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Comparison report of Digi-HTA and PECAN

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1. Background

Digi-HTA is a health technology assessment (HTA) model developed for digital health technologies (DHTs) used in social welfare, health care, and well-being in Finland. It assesses the suitability of a product or service for use by customers, professionals, and organizations in the sector. The assessment perspectives include effectiveness, costs, safety, data protection, security, usability, and accessibility. In addition, the assessment considers issues affecting the introduction of a digital product, such as changes to the treatment process and IT infrastructure. [1-3]

In the Digi-HTA process, the responsibilities are divided as follows: cybersecurity experts from the University of Oulu assess data security and protection aspects, while HTA experts from FinCCHTA evaluate all other areas. [4] Currently, there is no national-level reimbursement process in Finland linked to the Digi-HTA assessment; instead, Digi-HTA assessments have been part of regional procurement and implementation requirements.

In France, DHTs used for therapeutic or diagnostic purposes—also known as digital therapeutics (DTx)—can be included in the List of Reimbursable Products and Services (Liste des Produits et Prestations Remboursables, LPPR) for permanent reimbursement. [5] Similarly, the permanent reimbursement pathway for remote patient monitoring (RPM) solutions is called the "Liste des Activités de Télésurveillance Médicale" (LATM). The LATM pathway is based on previously implemented reimbursement pilot projects for RPM, conducted under the program "Expérimentation de Télémédecine pour l'Amélioration des Parcours en Santé" (ETAPES). In its first phase, the LATM pathway included the same five clinical indications, referred to as the "generic line," that were part of the ETAPES program: kidney failure, heart failure, respiratory failure, diabetes, and implantable cardiac devices. [6] It is now also possible to register RPM solutions under a brand name at the request of companies. This applies to products with indications or technical specifications that do not align with existing generic line requirements and that claim to offer superior benefits in terms of efficacy or organizational impact compared to current measures. [7]

In addition to the permanent reimbursement models for DTx and RPM solutions—LPPR and LATM—France introduced the PECAN (Prise en charge anticipée numérique) reimbursement and associated assessment model in April 2023. PECAN includes one-year transitional and temporary reimbursement access schemes for DTx and RPM solutions. [8] The PECAN process is intended for DHTs that show potential benefits but for which there is not yet sufficient evidence to qualify for LATM or LPPR registration. [6]

PECAN features a parallel assessment process involving a French HTA agency (Haute Autorité de Santé, HAS) and a digital health agency (Agence du Numérique en Santé, ANS). The evidence of clinical and/or organizational value is reviewed by HAS, while interoperability and cybersecurity aspects are assessed by ANS. [8] The Medical Device and Health Technology Evaluation Committee (Commission nationale d'évaluation des

dispositifs médicaux et des technologies de santé, CNEDiMTS) is an HAS committee that specifically assesses the clinical evidence of medical devices. [9] If an economic assessment of the product is required for the LPPR process, it is carried out by the Economic and Public Health Evaluation Committee (Commission d'évaluation économique et de santé publique, CEESP) of HAS. [10] The final decision on reimbursement is made by the Ministry of Health, and these decisions are published in the official journal by the Ministry of Health. [8]

The purpose of this document is to summarize the results of the comparative analysis of Digi-HTA and PECAN assessment criteria. The goal is to produce transparent and reliable reference material for the comparison work.

The comparison workflow was driven by the ongoing rise of DHTs and the increasing demand for high-quality and comprehensive assessment of mHealth, artificial intelligence (AI), and robotics solutions. Regarding the regulatory basis, the safety, performance, risks, and benefits of medical devices are strictly regulated before market access. This regulation-based approach can create the impression that DHTs placed on the market are uniformly applicable. However, market access does not guarantee the effectiveness or applicability of DHTs classified as medical devices. [11,12] The same applies to digital wellness technologies, where regulation is at a significantly lower level compared to medical devices. Furthermore, to assess and qualify DHTs, harmonization of assessment criteria is essential, so that the open market does not become siloed between countries. It is in the shared interest of manufacturers, users, and assessment bodies that digital solutions and mobile apps in the social, health, and welfare sectors are evaluated using harmonized criteria to support decision-making, while considering the needs of technology companies and citizens. The assessment criteria should not stifle innovation or research, but rather support them to ensure a high standard of quality. From this perspective, modularized and unified assessment methods support high-quality DHTs without creating additional market restrictions.

The analysis is divided into two parts: the first part focuses on the general aspects of the frameworks, and the second part on the cybersecurity requirements. A category-by-category comparison is presented in the following sections. The middle column, "Both," summarizes the requirements shared by both sets of criteria. The requirements unique to each set of criteria are summarized in the left- and right-hand columns. This comparison report has been prepared based on the naming conventions of the domains used by Digi-HTA.

This comparison work was conducted from January to September 2024 and is part of the Finnish Recovery and Resilience Plan, which is funded by the European Union's NextGeneration EU funding.

2. Comparison of the general parts of the assessment methods

Summary of the most important considerations in the comparison of Digi-HTA and PECAN.

1. The product assessed in PECAN must be a CE-marked medical device (all risk classes can be included) Digi-HTA is suitable for medical devices of all risk classes, as well as non-medical devices.
2. PECAN is intended solely for DTx and RPM applications, which may also incorporate AI algorithms. Digi-HTA is applicable to a wide range of DHTs such as digital health applications, DTx, RPM, AgeTech, AI and robotic solutions.
3. In Digi-HTA, there is a dedicated domain for AI products or products utilizing AI, whereas in the PECAN process, there is also a separate analysis grid for the AI components [1,13].
4. In Digi-HTA and PECAN, the key assessment domains were named partly differently. Digi-HTA has a specific domain for aspects related to robotics.
5. In both assessment models, the assessment of the product takes about 2-3 months.
6. The Digi-HTA assessment process and consultation is free of charge for the vendors. The preliminary consultations arranged by HAS are voluntary, non-binding, confidential, and provided at no cost [14]. The application for the PECAN process is free for the vendor, but a predetermined fee is charged for the permanent listing in LPPR or LATM.
7. Digi-HTA's requirements are based on partly both national and EU-level regulations, such as the Act on the Provision of Digital Services and GDPR (General Data Protection Regulation), as well as international standards. PECAN is based on the legislation of France and European legislation and regulatory requirements.
8. PECAN includes a national reimbursement model based on legislation, whereas the Digi-HTA assessment model currently provides informative data that can be used as part of the requirements for regional procurement decisions.

Product

Digi-HTA [1]	Both	PECAN [15,16,17,18]
Information about product maturity level: Technology Readiness Level (TRL) of the product. If the product has not yet been released, when will the finished product be available? Information about the CE-marking of the product. A declaration of conformity document is required for CE marked products. Is the product classified as a medical device according to MDD or MDR? If so, what risk class? Does the product have FDA approval? In addition, products classified as non-medical devices can be	General information about the product, its functionalities and supported platforms and post-market surveillance plan. Information about the intended purpose and intended users of the product. The exclusion criteria for use of the product. Note that in Digi-HTA, this is covered under the usability and accessibility domain. Both Digi-HTA and PECAN cover end-users and healthcare organizations.	Information about is product medical device and what is risk class. What are the specific medical purposes. Function of the device: therapeutic or remote medical monitoring. Information about it the product is CE marked and does it have a declaration of conformity. (CE marking ensures that the manufacturer has a post-market surveillance plan.) Has obtaining reimbursement been considered in the product's development? Has the product already been reimbursed as part of hospitalization services?

assessed. In those cases, a manufacturer provides a rationale document clarifying why the product is not classified as a medical device. Information about if the product is intended to replace current healthcare services and if so, what services? Information about if the product is already in use elsewhere in Finland or worldwide and if so, where and for how long? Information about company's post-market surveillance plans. If the product is battery-operated, what are the charging, idle and operating times?		Notion of equivalence Models and commercials refences Information on the product's usage methods, technical equipment (for example battery or cell lifespan under different usage conditions), warranty, shelf life, users, and required training, etc. Is there approval in another country? If applicable, devices or technologies that can be used together or that are essential for its operation.

Effectiveness

In the Digi-HTA effectiveness assessment, evidence provided by the company is utilized, including case studies, randomized controlled trials (RCTs), HTA reports, Cochrane reviews, as well as Real World Data (RWD) and thesis work related to the product being evaluated. This information is supplemented with a literature review. Digi-HTA does not specify the country of origin for studies. Transferability to the Finnish healthcare context is evaluated on a case-by-case basis. The assessment is based on the product benefit claims defined by the company, against which the available evidence is evaluated. If the product or service aims to impact the customer's health, it is the primary focus of the assessment. In other cases, the effectiveness is evaluated from the perspective of the organization acquiring the product, for example, its impact on the staff's work. [1]

The PECAN assessment evaluates the expected value of a product based on how well it improves the patient's health across different indications. The level of evidence required is determined on a case-by-case basis, considering the severity of the condition and the existing medical need for the product. However, HAS only accepts the following types of evidence: best practice recommendations, technology assessment reports, systematic reviews and meta-analyses, clinical studies, and organizational impact studies. The HAS does not accept abstracts, posters, conference presentations, theses, expert recommendation letters, preclinical studies, or general articles that are narrative, editorials, or opinion type from the author as evidence in its HTA process. PECAN prefers studies performed in France but accepts international studies for evaluating effectiveness. When dealing with international studies, the manufacturer must explain transferability to the French healthcare context in the dossier. The expected added value is assessed by comparing the results of the new technology or procedure to standard treatment. The

evaluation is categorized on a scale of ASA I-V, which influences pricing. Reimbursement is determined based on the value provided by the product. [19]

In PECAN, clinical evaluations are conducted for all therapies, but economic evaluations (modeling and budget impact) are only carried out if a high added value score and significant impact on health spending are claimed. Evaluations are applicable to all device classes (I, IIa, IIb, III). [15]

HAS evaluates the product based on the following three criteria: [16]

1. Impact on the care process components
2. Impact on required skills and capacities for care actors
3. Impact on society or the community (public health interest)

These criteria are further detailed into measurable sub-criteria.

There are several market access pathways for digital health devices, including DTx and RPM solutions, as well as early access for devices with limited clinical data. HAS offers flexible evidence requirements, taking into account the specificities of digital health, such as RCTs not being mandatory and organizational impact being considered. Devices can function in therapeutic or remote monitoring roles, and their value is measured by clinical improvements compared to standard treatments. [15]

Digi-HTA	Both	PECAN
Description of effectiveness from the perspective of healthcare organizations or system, and the availability of evidence to support it. Explanation for any missing evidence about the clinical benefits, behavioral changes system/organizational effects. Information about ongoing studies to investigate the product's effectiveness in Finland or in other countries. Information about any institutions (e.g., another country's HTA agency) that recommend the product.	Description of the product's health benefits, and the availability of evidence to support it. Description of the product's effects on users' actions or behavior favorable for their health, and the availability of evidence to support it.	HAS generally demands high methodological standards for clinical data, allowing lower standards if more rigorous trials are impractical. Preferably, trials should be prospective and comparative, preferably multicenter and randomized, with clinically relevant endpoints and adequate sample sizes estimated based on hypotheses. Positive results on primary and key secondary endpoints are expected, reflecting typical standards for medical device assessment.

Safety

Digi-HTA requires appropriate measures to ensure product safety. While the necessary measures are broadly outlined in the regulations, Digi-HTA includes more specific questions to assess safety. Important note is that the Digi-HTA also evaluates non-medical

devices, for which the relevant questions apply even when medical device regulations are not required.

In PECAN, CE marking, prerequisite to evaluation by the CNEDiMTS, ensures that the medical device is compliant with the general safety and performance requirements. PECAN evaluates only CE marked medical devices. [9] It should be noted, however, that even if there is a part of the product that is not CE marked, it still falls under the category of products to be assessed.

Digi-HTA	Both	PECAN
What is the company's process to handle customer safety events (deviations/errors, safety incidents, close calls or adverse events)? Is a risk analysis available for the product and will it be updated regularly? Have any product-related customer safety events been reported, and who is the person who's respond in the company for handling Manufacturer Incident Reports? National references for safety supervision. Has it been ensured that there are no errors in the product instructions or that their occurrence has been made as unlikely as possible? Is there any evidence available related to product safety. The company provides links to public results or attaches available documents (e.g., the declaration of conformity document) to response materials. Does the manufacturer implement appropriate measures to improve patient safety? Are there any undesirable effects associated with misuse of the product?		CE marking, prerequisite to evaluation by the CNEDiMTS, ensures that the medical device is compliant with the general safety and performance requirements. Manufacturers must set up, enforce and maintain a risk management system, throughout the device's life cycle.

Costs

The Digi-HTA process assesses the initial and maintenance costs associated with the use of the product. Additionally, it assesses other costs related to the product's adoption, such as

training costs and costs arising from infrastructure and IT changes. The costs for the end-user and the service provider have been detailed in the Digi-HTA assessment. There is no reimbursement system linked to Digi-HTA assessments in use in Finland at the time of writing. The cost assessment in Digi-HTA provides informative data for decision-makers, which they can use in their own decisions related to the procurement of DHTs. [1]

The French Social Security Funding Act of 2012 introduced a cost-effectiveness criterion for assessing healthcare products, including medicinal products and medical devices. This criterion is used in price setting when a manufacturer claims clinical improvement and significant impact on national health insurance costs. [20]

Medical and economic evaluations are included in the assessment of whether sufficient evidence and cost data are available. Commission for Economic and Public Health Evaluation (CEESP) conducts these evaluations, aiming to guide public decision-making and document cost-effectiveness criteria. If health-related quality of life is not a major factor, a cost-effectiveness analysis focusing on life expectancy is used. If quality of life is significant, a cost-utility analysis evaluating quality-adjusted life years is used. This analysis should be supplemented by a cost-effectiveness analysis, with the method chosen based on data availability. [20]

RPM solutions must be registered on the LATM list and monitored by a registered operator. Permanent reimbursement is valid for a maximum of five years and is paid in two separate flat-rate payments per patient. RPM solutions prices are predefined. [8]

DTx receive ongoing reimbursement by providing medical interventions through clinically evaluated software. They follow the same market access regulations as standard medical devices and are listed on the LPPR. HAS conducts the clinical evaluation, and CEPS sets the tariffs. During the first year, a transitional fixed compensation is provided, and the final price is negotiated after 12 months (only for DTx). RPM solutions prices are predefined and are not subject to negotiation. [8]

Digi-HTA	Both	PECAN [21]
If the cost-effectiveness data is not available, Digi-HTA focuses typically on comparing the costs of the new method with those of the current method. Accurate information on the formation of costs and the amount of costs for the end-users. Information about what kind of initial costs does the introduction of the product impose on the organization, including changes to buildings or facilities, a need for new	In the Digi-HTA and PECAN processes, the evaluation of cost-effectiveness is included if the necessary evidence is available.	In PECAN, it is not mandatory to provide economic evidence. If data available, HAS broadly evaluates cost-effectiveness. The economic evaluation must be conducted under real-world conditions. The production costs of the interventions studied are identified, measured, and valued independently of their sources of funding. Health-related effects are identified and measured from the

devices and software, as well as needed training? Information about the maintenance costs (e.g., monthly service fee) to the organization for the use of the product. Uncertainty factors related to the reported costs		perspective of the individuals affected by the interventions. When preference-based scores are used to evaluate changes in HRQL, they are obtained from a representative sample of the general population.

Technical Stability

The Digi-HTA – framework assesses the quality and reliability of the company's software product based on the following attributes: The software testing, error handling, update management processes, and minimization of downtime. Regardless of whether the product is CE marked or not.

Pecan technical stability is already partially perquisite for CE- marking [9].

Digi-HTA	Both	PECAN
Reference to IEC 62304 life cycle process standard. Description of the product's testing process. Information about the company's process for handling the error messages. How does the company inform the end-user or organization using the product about the updates and do software/system updates cause downtime in the use of the product? Has there been any downtime or impairment time in the use of the product during the last six months?		Technical stability is already partially perquisite for CE-marking. Where the company has described the technical environment necessary for the installation. [pecan guide]

Usability and accessibility

Digi-HTA asses the availability and the accessibility of the product from the end-user point view. Usability and accessibility will be assessed regardless of whether the product is CE-marked or not. If a digital application for healthcare professionals exists in the digital solution under assessment, this will be assessed by Digi-HTA as well. Digi-HTA refers to the Finnish national legislation requirements for accessibility if those are applicable to the product under assessment [1,22].

PECAN: Usability and accessibility are already partially perquisite for CE marking. Currently, there are no specific requirements for usability and accessibility in the PECAN process, but in the future, these are intended to be part of the criteria.

Digi-HTA	Both	PECAN
The product has been tested with users representing the real end-users of the product. The development of the usability and accessibility of the product should be a continuous process that can be influenced based on customer feedback. The manufacturer should clearly indicate for which users and indications the product should not be used, if there are any restrictions. The product offers accessibility for people with disabilities. Refers to WCAG 2.1 AA accessibility guidelines [22]. Has an accessibility assessment been conducted for the product? Is there an accessibility statement available for the product, which describes possible deficiencies in accessibility? [22,23] Is an electronic feedback channel available for users to submit accessibility feedback? Does the company respond to accessibility feedback within 14 days? [22] In the design of the product, the design guidelines of the mobile application platform have been followed. Mobile app platform accessibility features will be supported.		Usability and accessibility are already partially prerequisite for CE-marking. No specific requirements for usability and accessibility in PECAN assessing process.

Interoperability

In Digi-HTA information is required on whether the product has interfaces with websites, other software, third-party services, electronic patient records, or Finnish Kanta services. Additionally, details on the data formats used in these interfaces should be provided, including whether data can be exported in commonly used or standard formats. This information is primarily for informational purposes and is not separately scored. [1]

PECAN: The manufacturer must ensure their DHT can export all processed health data in a format that is readable, usable, and documented. Starting January 1, 2024, the device must also support transferring data to electronic health records with user consent. It must comply with two-factor authentication standards and reliably identify users by linking accounts to national identifiers and reference data. [24]

Digi-HTA	Both	PECAN
Information about whether the product has interfaces to websites, other software, other companies' services, electronic patient records or Finnish Kanta services. Information about the data formats used in any such interfaces • Can the data contained in the product be exported in a commonly used or standard format? • Are proprietary formats used to store and transfer data? If so, are the definitions of the original proprietary formats openly available?	Digi- HTA and PECAN emphasize the accessibility of health data, the importance of data formats, and the significance of user identification in the context of health applications and MD's. In Digi-HTA, the assessment of interoperability is primarily for informational purposes.	The manufacturer must commit to ensuring that the remote digital medical device allows the export of all the health data in processes. The export format must be readable, usable and documented by the manufacturer. The system must make available all of the health data and correspondent information it processes. The format of the file(s) made available must be readable, complete, usable, and documented by the manufacturer. The digital medical device (DMD's) interoperability and security standards require a 2-factor user authentication method. Requirement from 1 January 2024 onwards: The digital health application must enable data processed by the digital health application to be transferred to the electronic health record at any time with the end user's consent. In the case of RPM solutions used by HCPs, the system must be able to reliably identify users of the service by associating user accounts with national identifiers and data from the sectoral reference directory of natural persons.

Artificial Intelligence

Digi-HTA, evaluation framework, assesses AI by examining the specific problem it addresses, alternative non-AI -method, data sources, compliance with privacy regulations, and the AI model's performance. It also considers the impact on treatment processes, human involvement in decision-making, necessary training for users, and communication of the AI model's limitations and uncertainties. [1]

HAS has updated its guidelines for companies seeking reimbursement or an innovation pass for medical devices (DMDs) that incorporate AI, including machine learning [25]. These guidelines include a new mapping form that companies must complete, providing detailed information about the AI technology, including its intended use, data used for training, performance metrics, and explainability. HAS framework evaluates AI's purpose, benefits, data characteristics, development, and testing phases, emphasizing the device's usability and reliability in clinical settings. If DMD is based on at least one machine learning process, it should complete the mapping analysis grid. [12]

Digi-HTA	Both	PECAN
Purpose Define the specific problem or challenge that the AI solution aims to address. Non- AI solutions. Evaluate whether the problem could be addressed using methods other than AI. Confirm that the AI application has been tested and validated within the environment where it will be deployed.	**Purpose** Both Digi-HTA and PECAN focus to ensure that the device or solution is fit for its intended purpose, tested and suitable for the environment in which it will be used.	**Purpose** Assess the intended use and scope of the medical device, including its machine learning algorithms. Evaluate the benefits of the information or decisions generated by these processes, identify the target population and any unsuitable characteristics, and describe the operating environment of the smart system.
Data Describe the data sources (measurement and sensor data, patient information systems, user/organization - generated data, medical imaging data, public and private databases)? Are the data sources used in training the AI solution relevant to the real use case? Have data privacy (e.g., GDPR) and security issues been addressed in all phases of AI model training and validation? How have you ensured that the AI model can operate reliably in its intended use case if the data is incomplete?	**Data** Describe the data sources (measurement and sensor data, patient information systems, user/organization - generated data, medical imaging data, public and private databases)? Are the data sources used in training the AI solution relevant to the real use case? Have data privacy (e.g., GDPR) and security issues been addressed in all phases of AI model training and validation? How have you ensured that the AI model can operate reliably in its intended use case if the data is incomplete?	**Data** Specify the characteristics of the population used for initial model learning or relearning, including details on each sample. Define the methodology for separating or segmenting the samples.
Data collect Specify the amount of data used for training the AI model? Implement controls to prevent the system from being retrained with irrelevant data?	**Data collect and training process** Both Digi-HTA and Pecan emphasize learning data abilities and their meaning relevance to the functioning of the AI model. Both consider that training data and its usage need to be closely controlled and documented.	**Description of input data involved in decision-making** Specify the characteristics of the variables including their method of acquisition and origin. Describe any pre-processing applied to the data used for decision-making. List the output variables, including their characteristics such as type and unit.

The algorithm to be used. How and by whom was the algorithm developed. Does the algorithm's functionality depend on third- party services (e.g., cloud services)?	**Algorithm** Both deal with the type of algorithm and its development process, as well as the rationale behind the update and model selection.	**Model: description of training, validation, and testing, before and after MD deployment.** Describe the type of learning used and the tasks automated by the algorithm. Specify the update frequency and the criteria for model selection. Detail the training, validation, and test phases before MD deployment, as well as the strategies for updates if applicable, when human is involved in the retraining process.
AI performance. Describe the AI model performance by following metrics: Accuracy, precision, recall? **Decision making.** Does AI alter treatment processes, how? Describe the roles of AI and humans in the decision-making process? How much additional training is required to understand the operational logic and limitations of the AI model upon deployment? How are the basis for the AI model's decisions and any associated uncertainty presented to the user (e.g., confidence intervals)?	**AI performance and functional characteristics.** Both emphasize performance measurement and in particular, relevance of performance metrics. Both identifies AI and human co-operation in decision-making and seeks to ensure that the AI decision-making is transparent and comparable to existing guidelines. Both deal with explaining to the user the rationale for the model's decision making and uncertainty.	**Functional characteristics.** -Describe key processing operations that significantly impact performance. **System robustness.** Outline the tools used to generate antagonistic examples during performance evaluation and qualification. Specify the monitoring tools for system's performance post-deployment. **System resilience.** - Describe the system for detecting anomalies in input data during operational use. Outline the potential clinical and technical impacts of anomalies on the machine learning system. Specify the measures in place for addressing automatic or user-detected errors. **Explainability and interpretability** Indicate the explainability elements provided by the smart device. Identify the parameters that influence decision- making. Specify whether the decisions and actions of the smart device are compared to professional guidelines.

Robotics

The Digi-HTA includes its own domain for robotics-specific perspectives. However, most of the general requirements of the Digi-HTA framework can be applied as such to robotics.

[1] Robotics is not the focus of the PECAN model, as it concentrates solely on DTX and RPM applications, and therefore, there are no specific requirements related to robotics.

Digi-HTA	Both	PECAN
Robotic specific safety aspects. Information regarding potential infrastructure changes associated with the implementation of robotic solutions. Information on measures such as training or programming to ensure the robot operates in its environment. Information on aspects related to battery-operated robots.		No robotics-specific requirements, as robotics is not the focus of the PECAN model.

3. Comparison of the cybersecurity

The goal of this task is to compare the technical content of two cybersecurity requirement documents:

- Digi-HTA version of the HTA TT Information Security and Data Protection Requirements.XLSX (Soten hankintojen tietoturva- ja tietosuojavaatimukset) v1.3 (last version history entry is v.1.0.8, 17/12/2021) [26]
- PECAN:
    - Interoperability and Security standards for Digital Medical Devices (DMDs), Version: V1.2.2 (pdf - 526.38 KB) [24]
    - Interoperability and Security standards for Digital Medical Devices (DMDs) (requirements), Version: V1.2.2 (xlsx - 134.85 KB) [27]

The main focus of PECAN security-content seems to be compliance with "National Health Identity" of France and user data protection by GDPR compliance. There is only cursive mentioning of other kinds of security requirements. There are some references to security-related standards like ISO 10781 and ISO 13606-4, but they are also narrow in their scope. The requirements in the requirements document have many references to "INS Implementation Guide" and "National Identity Security Standard (Référentiel national d'identitovigilance - RNIV)". These do not directly specify more broad security requirements either.

The comparison presented below is based on product requirement categories presented in the article "Common cybersecurity requirements in IoT standards, best practices, and guidelines" [28]. All in all, the coverage provided by the two security requirement collections is different with PECAN being much narrower. PECAN has 81 unique requirements in seven category groups and Digi-HTA 241 requirements in 23 groups.

Cybersecurity requirements of the Digi-HTA and PECAN processes by category groups are presented in Table 1.

It is important to understand that the comparison concerns the *categories* of security requirements and not the detailed content of the requirements themselves. For example, whether there are security requirements for *Interface Security* or *Authentication*. Even within a category, the practical requirements may be quite different. This is unfortunate, but as there is no consensus on the best way to implement cybersecurity, the requirements vary between standards.

Table 1. Cybersecurity requirements of the Digi-HTA and PECAN processes by category groups

	Vendor security	Policies & laws	Development process	Security requirements	Security design	Security standards	Secure programming	Delivery & deployment	Administration	Interface security	Authentication	Access control	Security hardware	Backend security	Cryptography	Data protection	Service availability	Failure security	Audit logging	Intrustion detection	Indicdent response	Vulnerability management	System updates	User communication	Usability of security
Digi-HTA	5	5	12	4	12	3	5	8	11	14	3	1	2	7	19	1		2	5	3	4	8	3	2	
PECAN		4			1					10	1				5			1						1	
				Process requirements			Product requirements																		

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