and changes implemented and prepared. Both SVDGV and BfArM stress the importance of **cross-border harmonization of assessment criteria** and expanding and promoting **hybrid models** going forward.[32, 152] Other priorities from the authorities include: - **DiPA**, for which new legislation is expected in 2026[163] - **interoperability** with electronic health records[152] - **real-world performance measurement** and **value-based pricing**[3] For SVDGV[32] further priorities include: - simplified and faster access to DiGA for patients (**e-prescription**) - **removal of bureaucratic hurdles** that disproportionately burden especially young and innovative DiGA companies, such as numerous in part overlapping data protection / security requirements (e.g. penetration tests, ISO standards, BSI and BfArM certificates), high recertification costs with every update, and uncertainty in interpretation of clinical evidence requirements (which resulted in several temporary removals of DiGA causing reputation damage)

	- better inform patients and practitioners about DiGA, which includes incorporating DiGA into the training and further **education** curricula Also: - all permanently included DiGA reported medical outcomes, only a few the patient-relevant outcomes. **Operationalization** of these **novel outcomes** is complex. **New study designs** and acceptance **real-world data** are needed.[164] - most DiGA are not evaluated versus a single standard of care, and most studies consider indication-specific outcome measures. This makes common methods of **health economic evaluation** such as an incremental analysis and the cross-indication application of cost-effectiveness thresholds difficult to implement.[2] - increasing **regulatory requirements**, e.g. compliance with new German data protection and data security requirements (€160,000–€270,000 per DiGA, audits by BSI or BfArM, regular penetration tests, additional certificates, such as for software updates), significantly affect DiGA manufacturer growth.[32] - To ensure a smooth integration of new DiGA and to encourage their further development, what constitutes a "**significant change**" should be clear and pragmatically addressed.[32]

Status November 13, 2025

https://diga.bfarm.de/de/verzeichnis

Displayed are product icon, (abbreviated) name of product, (abbreviated) name of manufacturer, country of manufacturer, medical device class, reimbursement price, ICD-10 codes according to the DiGA Directory, prescription period and need for accessories. Text in gray indicates the app was listed in a previous category already.

Category **Status** ICD-10 codes	**Provisional listing**	**Permanent listing**[4]	**No longer listed**
Respiratory			Kaia copd Kaia HS
Reproductive organs, kidneys, and urinary tract N32.8: Other specified disorders of bladder N40: Benign prostatic hyperplasia N48.4: Impotence of organic origin N80: Endometriosis		Endo-app Endo H MDR - I €235,80 N80 90 days Kranus-E Kranus H MDR - I €235,00 N48.4 90 days Kranus-L Kranus H MDR - I €240,50 N32.8 N40 90 days Kranus-M Kranus H	

[4] In case of "significant changes" a manufacturer is required to promptly notify BfArM. DigiG introduces real-world application-related performance measurement. As of January 2026, patient-reported outcome and experience measures (PROMs and PREMs) and information on usage of a DiGA will be published in an online repository, updated on a quarterly basis, partially influencing reimbursement amounts

		MDR - I €681,30 N39.3 N39.42 90 days	
Cardiovascular I10: Essential (primary) hypertension I50.0: Congestive heart failure		ProHerz ProCarem MDD - I € 396,00- € 484,00 I50.02 I50.03 I50.04 +3 more 90 days hardware needed	Actensio mementor Rehappy Rehappy Vantis Vantis
Hormones and metabolism E11: Type 2 diabetes mellitis E10: Type 1 diabetes mellitis E66.00: Obesity due to excess calories E66.01: Morbid (severe) obesity due to excess calories	Glucura Perfood MDR - I €499,80 E11 90 days hardware needed Una HfD Una H MDR - I €740,00 E11 90 days	Hellob d Get.on MDR - I €222,99 E10 E11 90 days Oviva Oviva MDR - IIa €220,90 E66.00 E66.01 90 days hardware optional Vitadio Vitadio MDR - I €224,01 E11 90 days Zanadio Sidekick MDD - I €218,00 E66.00 E66.01 90 days hardware optional	Esysta Emperra Mebix Vision2B My Dose Meteda
Cancer C50: Malignant neoplasm of breast C61: Malignant neoplasm of prostate	Uroletics Rocketlane MDR - I €895,00 C61 license	PINK! C Pink g B MDR – I €234,50 C50 90 days Untire Tired of C MDR - I €618,00 C50 90 days	Cankado Cankado Mika Fosanis Optimune Gaia AG
Muscles, bones, and joints F45: Somatoform disorders M22: Disorder of patella M22.2: Patellofemoral disorders M22.4: Chondromalacia patellae M42.0: Juvenile osteochondrosis of the spine M42.1: Adult osteochondrosis M42.9: Spinal osteochondrosis, unspecified M42.16: Adult osteochondrosis of the spine, lumbar region M42.17: Adult osteochondrosis of the spine, lumbosacral region M42.96: Spinal osteochondrosis, unspecified, lumbar region M54: Dorsalgia M75: Shoulder lesions	c shoulder PrehApp MDR - I €419,00 M75 90 days eCovery eCovery MDR - I €574,00 M42.16 M42.17 M42.96 +15 more 90 days	c patella PrehApp MDR - I €223,49 M22.2 M22.4 M76.5 +2 more 90 days Hellob cs Get.on MDR - I €235,00 F45.40 F45.41 M79.7 90 days Kaia rs Kaia HS MDR - IIa €221,49 M54 90 days Mawendo Vivira	Orthopy Orthopy re.flex Kineto TR Selfa cs Selfapy

M76.5: Patellar tendinitis M79.7: Fibromyalgia		Mawendo Vivira MDD - I **€119,00** M22 license MDR - I €206,79 M42.0 M42.1 M42.9 +17 more 90 days	
Neurological F51.0: Insomnia not due to a substance or known physiological condition G35: Multiple sclerosis G43.0: Migraine without aura G43.1: Migraine with aura G47.0: Insomnia or disorders of initiating or maintaining sleep	sinCeph Perfood MDR - I €690,00 G43.0 G43.1 90 days	elevida Gaia AG MDR - I €243,00 G35 90 days Hellob s Get.on MDR - I €241,25 F51.0 G47.0 90 days levidex Gaia AG MDR - I €247,81 G35 90 days somnovia Gaia AG MDR - I €236,00 F51.0 G47.0 90 days	M-sense Newsense Rehappy Rehappy
Ears F32.0: Major depressive disorder, single episode, mild F32.1: Major depressive disorder, single episode, moderate F33.0: Major depressive disorder, recurrent, mild F33.1: Major depressive disorder, recurrent, moderate H93.1: Tinnitus		Kalmeda Pohl-B MDR - I €189,00 H93.1 90 days Meine Tin Bayoocar MDR - I €260,00 H93.1 license	
Mental health F06.7: Mild neurocognitive disorder due to a known physiological condition F10.1: Mental and behavioral disorders due to use of alcohol: harmful use F10.2: Alcohol dependence F17.2: Nicotine dependence F32.0: Major depressive disorder, single episode, mild F32.1: Major depressive disorder, single episode, moderate F32.2: Major depressive disorder, single episode, severe without psychotic features F33.0: Major depressive disorder, recurrent, mild F33.1: Major depressive disorder, recurrent, moderate F40.0: Agoraphobia F40.00: Agoraphobia, unspecified F40.01: Agoraphobia with panic disorder F40.1: Social phobias F40.2: Specific (isolated) phobias F41.0: Panic disorder F41.1: Generalized anxiety disorder F45.40: Persistent somatoform pain disorder F45.41: Pain disorder exclusively related to psychological factors F50.2: Bulimia nervosa F50.3: Atypical bulimia nervosa F50.4: Overeating associated with other psychological disturbances F50.8: Other eating disorders F50.9: Eating disorder, unspecified	elona e Elona MDR - I €535,49 F32.0 F32.1 F32.2 90 days hiToco medigital MDR - I €599,00 F90 F98.80 90 days Mindable Mindable MDD - I €765,00 F40.1 90 days Oriko Mindnet MDR - I €441,00 F90.0 90 days	attexis Gaia AG MDR - I €599,40 F90.0 F90.1 90 days deprexis Gaia AG MDR - I €228,00 F32.0 F32.1 F32.2 +3 more 90 days edupress SOFY MDD - I €224,80 F32.0 F32.1 F33.0 F33.1 90 days elona t Elona MDD - I €535,49 F32.0 F32.1 F32.2 +4 more 90 days Hellob cs Get.on MDR - I €235,00 F45.40 F45.41 M79.7 90 days Hellob p Get.on MDR - I €230,00 F40.01 F41.0 90 days Hellob s Get.on Hellob vp Get.on Invirto Invirto Sympatie	MindDoc MindDoc Selfa cs Selfapy Selfa p Selfapy

F51.0: Insomnia not due to a substance or known physiological condition F52.5: Vaginismus not due to a substance or known physiological condition F52.6: Dyspareunia not due to a substance or known physiological condition F60.31: Emotionally unstable personality disorder: Borderline F90: Attention deficit hyperactivity disorders F90.0: Attention-deficit hyperactivity disorder, predominantly inattentive type (ADD) F90.1: Attention-deficit hyperactivity disorder, predominantly hyperactive type F98.80: Attention-deficit disorder without hyperactivity G47.0: Disorders of initiating and maintaining sleep (insomnias) M79.7: Fibromyalgia		MDR - I €241,25 F51.0 G47.0 90 days MDR - I €235,00 F52.5 F52.6 hardware optional 90 days MDR - I €220,00 F40.00 F40.01 F40.1 F41.0 90 days hardware included Mindable Mindable MDD - I €245.50 F40.0 F41.0 90 days My7steps My7steps MDR - I €199,00 F32.0 F32.1 F33.0 F33.1 60 days NeuroNat Synaptik MDD - I €479.70 F06.7 90 days Nichtrauc Sanero MDR - I €211,00 F17.2 90 days NovegoA IVPNetw MDD - I €189,00 F40.0 F40.1 F40.2 F41.0 license NovegoD IVPNetw MDD - I €199,00 F32.0 F32.1 F32.2 +4 more license Priovi Gaia AG MDR - I €244,00 F60.31 90 days Selfa bes Selfapy MDR - I €232,00 F50.4 F50.8 F50.9 90 days Selfa bn Selfapy MDR - I €232,00 F50.2 F50.3 90 days Selfa dep Selfapy MDR - I €217,18 F32.0 F32.1 F33.0 F33.1 90 days Selfa ga Selfapy MDR - I €228,50 F41.1 90 days Smokefr Smokefr MDD - I €231,25 F17.2 90 days somnio memento MDR - IIa €224,99 F51.0 G47.0 hardware optional 90 days somnovia Gaia AG MDR - I €236,00 F51.0 G47.0 90 days velibra Gaia AG MDR - I €230.00 F40.01 F40.1 F41.0 F41.1 90 days	

		vorvida Gaia AG  MDR - I €185.00 F10.1 F10.2 90 days	
Digestion K58: Irritable bowel syndrome K58.1: Irritable bowel syndrome with predominant constipation K58.2: Mixed irritable bowel syndrome		Cara care HiDoc  MDR - I €248,00 K58 K58.1 K58.2 90 days	
Injuries M22.2: Patellofemoral disorders M22.4: Chondromalacia patellae M76.5: Patellar tendinitis		c patella PrehApp  €223,49 M22.2 M22.4 M76.5 90 days	Orthopy Orthopy 
Other R47.0: Dysphasia and aphasia R48.2: Apraxia Z73: Problems related to life management difficulty		Hellob sb Get.on  MDR - I €235,00 Z73 90 days neolexon Limedix  MDR - I €223,01 R47.0 R48.2 90 days	

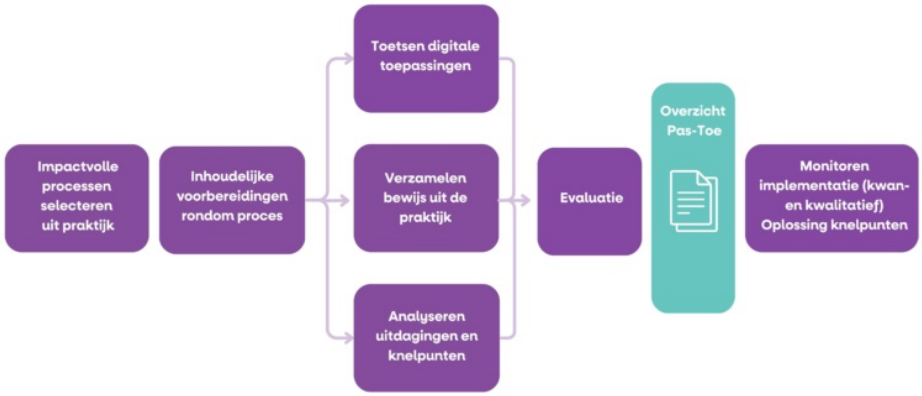
Italy

Policy	A draft unified bill on digital therapies is currently available, to be discussed in Parliament in the upcoming weeks to months. This bill intends to introduce a regulatory framework for digital therapies (DTx) in Italy, defining their structure, purpose and clinical requirements. As such it represents a significant step towards the regulation of digital therapies (DTx) in Italy, filling a regulatory gap and integrating these innovations into the National Health Service.[165, 166]. The draft will be subject to change after discussions in Parliament.
Scope	In the draft bill, digital therapies are defined as software-mediated therapeutic interventions with a specific therapeutic indication and designed to prevent, manage, or treat a medical condition or disease by modifying patient behavior in order to improve clinical outcomes. Digital therapies consist of a **digital active ingredient** and **digital excipients**. The digital active ingredient is primarily responsible for the clinical outcome and is attributable to a therapeutic algorithm; digital excipients are value-added services necessary to ensure the best patient experience and to enable long-term use of the therapy. For the purposes of placing them on the market, digital medical devices are CE marked as software-based medical devices at European level.[166]
Value	The value as specified in the draft bill seems to focus on clinical outcomes, acknowledging the indirect effect and need for value-added services.
Measures to capture value	According to the draft bill, within one month of the date of entry into force of the law, the Ministry of Health shall establish a Digital Therapies Evaluation Committee. This Committee shall provide preliminary and indicative guidance on digital therapies, with a view to their inclusion in the rapid assessment process for inclusion in the essential levels of care (LEA). The necessary assessments shall be carried out for the purpose of including digital therapies that meet the requirements in the tariff nomenclature. For the purposes of its inclusion in the LEA, a digital therapy must have been the subject of at least two clinical studies with high-quality evidence. The pathway is expected to be quite similar to medical devices in general, HTA by the Committee, more than CE marking, demonstration of usefulness compared to other therapeutic approaches. There is awareness that further measures are necessary to adequately inform professionals and the general public.
Impact	On the basis of the Committee's work, the Minister of Health shall submit to Parliament an annual report on the evolution of digital therapies and the availability of new technologies. The draft bill does not provide further details on impact assessments. Could be that academic initiatives at the hospital levels will be employed.
Reimbursement	Italy has a universal healthcare system called the Servizio Sanitario Nazionale (SSN). The SSN automatically covers all Italian citizens and legal foreign residents. It provides a full range of healthcare services with a free choice of providers. The reimbursement will probably focus on the digital therapy and not include the professional, at least in the public facilities (local health authorities, hospitals), as the professional is already covered by the system. Instead, the reimbursement for accredited private facilities must cover all costs, including personnel. Further details on reimbursement of digital therapies are not yet specified.

Pricing	Further details on pricing and the role of the regions and national authorities in it are not yet specified.
Execution	According to the draft bill, the Digital Therapies Evaluation Committee will be chaired by a member with proven experience in the field of digital devices and therapies from the Department of Planning, Medical Devices, and Health Professions. The Committee shall be composed of fourteen members appointed as follows: - three by the Permanent Conference for Relations between the State, the Regions, and the Autonomous Provinces of Trento and Bolzano - two by the National Agency for Regional Health Services (Agenas) - two by the Ministry of Health - one by the National Institute of Health (ISS) - one, by the Italian Medicines Agency - one, by the Higher Health Council - one, by the National Federation of Orders of Surgeons and Dentists - one, by the Federation of Italian Pharmacists' Associations - two, by the most representative national patient associations, competent in the field of digital therapies By decree of the Minister of Health, based on the recommendations provided by the Committee, the areas of intervention and specialist areas in which digital therapies are applied shall be identified, as well as the methods and requirements for their provision and prescription within the National Health Service.
Adoption	Not yet applicable.
Lessons learned	Too early to tell.

The Netherlands

Policy	In 2022, the Ministry of Health, Welfare and Sport and 13 other organizations in health care including health professional-, patient-, health provider organizations and insurers signed the Integrated Care Agreement (Integraal Zorgakkoord, IZA). The agreement focuses on care that falls under the Health Insurance Act, but also links up with other domains, including social care.[167, 168] It aims to make 70% of the suitable care pathways digitally or hybrid, aiming for use by at least 50% of the applicable patient population. The 2023 Healthy and Active Living Agreement (Gezond en Actief Leven Akkoord, GALA) promotes prevention related use of user friendly digital and hybrid care, to be detailed further in all contracts with care providers in 2025, and agreements how to achieve such transformation.[169] The 2025 Supplementary Care and Welfare Agreement (Aanvullend Zorg- en Welzijnsakkoord, AZWA), like IZA and GALA an agreement with relevant organizations in the field, further specifies, expands and aims to accelerate what was agreed in IZA and GALA.[170] Based on these agreements end of 2025 an acceleration agenda is prepared on digital and hybrid health, care and wellness for 2026 to 2028. Digizo.nu, a collaborative of the 14 IZA organizations, is one of the instruments in the ecosystem to scale digital and hybrid care and achieve a reduction in the workload of healthcare providers. It evaluates, stimulates and facilitates uptake of digital and hybrid care pathways that have been prioritized but is not directly linked to reimbursement. Another initiative for health apps (digitale gezondheidsapps), referred to as diga.nl, is a result of questions from a member of parliament[43] instigated by an article in a popular journal for medical professionals (“the failure of health care innovation due to financing rules”)[44]. This initiative provides temporarily financial support (lump sum) to 3 public funded health apps for (self)care with a large target group and scientifically proven effectiveness. Intent is to keep them afloat, working towards a sustainable funding model in the hybrid care landscape.[171] Other (not digital specific) routes to reimbursement exist.
Scope	(Digital and) hybrid care in IZA is described as the where possible, personalized, tailor-made mix of digital and face2face care and health support. The basic principles are by yourself if feasible, at home if feasible, and digitally if feasible[167], as simply explained in short videos (script can be used for translations)[172]. The focus is on process redesign. The digital applications involved can range apps, platforms, AI tools, and combinations of software and hardware. According to the website, to be eligible for Digizo.nu an application: - needs to fall within the Digizo.nu definition of a potential hybrid (care) process - may require certain certifications such as MDR or NEN7510 - needs at least 120 paying users, across at least 3 Dutch (care) providers, with each at least 20 paying users, using the application for at least 1 year However, on a case-by-case basis these requirements can be adjusted. Manufacturers may be foreign, but support and documentation need to be available in Dutch. Aim is to assess at least 2 applications per potential hybrid (care) process, unless there is only 1 relevant application.[173] The 3 current diga’s were selected on the basis of a number of criteria, including a large patient population, proven effectiveness and public funding.[171] Zorginstituut Nederland (ZIN, the National Health Care Institute) distinguishes a technical variant (technische variant). Existing, effective care that is offered in a digital or hybrid form, where the digital or hybrid form can be considered a

	variant of the original already insured type of care. To be considered a technical variant, composition and expected effectiveness should not significantly differ from the original already insured type of care. This has to be assessed on a case-by-case basis.[174] ZIN assesses if products meet the state of science and practice (stand van de wetenschap en praktijk) and as such may be eligible for reimbursement. Thus far no digital health applications have been through such an assessment.
Value	IZA and additional agreements aim to ensure the provision of affordable, good-quality, and, above all, accessible care, now and in the future. This requires a transformation to hybrid healthcare. By 2026, the use of hybrid care is intended to lead to demonstrably different working methods and a reduction in the workload of healthcare providers, while maintaining accessibility and quality. Digital and hybrid care is often a more efficient way of providing care that can improve quality of life, quality of care and sustainability of healthcare. Good digital tools can help people assess the need for care and also support shared decision-making. Robust integration of digital (self-care) tools, such as "thuisarts.nl" and "apotheek.nl" or other applications, into the healthcare landscape prevents unnecessary reliance on primary care.[167] GALA aims to reduce health inequalities, achieve healthy living environments that encourage exercise and social interaction, local social cohesion supported by accessible facilities, making a healthy lifestyle possible for everyone, strengthening mental resilience and mental health, and healthy and active ageing.[169]
Measures to capture value	 *Digizo.nu method: 1. Select impactful (potential hybrid) processes, 2. Preparatory work, 3. Test digital applications, 4. Assemble real world evidence of value, 5. Analyze challenges and bottlenecks, 6. Evaluate, 7. Uptake in the implement list, 8. Monitor implementation (quantitative and qualitative) and resolve bottlenecks[175]* The Digizo.nu website displays the healthcare processes that are currently investigated in the various healthcare sectors, such as GP and medical specialist care (step 1). [39] Being on the list means that the participating organizations in IZA see potential to make the process hybrid, and want to assess its impact (value), and what hurdles need to be resolved (step 5) before scaling on a national level (step 7[176]).[177] Within the processes digital products that have been positively assessed (step 3) and the status of the work (publication, on the agenda, assessment, value appraisal) are visible. A click on the product reveals version of the assessment framework for digital health applications (“Leidraad”[178]) used, date of reassessment if applicable, some assessment results and technical aspects. Leidraad is adjusted for the process that is assessed. The evaluation report (step 6) includes further process-specific measures that may be necessary such as training for professionals and patients. In AZWA, a national helpdesk for questions about digital health has been agreed upon, which works with local support organizations. The website

	Thuisarts.nl is and remains the place where citizens can find reliable information about health and care. Thuisarts.nl will be further expanded and improved to prevent having to ask health professionals for help.[170]
Impact	Fundamental is the process redesign (step 4) from IST (current situation) to SOLL (new situation) in understandable flow charts. The rationale for the IST to SOLL changes (claims or KPI's: better than, less than, etc.) are translated into measurement plans with must have's, should have's, could have's, won't haves and cut-off values. A quick scan of scientific and grey literature is used to validate the claims and determine what additional research may be needed prior to and during widescale implementation.[179] Focus is not really on the proven effectiveness of the application in for instance a randomized controlled trial, but on effectiveness of the intervention in the process as a whole.
Reimbursement	Providing hybrid care requires (upfront) investments and an appropriate financing system that is reflected in the contracts with healthcare providers, with incentives focused on providing care as efficiently as possible.[167] Digizo.nu does not equal reimbursement. The IZA organizations will ensure that the question of how to deal with applications that promote health but have no direct link to the Health Insurance Act (Zvw) is resolved, for example in the context of prevention. This also applies to Personal Health Environments (PGOs).[167]
Pricing	Often the healthcare provider will primarily negotiate terms with the one or two largest health insurers within their patient population (of the currently 10 available[180]), terms that the other insurers will then follow. The manufacturers will then negotiate with individual healthcare providers or a group of healthcare providers or the healthcare insurers on behalf of the healthcare providers. Several healthcare insurers also provide wellness apps directly to the persons they insure free of charge.[181-187]
Execution	PDIZA, a small temporary department within the ministry, is process coordinator of the IZA implementation.[168] The Board ('Bestuurlijk overleg') with representatives of the IZA organizations drives and monitors implementation. Digizo.nu: Sectors investigate which care pathways are suitable for digital and/or hybrid care (step 1). Only for these care pathways, Digizo.nu coordinates the next steps, developing with experts from the IZA organizations and executing the value assessment (step 4) that is to result in evidence that is acceptable to all organizations, and measuring impact and support in resolving remaining issues (step 8). Digizo.nu also developed the assessment framework (Leidraad) in collaboration with dozens of experts and healthcare professionals from several sectors. A healthcare provider can submit an application they use in practice.[173] The manufacturer fills out the intake form[188] and completes the Leidraad. Domain experts and healthcare professionals review the manufacturer's responses, submit written follow-up questions, and conduct an interview once the answers to those questions have been received. They then jointly decide whether a positive assessment can be issued. In step 7 of the Digizo.nu method, healthcare providers are stimulated to implement the positively assessed digital and hybrid processes while hurdles are being removed, or explain why they do not choose to scale up (yet).[189] The insurers pay the healthcare providers. The healthcare providers decide which product – either or not from the Digizo.nu website - they use in the hybrid care pathway and negotiate the terms with the manufacturer or have someone else negotiate on their behalf. The IST SOLL flowcharts provide guidance for implementation of the hybrid care pathways. A role for Digizo.nu for the diga.nl apps is envisioned.
Adoption	Intent is to include more on adoption in the digital care monitor.[190] How to operationalize the 70% hybrid / digital care pathways and 50% of the

	population within them was tried but failed thus far, stumbling into different stakeholder perspectives and interests. It is however perceived as effective as a guiding principle, similar to the motto by yourself if feasible, at home if feasible, and digitally if feasible. More detailed information as to uptake by healthcare providers, professionals and downloads for Digizo.nu, diga.nl and other digital / hybrid processes was not found.
Lessons learned	Lessons learned from the stakeholder interviews include: - The **reimbursement system needs changes to adjust to** / incentivize 'by yourself if feasible, at home if feasible, and **digitally if feasible'**, and **transformation** across organizations instead of local optimization. - **Predicting** eligible users, benefits, and **business cases**, **undoing routines** in care pathways, adjusting guidelines, interoperability, **and scaling** beyond front runners, pilot projects and grant funding **are all challenging.** - **Lump sum does not** persuade investors nor **incentivize** existing and new manufacturers. The budget is too low to stay afloat, let alone innovate, especially in case of medical devices. The conditions are still volatile and uncertain, which worsens the situation. There seems to be a **fear** to end up in a situation **of having to pay too much** perhaps after experiences with EHR systems. - The current version of the **Leidraad is too** (unworkably) **long** and not harmonized. - Digizo.nu is **more larger companies, health economics and infrastructure** tools and less smaller companies, health outcomes and therapeutics. Being an evidence based digital medical device is currently hardly a viable strategy. - **Healthcare providers can only transform so many processes at the same time**, are running out of transformation budgets and may prefer products that fit several processes. - The Netherlands is already **complicated to** local **companies**, let alone foreign companies, who do not speak Dutch, have no local contacts, etc.

Status September 29, 2025

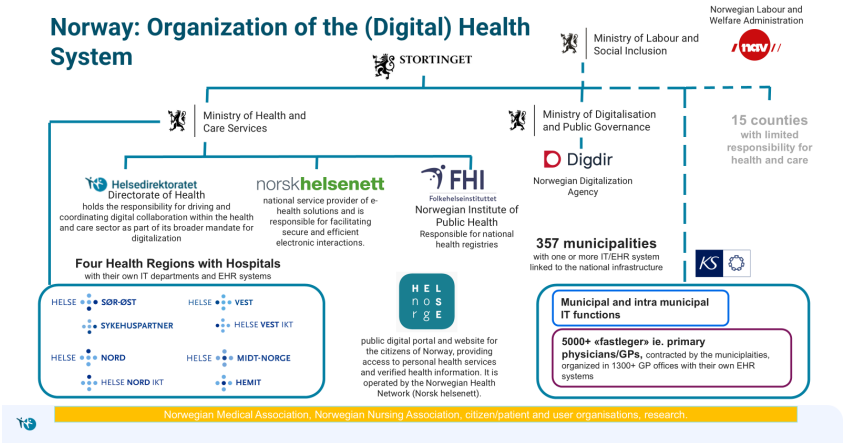
https://www.zn.nl/actueel/drie-digitale-gezondheidsapps-krijgen-in-2025-ondersteuning-van-zn/ and further desk research

Displayed are product icon, (abbreviated) name of product, (abbreviated) name of manufacturer, country of manufacturer, medical device class if found. Hardware components seem not to be applicable. The categories were added based on the product descriptions.

Category	**'diga.nl'**
Cancer	Untire Tired of C MDR - I
Dizziness	Vertigo tr AUMC/ Curavista ?

Urin control	URinCon UMCG/ Curavista MD..- ..

Norway

Policy	Before 2024, the eHealth Agency was an independent entity, but as a result of a national reform the eHealth agency was merged with the Norwegian Directorate of Health (Helsedirektoratet). Helsedirektoratet reports to the Ministry of Health and Care Services (as did the eHealth Agency).[191] The official government white paper The National Health and Collaboration plan 2024-2027 describes the ambitions to tackle challenges related to access to professionals, poor coordination between services and equal access to health and care services for the population. One of the 6 main measures is a new strategy for digitalization of health and care services.[192] In addition, Helsedirektoratet coordinates the health sectors' National eHealth Strategy 2023-2030, that describes the objectives related to digitalization in the health and care sector in specific.[193] 
Scope	The wording used on the national health portal Helsenorge[194] is health tools (Verktøy). Health tools are described in the portal as quality-assured apps, videos and other health tools that support you in your everyday life and during treatment and meet requirements for healthcare quality, privacy and security. An approved definition is in the making. The current tools are mostly stand-alone and do not include medical devices. Yet a framework is needed for both wellness apps and medical devices, including AI.
Value	The vision of the national eHealth strategy is working together toward comprehensive, safe, and innovative services that promote health and empowerment. The strategic goals are: - Active participation in one's own and close one's health - Accessible information and strengthened collaboration - Easier working day for health care professionals - Health data for renewal and improvement - Cooperation and instruments that strengthen development and implementation capacity[193] The National Health and Collaboration plan 2024-2027 goals include good patient pathways, good health and wellbeing, regardless of social background and where you live. Technology and digital collaboration will help maintain or improve the quality of treatment for patients and facilitate participation. Funding schemes are adjusted to facilitate better collaboration.[192] The new strategy for digitalization will clarify responsibilities, prioritize digital interaction and establish a health technology procurement program (Helseteknologiordningen). This will stimulate local / municipal implementation of measures for a better

	working life for those working in the service, introduce personnel-saving digital solutions and technology, and improve patient processes and efficient use of resources.[192] Psychologists see huge potential. Tools can provide self-help and reduce the capacity needed in healthcare. Patients who are not ill enough for healthcare or those on a waiting list can be provided something and avoid decline.
Measures to capture value	There is an app library (the "Toolbox") now for 7 years. It includes 38 applications of various sorts from public health bodies or hospitals that are made available to all citizens. Six of them, all mental health related, are licensed.[195] There is a catalogue with requirements to qualify for the Toolbox which is based on CEN-ISO/TS 82304-2.[196] A next step is further guidelines how to assess these. In the pilot phase ("Safety apps" project) a combination of self-assessment and verification was tried. The experiences showed a need for some of kind of assessment.
Impact	Overall expected impact is not quantified. Yet experiences with Tankevirus (Thought virus), an app in the Toolbox for mild to moderate anxiety and depression, provides inspiration for impact measurements. Tankevirus features three 10-minute introductory videos based on cognitive behavioral therapy (CBT) and the next 20 days every morning a 1–2-minute video offering tips and tasks to manage negative thoughts.[197] Push notifications improve adherence. Users measure their mental health in the app before using it, after using it (21 days later), at 3 and 6 months using validated questionnaires. These are the 4-item Patient Health Questionnaire (PHQ-4) and the 8-item somatic symptom scale (SSS-8), alongside a general health Visual Analog Scale, age and gender. In total, 109.000 unique users (77% female) initiated the app, 40.000 completed the main series, 15.000 all videos. Of the ones who completed the app, 70.1% reported reduced anxiety and depression. The app was found cost-effective at €400 for a user who completed the app. If including improvements up to 6 months, the average QALY gain was €2,800 per user who completed the app.[198] Users were found to be in need of treatment. Their condition improved as much as with regular treatment.
Reimbursement	The tools licensed do not include hardware. Some in the pilot phase did. The license is to cover the expenses of the app, development, maintenance etc., not health professionals. Norway has universal health coverage, about 10 percent of the population has private insurance, mainly for quicker access to and greater choice of healthcare providers.[199]
Pricing	Pricing (lump sum) was determined by the budget available and turns out to be not enough to cover expenses, let alone pay for innovation, and as such not a functioning sustainable model. Lump sum does not provide an incentive. Most of the tool developers are looking at other markets yet fail to succeed everywhere. The market is not ready yet. They are research based, have documented results, but because of lack of market uptake they are (one after 10 years) dependent on research funding to survive. To scale a fundamentally other model is needed. Reimbursement is for that reason explored. Assessments are free of charge.
Execution	Helsedirektoratet is responsible for the Toolbox. The government decided to license the 6 apps during the pandemic, as one of the many measures taken then. Since then, money to continue has been found here and there. Helsedirektoratet (two persons, Øystein and Arve) decided on the assessment criteria. Helsedirektoratet, psychologists, security experts and

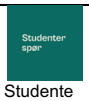
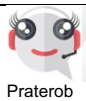
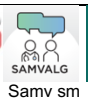
	third-party security compliance companies assessed the tools. The budget Helsedirektoratet had available determined the licensing fee (the developers should not have agreed looking back). The developers currently measure impact. The hope is that researchers at some point can play a role in these measurements. That however depends on funding.
Adoption	The apps that are licensed report downloads every month. Some can track adherence, but that information is not yet used. Driven by marketing and trust in the national health portal, the downloads approach 300.000 on a population of 5.6 million[61]. Without marketing (in all kinds of media including social media) the numbers are flat. The smoking / vaping / snus cessation app Slutta (daily motivational messages, advice and tips, and an overview of the time since smoking cessation), created by Helsedirektoratet, available for free, is most popular with some 2 million downloads.[62] Health professionals can recommend a tool by clicking it in the Toolbox, yet very few know this feature due to a limited marketing budget. No guidance is given currently on integration of tools in care pathways. Contacts with medical societies are ad hoc.
Lessons learned	- A **deal that's not good for the developers is a big mistake**. We are sort of killing them softly. We should have made an agreement with room for innovation where developers can thrive. - We need to **invest more in implementing the apps in healthcare**. Then we would need less for marketing. - **Helsenorge** as a **trusted platform** with **many services and visitors** is a **great home for the Toolbox**. Everybody has Helsenorge on their phone. There are 10 million visitors every month, 16 visits per person in 2024. - We've learned **developing apps as an authority is not a good model**. There is a need to stimulate continuous innovation, yet authorities are not good at agile, budgets are not always available, and with authorities engaging in app development there are no incentives for others to enter the market as there is no market potential. There is a tradition in Norway that healthcare is supposed to be free, and our health trusts have a tendency to think in-house development first, instead of procurement. In part due to skepticism towards big tech and an anxiety of paying too much, that big tech is going to run off with all our money. Yet this is small tech, not big tech.

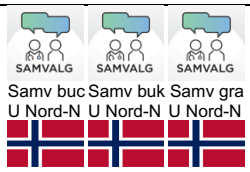
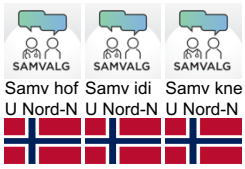
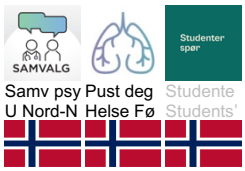
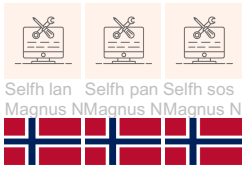
Status December 8, 2025

https://tjenester.helsenorge.no/verktoy

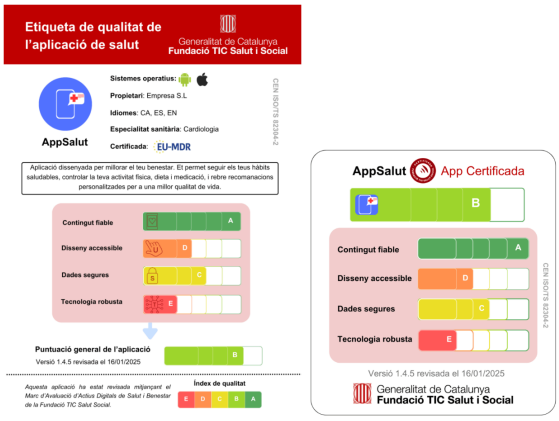
Displayed are product icon, (abbreviated) name of product, (abbreviated) name of manufacturer, country of manufacturer. Text in gray indicates the app was listed in a previous category already.

Category	Licensed	Other
Lifestyle and exercise		 Gå10 Helsedire Kosthold Helsedire Slutta Helsedire

		 Smart mo Helsedire  Studente Students'
Thoughts and feelings	 Grubl Maths in  Skamløs Helsedire  Tankevir Brorson  UngSpo Youwell	 Hva er in Helsedire  NetOpp Arctic Uni  Opp Arctic Uni  Selfh dep Magnus N  Selfh pan Magnus N  Selfh sos Magnus N  Studente Students'  SyktFrisk SyktFrisk  Ung face Oslo Univ
Pregnancy and childbirth	 Mamma Changet	 Praterob Helse Be  Samv sm U Nord-N  Studente Students'
Daily advice and tips	 Skamløs Helsedire  UngSpo Youwell	 Kosthold Helsedir  Opp Arctic Un  Selfh kor Magnus N  Selfh dep Magnus N  Selfh lan Magnus N  Selfh pan Magnus N  Selfh sos Magnus N  Slutta Helsedire  Studente Students'  SyktFrisk SyktFrisk  Ung face Oslo Univ
Illness and injuries		 Samv alf U Nord-N  Samv ala U Nord-N  Samv bry U Nord-N

		    
Mental health	 	   

Spain (Catalonia)

Policy	In Spain healthcare is a regional responsibility. Catalonia (8 million inhabitants) is the most advanced region in adoption and integration of digital health applications. Their **mHealth plan** (2015)[200] resulted in 2017 in an assessment framework, which has recently adopted CEN-ISO/TS 82304-2 as a basis, alongside requirements by the Department of Health and other European directives, as outlined in the Good Practice Guide for Digital Assets for Citizens.[201, 202]
Scope	The scope of products of interest to the health system are referred to as **digital assets** for citizens and health professionals. Digital assets are digital solutions that allow the practice of health and social welfare activities centered on the person, and are accessible through a web page, a mobile application or other user interfaces. These elements can interact with other technologies, such as sensors for patient monitoring, virtual reality or artificial intelligence, and at the same time redefine the relationship between professionals and patients in terms of efficiency and effectiveness.[203] The scope includes both medical devices and wellness applications, and both products developed within the Catalan Health System (CAT Salut) and by a private company.
Value	Digital assets are considered to have great potential to facilitate the **management of health and well-being** of the population. Their evaluation and subsequent certification allow to ensure their quality, good use, and benefit by the people who use them.[203]
Measures to capture value	Measures to capture the value include a **directory**[203], which displays the **health app quality label**, inspired by the CEN-ISO/TS 82304-2 label. A **health app quality leaflet** is being developed and will contain more detailed information on the quality of the asset, including the most relevant results of the assessment, such as risks, contraindications and limitations of use. It will be available in two formats, a browsable app and a downloadable document.  Several **reference documents**[204] and a **self-assessment test**[205] have been developed **for manufacturers**. To ensure **health professional digital competences** a project to identify current competences and define minimum competences started 4 years ago.[206, 207] Training plans are currently finalized. For citizens instead of digital competence trainings a color code to show if a digital asset is easy or difficult to use is considered. The **mConnecta platform** was developed to gather data from different mobile sources, including mobile apps, medical devices and sensors, which provide data on an individual's state of health, such as blood sugar levels, blood pressure, heart rate. At the discretion of

	the doctor the data can be added to the patient's clinical file and used for data-driven decision-making. Citizens can see the data in the Meva Salut (My Health) portal.[208]
Impact	Nothing yet.
Reimbursement	In view of the large number of health problems that need to be monitored, an expert committee representing the various health institutions was established to do a cost-benefit analysis. They concluded in 2021 that one of the priorities should be monitoring persons with **diabetes**. A **purchasing protocol**[209], a 4-year tender with (new) 8 different parts (lots) e.g. the full service for pediatric diabetes patients, for pregnant diabetes patients, for type 1 patients, etc., was created to acquire everything from glucometers to diabetes medicines. One of the requirements was that glucometers connected to apps should be accredited. The quality and reliability of apps were ensured with the same certification and an expert committee to evaluate them. Providers have to integrate standardized relevant data into the health system, following a standard for clinical terminology.[210] Four out of the 8 manufacturers currently do. A facilitating factor for the tender approach was that a previous diabetes tender was expiring.
Pricing	The app, glucometer, testing strips etc. that were selected in the tender process are all reimbursed. Health professionals are already paid, not separately as a result of the tender. Manufacturers had to pay for the assessment, yet that policy has changed as it was a showstopper for manufacturers. Now CAT Salut provides a budget to TIC Salut to do assessments. The business model for manufacturers was considered in the sense that CAT Salut organized a public consultation to inform the tender.
Execution	The Department of Health is responsible for the implementation of the mHealth plan. TIC Salut (the mHealth office) decides on assessment criteria and assesses the digital assets with support of a functional experts committee composed of members from official colleges, scientific societies and associations, healthcare and social welfare professionals from various fields.[202] CAT Salut (the Catalan Health Service) decides on reimbursement, determines reimbursement rates, pays, provides guidance on integration, and measures impact.
Adoption	Approximately 150.000 Catalan citizens are diagnosed with diabetes. Given the tender model a health professional can only prescribe the product (service) from the manufacturer that won the tender lot. Providing health professionals with a choice of digital assets to enable more personalization is currently not possible.
Lessons learned	- Establishing the new requirements is perceived as positive - Interoperability and in particular sharing a standardized set of data using HL7 FHIR and SNOMED CT has been difficult for manufacturers - The citizen-perspective should be included more

Status September 27, 2025

https://ticsalutsocial.cat/que-fem/actiusdigitals/actius/

Displayed are product icon, (abbreviated) name of product, (abbreviated) name of manufacturer, country of manufacturer, medical device class, if applicable hardware component (e.g. sensors).

Category Status	Not yet connected	Connected
Diabetes Endocrinology (reimbursed)	Eversens Sensonic MDR - III hardware Glooko Glooko MDR - I hardware Minimed MedTronic MDR - IIa hardware OneTouc Lifescan MDR - IIb hardware	Contour Ascensia MDR - IIb hardware FreeStyle Abbott MDR - IIb hardware Guardian MedTronic MDR - IIa hardware MySugr Roche MDR - IIb hardware
General health (Public health and prevention)	Vitalera FollowHe MDR - IIa hardware	Infermera College of not MD
Gynecology Obstetrics (Physiotherapy) (Health and sports)	ActitudP IdISBa not MD LactApp LactApp not MD	
Oncology		ICOnecta ICO not MD
Urgencies		061Salut Governm not MD

Appendix 2 – Interviewees

Belgium
Wim Dunford – Scientific analyst telemedicine at National Institute for Health and Disability Insurance
Liesbeth Louagie – National Institute for Health and Disability Insurance
Steven Vandeput – Advisor Digital health at beMedTech, the Belgian Federation of the industry of medical technologies

Denmark
Julius Rechendorff – Senior advisor at the Danish Medicines Agency

England
Liz Ashall-Payne – Founder at Organisation for the Review of Care and Health Apps (ORCHA)
Elizabeth Watson – International Tech Policy Lead at NHS Transformation Directorate

Estonia
Kristin Kuusk – Internal Medicine Service Manager at Tervisekassa, the Estonian Health Insurance Fund

Finland
Jari Haverinen – Senior planning officer at FinCCHTA

Germany
Diana Meskendahl – Director Strategic Projects at Spitzenverband Digitale Gesundheitsversorgung

Italy
Giuseppe D'Avenio – Senior researcher at Istituto Superiore di Sanità

The Netherlands
Atse Aukes – Chief Growth Officer at Tired of Cancer (Untire app, reimbursed in Germany and licensed in the Netherlands)
Renée von Berg – Programmamanager Digitale Zorgprocessen at Elisabeth-TweeSteden Ziekenhuis (ETZ)
René Bouma – Landelijk projectleider diga.nl at Zorgverzekeraars Nederland and Strategisch adviseur zorginnovatie at Zilveren Kruis
Astrid Chorus – Senior adviseur Pakketbeheer at Zorginstituut Nederland
Chris Flim – Coordinating / Specialist policy officer digital, hybrid, AI, healthcare innovation at the Ministry of Health, Welfare and Sport
Dennis Groen – Informatie Architect at Elisabeth-TweeSteden Ziekenhuis (ETZ)
Anthony Heil – Beleidsmedewerker at the Nederlandse Zorgautoriteit
Dennis Japink – Coördinator waardebepaling & evaluatie at Digizo.nu and Medisch adviseur digitale zorg at Zorgverzekeraars Nederland
Hareld Kemps – Professor of remote patient management in chronic cardiac care at Eindhoven University and cardiologist at Máxima Medical Center Eindhoven
Merel van Raamt – Projectleider Digitalisering bij Zorgorganisatie Eerste Lijn
Robin Toorneman – Senior Health Innovation Advisor at Zorginstituut Nederland
Tonko Wedda - Lead Assessment of digital health technology and eHealth at Digizo.nu

Norway
Peter Giovanni Hellevang – Adviser at Helsedirektoratet
Thor Steffensen – Senior adviser at Helsedirektoratet
Øystein Tveite – Project manager at Helsedirektoratet

Spain (Catalonia)
Carme Pratdepàdua Bufill – Responsible de l'Oficina mHealt.cat at Fundació TicSalut

Value
Robin van Kessel – Fellow at London School of Economics Health & World Economic Forum, Assistant professor at Maastricht University
Jochen Klucken – Chair and Full professor of Digital Medicine at University of Luxembourg, PI Digital medicine at Luxembourg Institute of Health and Digital medicine strategy at Centre Hospitalier de Luxembourg

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