



The Nordic Interoperability Project

Making Cross Border Patient & Health Data Mobility The Nordic Reality!

“A little less conversation,
a little more action, please!”



SHARING AND USING HEALTH DATA – THE NORDIC REALITY!

HIMSS Nordic Workshop in Sitges
May 2018

The starting point

- A much-discussed topic
- But little action
- Let's make something happen!

A strong team of
partners and
supporters.

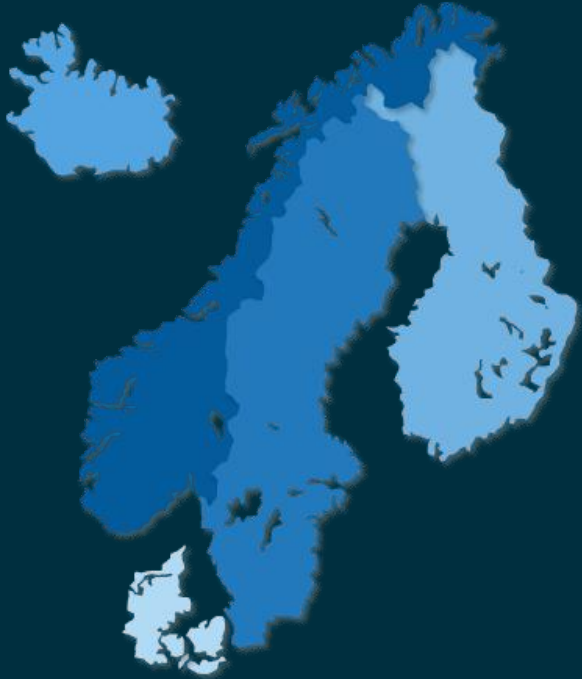


Nordic Interoperability Project



We support the ambition set by the Nordic Council of Ministers!

“In 2030 the Nordics will be the **most sustainable and integrated health region** in the world, providing the **best possible personalized health care** for all its citizens.”

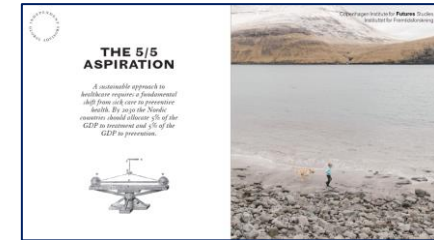
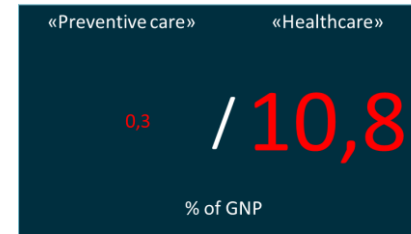


Why is this ambition so important?

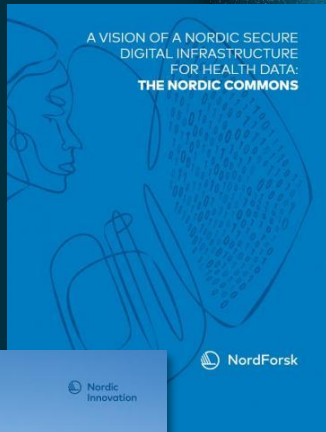
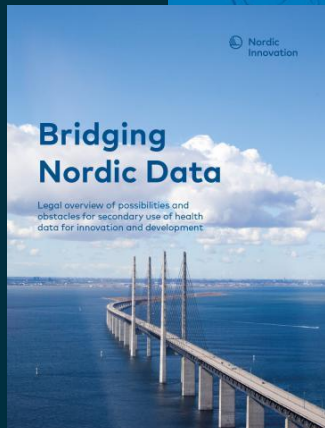
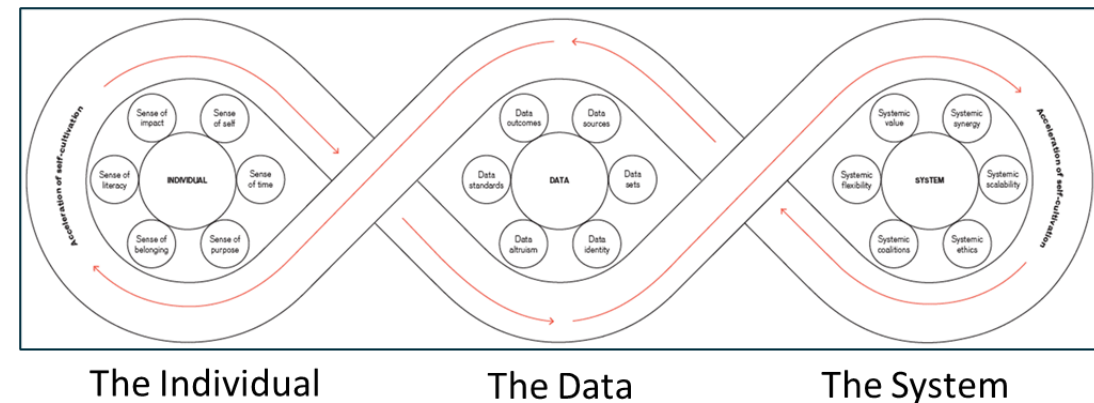
- Building a better and safer everyday life for the Nordic citizen/patient
- Building a bigger Nordic home market for the Nordic healthcare industry
- Building a Nordic market for the international healthcare industry
- Building a simplified access to health data for research and innovation

Nordic Health 2030

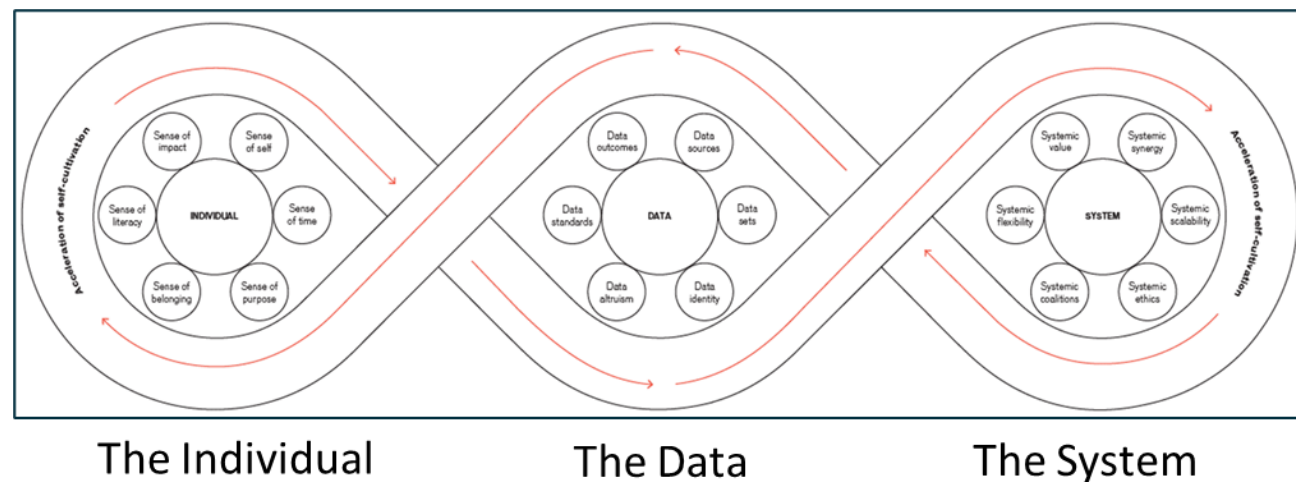
- The Nordic Healthcare system is not sustainable!
- Too much focus on “sick care”, too little on “preventive care”!
 - 10,3% of GDP on healthcare, 0,3% of GDP on preventive care.



- A shift is needed towards more balance, hence “the 5/5 Aspiration”.
- We need a different way of thinking and a different way of working:
 - We need *a new social contract with the individual.*
 - We need *new ways of sharing data.*
 - We need *new business models also rewarding preventative care.*
- Sharing of data between “the individual” and “the system” is key.



N!P Platform thinking:
Creating enablers for
innovation and business
development.



System
focus:



Nordic Patient Data Lake

Individual
& System
focus:



Nordic Digital Health & Medication Platform

Individual
& System
focus:



Nordic Health Passport



THE DIGITAL HEALTH POTENTIAL

With over **375,000** health & fitness related apps currently on app stores & **5 MILLION** downloads per day it is difficult to deny the rising popularity of the industry

The challenge in the Nordics:

- **No guidance** to help separating the good from the bad!
- A **wasted resource** in the healthcare ecosystem!



The Digital Health Challenge

Uptake issues in key populations.

To unleash the power of
digital health:

- Awareness
- Accessibility
- Trust
- Governance

To unleash the power of digital health:

5 steps to Digital Health Adoption & Integration

Assessment & Accreditation

- Create or Adapt an accreditation or endorsement approach to screen and filter digital health solutions for compliance with key standards & to establish safety & efficacy
- Facilitate Micro-Assessment processes at a local level

Promotion & Dissemination

- Establish a dissemination and activation strategy and approach to promote the adoption of these products in your target population and communities
- Leverage existing assets to drive self management & prevention agenda's

Professional Activation

- Build a professional focussed activation strategy to support professionals to embed digital health into day to day practice
- Create systems & processes that mimic existing formularies & decision support tools
- Provide suitable support & training

Pathway Integration

- Build digital tools into common/key care/condition pathways to ensure integration becomes embedded in existing health and care delivery models
- Use this as a sustainable way to develop and populate formularies and support professional engagement and activation

Financing & Prescribing

- Create a suitable commercial framework and process to manage the "prescribing" of selected digital health tools to ensure sustainability and growth
- Establish end user neutral prescribing solutions
- Create common ROI evaluation tools as part of the assessment process

In partnership with:



The digital health
opportunity:



The Core Essence:

“Unlocking the power of digital health is not about a standard. It’s about a system!”

“Evaluation & Activation!”



Nordic Digital Health & Medication Platform

Accreditation and dissemination of health apps in the Nordics.

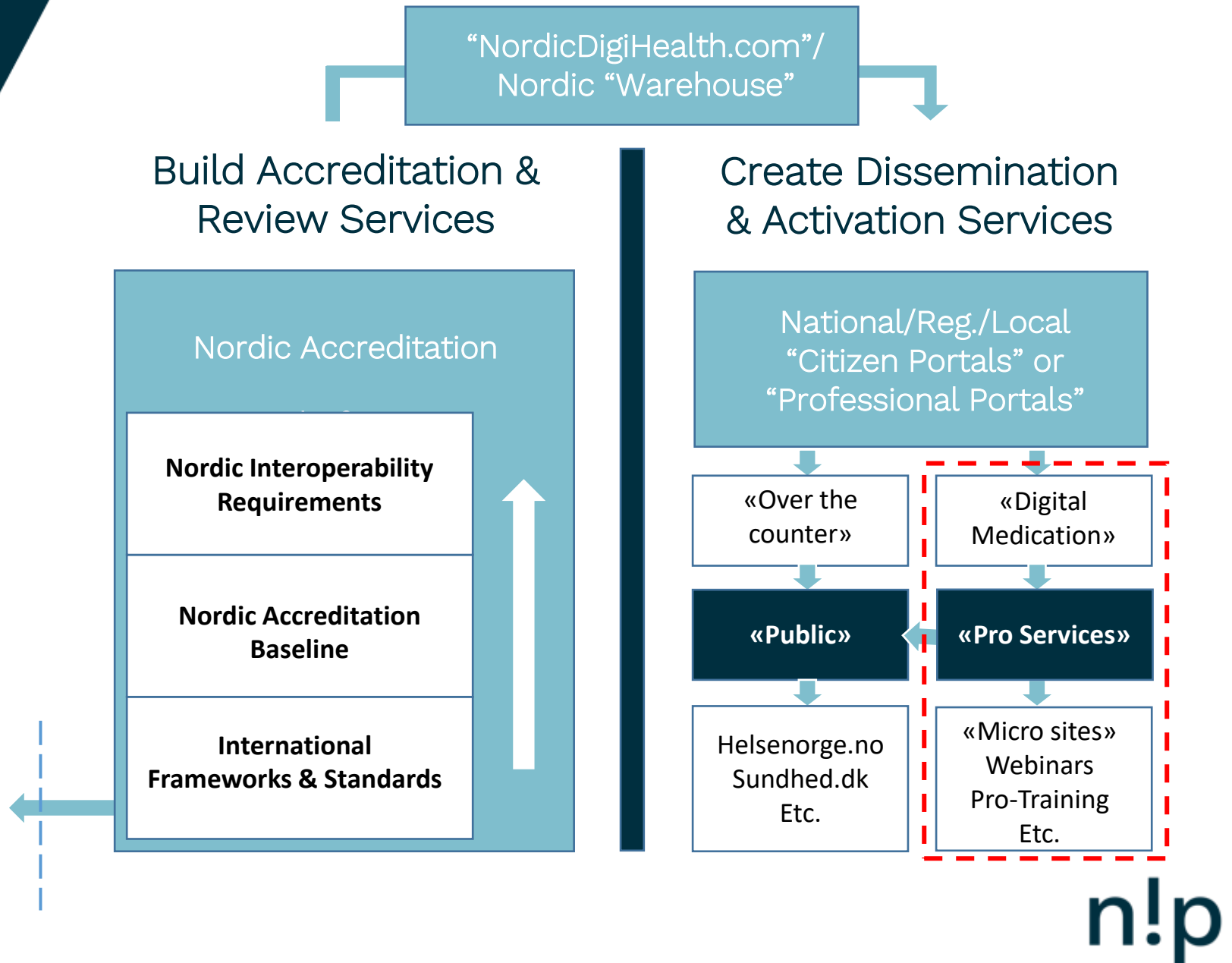
Regulating an unregulated market to assist the citizens & health ecosystem, and build a one common Nordic home market for the health app industry.

Building a Nordic ecosystem:

Nordic Digital Health & Medication Platform

“NordicDigiHealth.com”

NHS/UK,
Germany,
Holland,
Israel, NZ,
Australia...



The emerging Nordic Baseline Review:

Scene Setters - Functional and Use case Analysis



Data & Privacy



Fully aligned with ISO-82304-2 and GDPR



Professional backing



Discussion over 'suitably qualified' professional/organisation



Clinical/Medical Regulation



Aligned with MDD/MDR



Evidence of Effectiveness



Discussion around the use of the Adapted Evidence Standards Framework



Clinical Safety



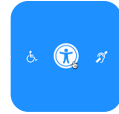
Clinical Assessment in scope, Clinical Risk management still being discussed



Security & Technical Stability



In scope, but the principles of the Security Matrix being discussed



Usability & Accessibility



Aligned with core standards



User Experience

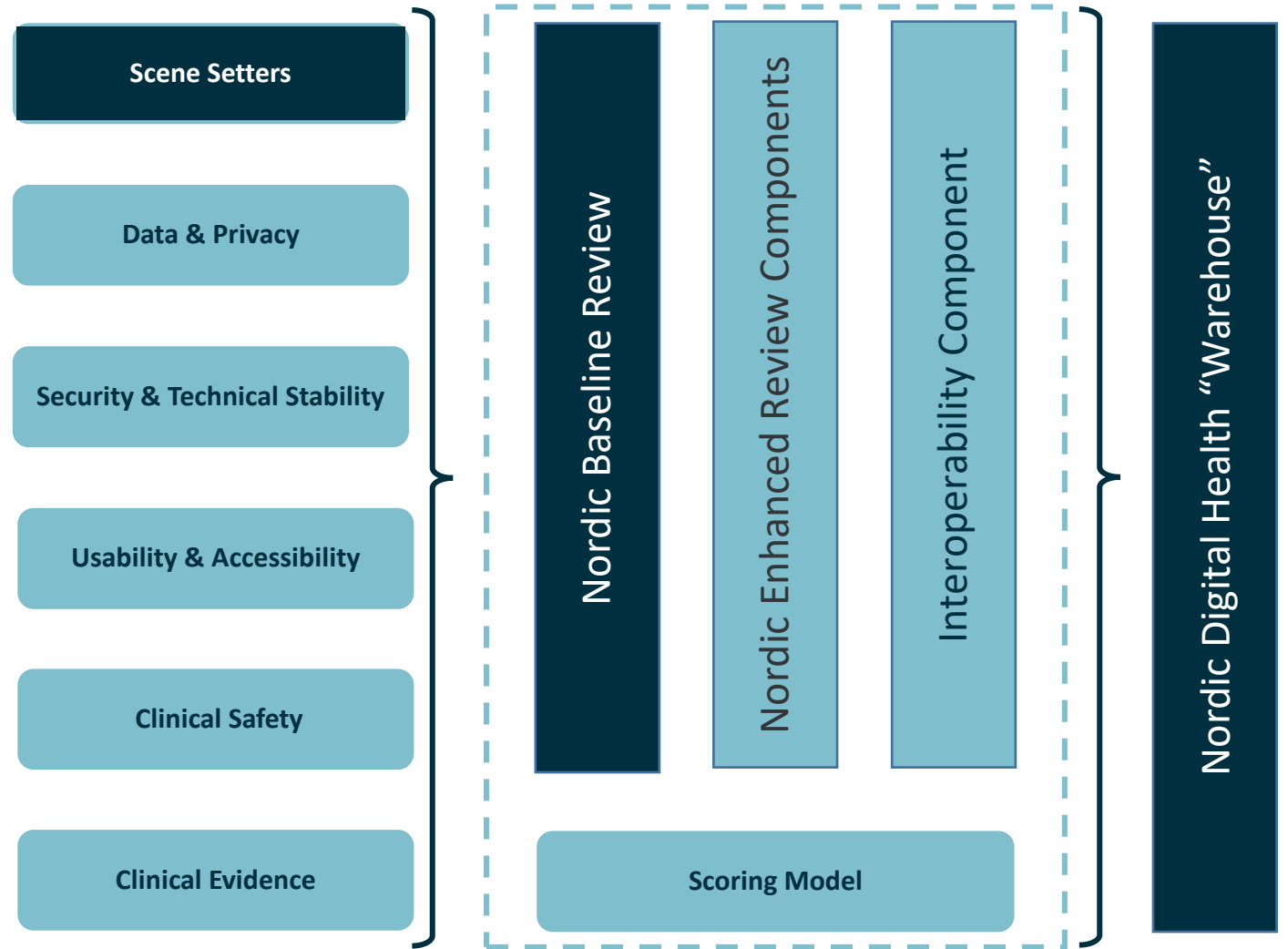


Range of UX assessment options being considered

Baseline Assessment

Interoperability Layer

The emerging Nordic Assessment Set Up:



The emerging Nordic Accreditation Set Up:

Nordic (Digital Health) Baseline

confluence.external-share.com/content/65d17ee6-7945-4e0e-b8fa-946264f94a2a

DATA & PRIVACY

Privacy Policy

Initially, the review identifies the relevant privacy policy for the app, which is available to users through the app and/or the App Store or Play Store. The more transparent the privacy policy, the better. Ultimately, the privacy policy must clearly identify:

- what data is collected from the user and
- if the user is informed of the developer's data collection practices
- if the user's consent is obtained.

The privacy policy should accurately reflect the data collection practices. The review considers if the user is able to opt out of data collection.

Question
Is there a Privacy Policy clearly available via the Web?
Is there a Privacy Summary published anywhere by the developer?
Is the Privacy Policy made immediately available via the app?
Is the policy made available when the user is signing up?
Is it published within the app?
Is it available externally via the app, or via a linked website?
Is it available via the relevant app store?
What data does the Privacy Policy state the developer collects?
Is the policy accurate, with regards to the data the app collects?
Does the app state that data collected by the app is shared with third parties?

SECURITY & TECHNICAL STABILITY

Technical Stability

Question	Answer Type	ORCHA Question Reference Source	Framework
Does the App connect to an internet-based service?	Yes/No	ORCA_MD11	OBR
List the APIs	Free Text	ORCA_MD11	OBR
Does the App connect to a medical device?	Yes/No	ORCA_MD11	OBR
Does the App connect to NHS Services (e.g. NHS App)?	Yes/No	ORCA_MD11	OBR
Does the App operate without wi-fi?	Yes/No	ORCA_MD11	OBR
Does the App operate without cellular network?	Yes/No	ORCA_MD11	OBR
Is the platform Web based or Mobile?	Yes/No	ORCA_MD11	OBR
Does the App access, process or store Personal Data?	Yes/No	ORCA_MD11	OBR
Is sensitive data persisted to the mobile device?	Yes/No	ORCA_MD11	OBR
Does the App access, process or store Personal Data?	Yes/No	ORCA_MD11	OBR
What Permissions does the App request?	Free Text	ORCA_MD11	OBR
Does the App provide Alerts or Notifications?	Yes/No	ORCA_MD11	OBR
Does the App provide Suggestions?	Yes/No	ORCA_MD11	OBR
Does the App undertake calculations?	Yes/No	ORCA_MD11	OBR
Are the source code and any configuration files available?	Yes/No	ORCA_MD11	OBR
Provide details of any associated processes.	Free Text	ORCA_MD11	OBR
Do you have the capacity to rollback to a previous version?	Yes/No	ORCA_MD11	OBR

CLINICAL SAFETY

Medical Devices

It is proposed that the NORDIC Assessment assess if the app is likely to be a medical device under the current guidance from the MDR (https://ec.europa.eu/growth/sectors/medical-devices_en). We then evaluate if the app displays the relevant CE mark.

Question	Answer Type	ORCHA Question Reference Source	Framework
Is the app a medical device?	Yes/No	ORCA_MD11	OBR
Does the app have a CE mark?	Yes/No	ORCA_MD11	OBR
Does the app state that it has been assessed by the MHRA or other relevant body, and does not require a CE mark?	Yes/No	ORCA_MD11	OBR
What class is the app certified as?	Free Text	ORCA_MD11	OBR
Has the app been FDA approved? (Food and Drug Administration)	Yes/No	ORCA_MD11	OBR
Has the app been FDA cleared?	Yes/No	ORCA_MD11	OBR

Safety/Risk Management

It is proposed that the assessment looks for any safeguarding measures in communication functions of the app, if relevant.

Question	Answer Type	ORCHA Question Reference Source	Framework
Is there a statement or any evidence showing that appropriate safeguarding measures are in place around peer-support and other communication functions within the platform? (Tier 2a requirement Only asked of apps that require such measures because of its functional capabilities / intended purpose)	Yes/No	ORCA_MD13	OBR
Does the Developer clearly identify who the app should and should not be used by?	Yes/No	ORCA_S01	OBR
Does the Developer publish their risk management processes?	Yes/No	ORCA_S02	OBR

Nordic Innovation

n!p



N!P “Warehouse”:

- Accessibility
- Categorization
- Governance

n!p WAREHOUSE

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Your Health App Finder

We've reviewed thousands of apps, so you can find the best.

Search by condition or keyword...

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☐ Prioritise COVID-19 Support Apps

View Filters

Top rated

Mental Health

See Apps

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Search and recommend the best apps

Diabetes Insipidus

Categories Features/Functions Age Country Cost Platform

Search results for 'Mental Health'

231 results

Sleep by Wysa - sleep stories for deep sleep

Apple iOS Cost: In App Purchases

Description Lvl 3 85%

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N!P “Warehouse”:

- App Info Cards

**my mhealth**
Developer: my mhealth Limited

Apple iOS
In-App Purchases

Version: 1.8.8
Reviewed on: 04/09/2018

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Level 4 

Developer description:

It was assessed as a Level 4 App. These Apps can be focused on general health or specific conditions and contain advanced and complex features that are subject to formal regulation. Where they collect data we assess their data use policies and compliance with relevant standards. Because they are health focused we also assess their compliance in the Clinical Assurance as well as the User Experience domains.

[Show more](#)

App Details:

Categories:

[Asthma](#) [Chest Infection](#) [COPD](#) [Angina](#)

[Diabetes](#) [Type-1 Diabetes](#) [Heart Attack](#)

[Type-2 Diabetes](#) [Heart Failure](#)

Summary

It was assessed as a Level 2 App. These apps are focused on general health. They may collect data and they may have a number of more advanced features. Where they collect data we assess their data use policies and compliance with relevant standards. Because they are health focused we also assess their compliance in the Clinical Effectiveness as well as the User Experience domains.

Data	91.6%	View Details
Professional Assurance	91.6%	View Details
Clinical Assessment	91.6%	View Details
Clinical Risk & Safety	91.6%	View Details
Usability & Accessibility	91.6%	View Details
Security & Technical Stability	91.6%	View Details

“Must wins” for a Nordic wide solution:

1. Addressing both **individuals** & **professionals**
2. **Common evaluation criteria** across the region (The Nordic Baseline & Extended Review) with local flexibility
3. **Flexible delivery model** for the operative evaluation process (centralized/decentralized), but based on the common evaluation criteria
4. **Common Nordic “storage & distribution” for approved solutions** for easy governance and Nordic wide accessibility (NordicDigiHealth.com)

Helping & challenging the Nordics to be the most
integrated health region in the world by 2030!
