Appendix 1: Country Findings

Estonia
Policies put in place many years ago to support a digital health policy-making environment
The Estonian healthcare system is predominantly funded by mandatory health insurance contributions from a social payroll tax paid by the employer, with 94% of the population covered by the main purchaser of healthcare services - the Estonian Health Insurance Fund (EHIF) (Lotman & Viigimaa, 2020). According to the Estonian eHealth strategic development plan, the eHealth strategy is funded by various parties, including the budget of the Ministry of Social Affairs and EHIF, with the latter being the leader for the uptake of digital health technologies. In 2020, the EHIF led a process to adjust the UK National Institute for Health and Care Excellence (NICE) Digital Health Technology Assessment Framework for the Estonian context and this framework now enables the assessment of efficiency and cost-effectiveness of digital health technologies (Estonian Health Insurance Fund, 2020). In 2021, the EHIF initiated an analysis for creating a detailed framework for the assessment of digital healthcare technologies with potential pathways and recommendations for national reimbursement. The main recommendations were i) creation of a coordinating organization that should include various stakeholders, ii) the processes for medical devices and non-medical (wellness) devices should be distinguished, iii) supportive algorithms for developers should be provided, iv) assessment for cost-effectiveness should be considered and assessed as context-specific, v) evaluation regarding interoperability and connectivity is needed, vi) paths of assessment for various telemedical services should be analysed (Taltech Centre for e-medicine, 2022).
Current efforts focus on reimbursement rules for digital health technologies
Reimbursement presents a major hurdle for the implementation of digital health technologies and the Estonian model is still a work in progress. For example, e-consultation is on the EHIF's List of Healthcare Services as a service, while the continuous glucose monitoring systems and sleep apnoea devices are reimbursed as a device through the List of Medical Devices. Cardiac implantable electronic devices (CIEDs) are in the List of Medical Devices, but the remote monitoring solution of CIEDs is reimbursed through the List of Healthcare Services. Examples of e-health solutions that are reimbursed as a service, include also innovative pilot projects for the remote monitoring of psoriasis patients and oncological patients, reimbursed monthly to healthcare providers (HCP).
Opportunities for RWD and RWE particularly around patient experience and to support clinical decision-making
Currently, there is no uniform framework for the collection and analysis of RWD or RWE systematically, but there are opportunities in improved cooperation between different institutions. RWD is collected thoroughly on the bills provided by the HCP-s and on the use of digital prescriptions by the EHIF. RWE is collected on a selective basis, with the emphasis on quality indicators of the HCP-s. The policy for the collection of RWD and RWE on digital healthcare services is being compiled and will be drawn up in coordination with the corresponding EU legislation. Pharmacovigilance is provided by the State Agency of Medicines and regulatory control for medical devices is provided by the Health Board. An example could be derived from remote monitoring (RM) of and CIED-s. This process is helpful in reducing outpatient visits and detecting events early (Simovic et al., 2022) and should improve healthcare availability in geographically underserved areas. RM of CIED-s has been implemented with success in Estonia since 2011. According to the ESC CRT Survey II, 72.4% of CRT devices were monitored by telemetry in 2016 in Estonia (Dickstein et al., 2018). The reimbursement of RM of CIEDs was approved by the EHIF in 2018, but implementation of the reimbursement was initiated in 2021. It was assessed to safely and effectively reduce hospital visits and response times and to be cost-effective (Estonian Health Insurance Fund, 2022). Reimbursement is performed on a quarterly basis to the healthcare providers. It is expected to reduce the use of other reimbursed services, such as outpatient visits. Real-world data is collected from the CIED-s and this informs clinical decision-making. This data is collected by the treating clinical team at the HCP. RWD on the overall use of the service is collected by the EHIF based on the claims from HCPs. During 2021, a total of 1052 patients received the RM service, 80% of the patients were male, mostly aged 60-75 years. No RWD data on the patient experience has been collected to date, although it would be useful (Estonian Health Insurance Fund, 2018). For clinical decision making, it would be useful to estimate the impact of the RM service on the overall clinical outcomes.

Finland

Legal and national frameworks put in place for the monitoring and assessment of digital health technologies

Finland provides its residents universal healthcare through the municipal health system, supplemented by private, occupational and student health systems. The central government oversees and steers the system's functioning (Keskimäki, 2019). In 2023, a major reform will transfer responsibility for public primary healthcare from municipalities to self-governing wellbeing services counties. Collaborative areas will be established to secure specialised care based on the current hospital districts. The reform transfers the primary funding of public healthcare to the state (Ministry of Finance, 2022).

Finland has a long history of national data resources on population health, promoted by recent legislative amendments ("552/2019," 2019a; "553/2019," 2019b). All providers with an information system for processing patient data are obliged to provide data on care and outcomes to the national register ("784/2021," 2021a). Public providers shall also record data on how the patient has been contacted, which is relevant for digital health. In terms of remote contact, data is recorded either as a) synchronous transactions (phone, chat, or video connection) or as b) asynchronous transactions (a letter, e-mail, or digital service) (Häkkinen et al., 2019).

Legislation promotes the implementation of effective digital health technologies. The assessments of the cost-effectiveness of care and technology suitability with the Digi-HTA tool are centralised (Northern Ostrobothnia Hospital; "582/2017," 2017). Legislation does not bind the use of assessment in decision-making, but providers may choose to require a technology company to request a free-of-charge assessment, for example, before commencing procurement or piloting (Haverinen et al., 2019). The assessment considers, for example, accessibility, such as the results of usability testing among potential different end-users (e.g., vulnerable groups) (Haverinen et al., 2019; Northern Ostrobothnia Hospital, 2022).

Renewed focus to improve national efforts around standardised data collection

The national strategy to monitor digital health technologies in use has been based on collecting RWD and RWE from the population at a general level. Population surveys about perceived benefits and barriers are regularly commissioned (Hyppönen & Aalto, 2019; Kyytsönen et al., 2021a), remote transactions in the population are monitored from the national register (Kyytsönen et al., 2021b), and evidence on the challenges of vulnerable groups has been collected using qualitative research methods (Kaihlanen et al., 2022). The strategy has provided an overview of population's use and experiences of the technologies, and an understanding of their different distribution in the population, potentially strengthening the existing inequalities (Heponiemi et al., 2020; Hyppönen & Aalto, 2019; Kaihlanen et al., 2022; Kyytsönen et al., 2021a). However, the disadvantage has been that the data cannot be well linked to a particular technology, which has hampered the monitoring of quality and effects, the targeting of development work and evidence-based decision-making. The strategy can be partly explained by the lack of a common market or a national reimbursement scheme for digital health technologies. In the public sector, the procurement of the technologies is conducted regionally through tendering, meeting the needs of local healthcare providers, which has led to nationally fragmented implementation ("1397/2016," 2016).

Opportunities to collect data more systematically particularly for vulnerable patient groups

Nationwide health data resources are exceptionally comprehensive and of high quality, as the use of electronic health records is close to 100%, from where patient data is transferred to the national register for up-to-date monitoring (Reponen et al., 2021). The national register can be expected to cover data of different vulnerable patient groups, who may not be reached by surveys or providers' online feedback forms. More information could be obtained by combining register data on remote transactions with register data on population care and treatment outcomes. Additionally, more detailed data on the use of digital health technologies (e.g., type of technology, effects, and patient experiences) could be collected and stored in the register.

Development work for more systematic monitoring is ongoing, including the development of national quality registers for monitoring care pathways, remote transactions and PROM and PREM indicators (Jonsson et al., 2019; Ministry of Finance, 2022). An assessment framework for monitoring specific digital health technologies has been commissioned, emphasising patients' experiences, which could be evaluated with several indicators and data sources (Koivisto, 2021). There is a need to develop a national assessment process for digital medical interventions, which would adapt the combination of the marketing authorisation process for medicines and the Digi-HTA (Ahlqvist & Kalliola, 2021, 2022). A proposal to establish a national effectiveness centre could connect different national actors, it does not comment on digital health technologies, but centralising the related data collection and assessment could be a natural continuation of the effort for national harmonisation (Torkki & Mäki-Opas, 2021).

Germany
Recent policy initiatives to support assessment of digital health technologies
Health insurance is compulsory in Germany and provided either under the statutory health insurance (SHI) scheme or through substitutive private health insurance. SHI covers 88% of the population and is provided by 97 competing, not-for-profit sickness funds. The federal government sets out the overall legal framework, details for planning, the provision of services and payment are negotiated and defined at the federal state and corporatist level, including payers and providers. The German healthcare system has a comparatively low level of digitization among peer countries, both in terms of overall digital infrastructure and in the uptake of e-health services (European Commission, 2020). First steps to introduce an electronic health card were initiated in 2004 (SHI Modernization Act), but only the E-Health law, passed in 2015, set the initial course for the establishment of the secure nationwide digital infrastructure (Blümel et al. 2020). Overall, many measures came into force, including stipulating the mandatory introduction of an electronic health record (German acronym: ePA). E-prescribing, proposed in 2019, has not been fully implemented until now (BMG, 2019a, 2019b). A fast-track pathway was established to foster innovation and access to prescription-based digital health applications (DiHA; German acronym: DiGA). In addition, the establishment of the Health Research Data Centre at the BfArM was initiated, also aiming to enhance the use of RWD (BMG, 2019b). In addition, processes for the introduction of digital care applications (German acronym: DiPA) and the expansion of telemedicine were addressed and investment to support the digitization in hospitals (BMG, 2020). Due to several challenges, the Ministry of Health developed a national strategy for digitisation using a participative process, which was published in 2023 and includes guidance on how to evolve healthcare processes, data use and technologies to improve health care (BMG, 2023). One field in which Germany is playing a pioneering role internationally is the fast-track pathway for DiHA.
Fostering innovation with the Framework for early HTA decision-making on digital health applications − The Fast-Track Pathway
With the growing supply of DiHA and the challenge of identifying safe and effective DiHA, a framework for a systematic early HTA process was implemented (Essén et al., 2022). DiHA under this framework include medical devices of class I or IIa according to Europe's Medical Devices Regulation (MDR) that have a primarily digital mechanism of action and are used primarily by patients. DiHA are approved conditionally or permanently as part of the SHI's benefit basket after running an assessment at the Federal Institute for Drugs and Medical Devices (BfArM, 2022). Provisionally listed DiHA are covered by SHI while evidence on healthcare effects is generated, including clinical outcomes such as morbidity, and quality of life, but also patient-centred outcomes in terms of structural and procedural effects (e.g., access to care, health literacy, adherence, and patient satisfaction). A special feature of the approach is the opportunity to use RWE in the evaluation process. Nevertheless, until now decisions were mainly based on randomised control trials (RCTs). Once included in the SHI's directory, manufacturers can freely set their prices for the first year. From the 13th month after inclusion, a price negotiated between the manufacturer and the Federal Association of Sickness Funds applies. Evidence shows a wide price range and criticism that legal conditions place too little emphasis on the current benefit (Lantzsch, 2022). Therefore, a reform on the reimbursement followed, grouping DiHA based on their indication and positive healthcare effect to calculate maximum prices covered by SHI.
Opportunities for RWD and RWE after market entry can be leveraged using current government policies for DiHA
No process is in place to request data of the digital health technology after market entry. However, data collection may offer opportunities to analyse for example therapy discontinuations, frequency of use and compliance. Further studies accompanying the application should be conducted regularly after market entry to be able to estimate the performance and the real value of the DiHA. The price of the DiHA could then be reflected with these (new) study results (TK, 2022). At the time of market approval, there is often no meaningful data available for an early benefit assessment. For specific drugs, a framework regarding generating RWE and evaluating benefits is in place. In the case of DiHA, Germany's regulatory framework paves the way for the use of real-world evidence, while a systematic approach to do so is missing, but would be urgently needed. There is a need for suitable methods, assessment criteria and standards for evaluating DiHA regarding their health (economic) benefits. Challenges arise from rapid technological progress or separating the digital innovation from the associated healthcare concept. Now that initial experience has been gained with the evaluation framework for DiHA, corresponding evidence standards should also be developed, as different types of evidence beyond RTCs may be required (Stern et al., 2022).

Italy
Renewed institutional focus on supporting digital health technologies
The Italian National Health Service (INHS) is decentralised and regionally based (19 regions and two autonomous provinces), with the central government exercising overall stewardship and regions responsible for the organization and delivery of services (Ricciardi and Tarricone, 2021). Although belatedly compared to other countries, INHS initially set out its National eHealth Information Strategy in 2011, thereby identifying areas with the most significant priority of intervention (Ministero della Salute, 2011). Among them, policy focus was primarily directed at telemedicine services, the implementation of a national Electronic Patient Record (the so-called Fascicolo Sanitario Elettronico – FSE), and the digitization of prominent procedures such as booking and prescription services. Consequently, national guidelines on both telemedicine services (Ministri, 2014) and the presentation of regional plans for FSEs were issued in 2014 (Agenzia per l'Italia Digitale, 2014). Other national-level documents were published in 2016, as the Digital Healthcare Agreement stipulated that eHealth would be the key factor to realize new models of care primarily through the spread of the FSE (Ministero della Salute, 2016a) and the National Chronic Care Plan provided guidelines for the management of chronic patients and included dedicated sections to eHealth as a strategic platform for its overall success (Ministero della Salute, 2016b). Despite the extensive release of national guidelines, regional adoption of these plans remained scattered, and the implementation was substantially non-existent by the beginning of 2020, when the Covid-19 pandemic emerged.
National RWD efforts have been primarily focussed on population-level Big Data
Up to the pandemic, the most significant source of RWD used for national level policies in Italy had been administrative databases, that mainly track healthcare resource consumption per individual patient. Information on pharmaceuticals, hospital admissions, specialist services use, access to emergency services, integrated homecare, assistive medical devices, and prostheses have been collected longitudinally in standardised and complete formats for over 10 years to assign reimbursement rates to each individual service or product delivered (Skrami et al., 2020). On the other hand, the administrative purposes do not always guarantee sufficiently granular and informative details for clinical purposes. Over the past years, the majority of the 21 Regional Healthcare systems have either chosen among internationally recognized providers or taken advantage of resources available internally to develop systems for analysing these population-level Big Data and stratifying their citizens. As a result, they have defined clusters of individuals not only based on comparable healthcare needs and associated risk levels, but also on their supposed under- or over-treatment as compared to idealised care pathways. While RWD have so far been used mainly for epidemiological and regional governance purposes, digital health technologies are yet to be included among the contemplated sources of RWD to harness.
The National Recovery and Resilience Plan: renewed opportunities for RWD and RWE
The global pandemic has pushed the INHS to speed up its digitization process, creating new opportunities to produce and leverage on RWD (Petracca et al., 2020). On the one hand, telemedicine policies have been reactivated and basic telemedicine services are now reimbursed nationally based on a shared set of rules and criteria. More importantly, as part of the Next Generation EU programme, the Italian Government has negotiated its National Recovery and Resilience Plan (NRRP), with at total amount of € 222.1 billion, of which € 18.5 billion are dedicated to specific health purposes (Presidenza del Consiglio dei Ministri, 2021). The overall health-related goal of the Plan is to strengthen community prevention and health services, modernise and digitise the health system, and ensure equal access to care. As part of this Plan, the Italian Government has set up a national platform for the provision of telemedicine services. The tender for the platform has recently been awarded with the aim of providing healthcare professionals with high-quality and validated tools to improve care processes. The Plan also exemplified the national vision in terms of collection, analysis, and use of RWD. The INHS aims at systematically collecting individual patient data by revamping its electronic patient record (*FSE*) and fostering Individual Care Plans (*Progetto di Assistenziale Individuale integrato - PAI*). The FSE remains a repository of retrospective, non-standardised health data that qualify as "Big Data", requiring sophisticated textual analyses and natural language processing tools for government or research purposes. However, recent policy guidelines have introduced new incentives to promote its adoption, such as the binding requirement for all public and private providers to upload information on every single health service, with an expected 100% coverage by 2026. On the other hand, the PAI intends to collect prospective data, with indicators of expected clinical outcomes. It should be mandatory for chronic and frail patients. Its format is standardised and includes diagnosis, 12-month treatment plans, expected outcomes and lifestyle. Digital health technologies are not yet envisaged but this initiative offers an opportunity for future monitoring and collection of DHT-related data. The NRRP also envisions the creation of a national cloud where all FSE and PAI data will be collected.

United Kingdom (England)
Many stakeholders involved in digital health policy
The health system is decentralised in the United Kingdom since 1999 and devolved to the four nations: England, Scotland, Wales, and Northern Ireland, with the English NHS being the largest health service with 80% of the population (OECD, 2019). All use a general taxation-funded approach to health system financing, but each have their own planning and monitoring frameworks and public health agencies but differ in the way services are organised and paid for. All four nations have published digital health related strategies in recent years. They share some areas of policy focus (Sheikh et al., 2021): strong leadership to foster an open culture for innovation; improved governance to ensure agreed standards are met; investing in health information technology infrastructure, workforce development to ensure staff have the right skills to collect, process, and analysis of data for policy and planning, an electronic personal health record accessible for patients across multiple health and care settings. In England, for example, there are several policy-making bodies involved in digital health technologies with no one authority having complete oversight (Srivastava, 2020). There are regulators, statutory bodies along with other key stakeholder groups (NHSX, 2019a). NHSX, within the Department of Health and Social Care was most recently created in 2019, to lead the digital transformation agenda in the NHS (NHSX, 2019b).
Current data collection efforts inform policy in primary care
Before the pandemic, there was little patient uptake of a virtual primary care systems and digital tools on the demand side, but also on the supply side, there were variations in digital maturity, the digital infrastructure, guidance, and incentives on using digital tools and provider interest (Atherton et al., 2018; Hammersley et al., 2019; Hughes G et al., 2020). Around 13% accessed telephone appointments before the pandemic in England (Nuffield Trust, 2020). The pandemic contributed to widespread data collection of RWD particularly related to virtual primary care and public health Covid-related surveillance purposes (Hughes G et al., 2020; Sheikh et al., 2021). Around 85% of consultations in England were done remotely at the height of the pandemic and video consultations are now available in 99% of GP practices (NHSX, 2020). Increasing the use of patient involvement through different platforms and services have led to increases in RWD data collection but these are not necessary collected in a systematic fashion to inform decision-making. For example, there is Accrux which is two-communication tool for text/SMS used to complete asthma reviews or depression management scores (Primary Care Training Centre, 2020). Systematic collection of patient experience comes from the NHS GP patient survey and are used to inform monitoring and quality frameworks such as the NHS Outcomes Framework.
Opportunities to embed RWD and RWE could expand to include clear rules around reimbursement and for ongoing monitoring
NICE's recent real-world evidence framework identifies opportunities to further leverage the potential of RWD and RWE; expanding the evidence threshold and data requirements for artificial intelligence and includes both fixed and adaptive algorithms (NICE, 2022). These national frameworks aim to support local decision-making. The extent to which these frameworks leave too much flexibility between the manufacturer and commissioner (payer) remains an open question. Reimbursement in the case of primary care, there is no explicit fee for digital related services. GPs work under the General Medical Services (GMS) Contract, which is held with practices, not individual GPs. A fixed national global sum, determined according to a refined weighted capitation formula, is adjusted to account for differences in population health needs, with an average of GBP 151 per patient in England (Cylus J et al., 2015; Oliver, 2019). The GP contract sets out digital primary care requirements included in a 'core digital offer' (e.g., video and online consultations) (NHS England and NHS Improvement, 2021). Missing are clear rules for financing and reimbursement of digital health technologies, drawing on evidence to inform price setting. Systematic financial data collection could gather evidence on costs, sustainability, and cost effectiveness to inform policy (Scobie S & Castle-Clarke S, 2019).

Appendix 2

Table 1A. Digital health technology policy framework – building block principles

Principle	Digital health technology policy framework – Building block principles	% Voted for inclusion	Round	Sensitivity analysis	
				Consen-sus 70%	Consen-sus 80%
Institution	A central institution (or agency) oversees the implementation of the national digital health strategy with the support of all relevant stakeholders for the collection, use and best practice of real-word data and real-world evidence.	87	2	-	
Collection	Real- world data is collected with the user's informed consent and follows country legislation/guidance on data protection.	87	2	-	
Collection	The national digital health strategy supports sharing data across settings that follows country legislation/guidance on data protection and interoperability.	81	1	-	
Policy scope	Real-world evidence needs for decision-making are aligned where appropriate to support national and sub-national health policy priorities.	80	3	-	
Policy scope	The national digital health strategy explicitly defines digital health technologies, real-world data and real-world evidence drawing on working definitions	80	1	-	
Institution	There is a central institution (or agency) that provides guidance to balance transparency and accountability with respect to access and use of real-world data needs for quality assurance.	78	2	-	Remove
Policy Scope	The national digital health strategy takes a broad and inclusive approach in its definition on the scope of real-world evidence.	76	3	-	Remove
Collection	The national digital health strategy supports the collection and use of real-world data and real-world evidence to inform decision-making by making recommendations.	75	1	-	Remove

Table 2A. Digital health technology policy framework – post-market surveillance and digital health technology vigilance

Principle	Digital health technology policy framework – Post-market surveillance and digital health technology vigilance	% Voted for inclusion	Round	Sensitivity analysis	
				Consen-sus 70%	Consen-sus 80%
Collection	Real-world data collection includes clinical outcomes, and user experience that could come from patients, carers, and healthcare professionals.	86	2	-	
	Guidance and best practice of a) real-world data and b) real-world evidence are routinely shared and publicly accessible to increase transparency for digital technology vigilance and post-market surveillance.	81	1	-	
	National and where appropriate, sub-national agreements are in place with companies (e.g., developers, manufactures, and vendors) on the collection and reporting requirements of real-world data and real-world evidence	80	3	-	
	Real-world data is routinely collected in a comparable way where possible and consistently over time to allow for within and between country comparisons.	78	2	-	Remove
	The collection of real-world data uses study designs and collection methods to support and inform the national digital health strategy for ongoing evaluation, monitoring and evidence requirements	78	2	-	Remove
	In the data collection, the characteristics of the type of digital health technology (e.g., real-time virtual consultation, remote monitoring platform) and its function (e.g., diagnosis, monitoring, self-management, treatment) are collected with sufficient precision, instead of collecting data in overly broad categories.	77	2	-	Remove
Decision-Scope	The national digital health strategy supports the appropriate use of real-world evidence to inform clinical decision-making.	76	1	-	Remove
	Depending on the type of evidence, real-world evidence that is based on routinely collected real-world data is used to inform decision-making. This could include in relation to utilisation, benefits, quality, equity, accessibility, safety, and reimbursement.	76	2	-	Remove

Table 3A. Principles where consensus was not reached

Digital health technology policy framework – Principles did not reach 75% consensus	% Voted for inclusion	Median	Round	Consensus 70%	Consensus 80%
The most appropriate and relevant real-world evidence study designs are used to support and inform the national digital health strategy for ongoing evaluation, monitoring and evidence requirements in accordance with national regulation policy.	65	4	3	-	-
The national principles and standards are discussed with supra-national organisations and initiatives (e.g., to support transferability, harmonisation of terminologies, guidance on standards, best practice of real-world evidence, how to aggregate real-world data, applicability of real-world data).	60	4	3	-	-
There is a central institution (or agency) that enforces the rules and strategies and is accountable in relation to the national digital health strategy.	60	4	3	-	-
The national digital health strategy uses criteria where appropriate to prioritise decision-making with respect to real-world data and real-world evidence (e.g., this could include availability of good quality data, prioritisation by severity of disease, risk of the technology, prevalence or cost of treatment).	56	4	3	-	-

Table 4A. Responses by expert affiliations: Digital health technology policy framework – building block principles

Principle	Digital health technology policy framework – Building block principles	Heath care professional	National/ regional institution	Scientist/ Academic research
Institution	A central institution (or agency) oversees the implementation of the national digital health strategy with the support of all relevant stakeholders for the collection, use and best practice of real-word data and real-world evidence.	100%	100%	83%
Collection	Real- world data is collected with the user's informed consent and follows country legislation/guidance on data protection	100%	80%	83%
Collection	The national digital health strategy supports sharing data across settings that follows country legislation/guidance on data protection and interoperability.	75%	57%	88%
Policy scope	Real-world evidence needs for decision-making are aligned where appropriate to support national and sub-national health policy priorities.	83%	80%	88%
Policy Scope	The national digital health strategy explicitly defines digital health technologies, real-world data and real-world evidence drawing on working definitions	67%	86%	83%
Institution	There is a central institution (or agency) that provides guidance to balance transparency and accountability with respect to access and use of real-world data needs for quality assurance.	80%	80%	100%
Policy scope	The national digital health strategy takes a broad and inclusive approach in its definition on the scope of real-world evidence.	33%	80%	100%
Collection	The national digital health strategy supports the collection and use of real-world data and real-world evidence to inform decision-making by making recommendations.	75%	29%	89%

Table 5A. Responses by expert affiliations: Digital health technology policy framework – post-market surveillance and digital health technology vigilance

Principle	Digital health technology policy framework − Post-market surveillance and digital health technology vigilance	Health care professional	National/ regional institution	Scientist/ Academic research
Collection	Real-world data collection includes clinical outcomes, and user experience that could come from patients, carers, and healthcare professionals.	100%	80%	100%
	Guidance and best practice of a) real-world data and b) real-world evidence are routinely shared and publicly accessible to increase transparency for digital technology vigilance and post-market surveillance.	75%	71%	94%
	National and where appropriate, sub-national agreements are in place with companies (e.g., developers, manufactures, and vendors) on the collection and reporting requirements of real-world data and real-world evidence	83%	80%	50%
	Real-world data is routinely collected in a comparable way where possible and consistently over time to allow for within and between country comparisons.	100%	40%	100%
	The collection of real-world data uses study designs and collection methods to support and inform the national digital health strategy for ongoing evaluation, monitoring and evidence requirements	80%	60%	80%
	In the data collection, the characteristics of the type of digital health technology (e.g., real-time virtual consultation, remote monitoring platform) and its function (e.g., diagnosis, monitoring, self-management, treatment) are collected with sufficient precision, instead of collecting data in overly broad categories.	40%	80%	100%
Decision-Scope	The national digital health strategy supports the appropriate use of real-world evidence to inform clinical decision-making.	83%	57%	76%
	Depending on the type of evidence, real-world evidence that is based on routinely collected real-world data is used to inform decision-making. This could include in relation to utilisation, benefits, quality, equity, accessibility, safety, and reimbursement.	100%	60%	75%