



Simple Guide for the Manufacture of Digital Health Interventions

Essential Standards

Introduction

The role of a manufacturer is complex and the standards and regulations can be difficult to navigate. Here we have signposted the main areas we need to be mindful of when developing technologies within the health industry.

The Essentials

This link is the latest list of harmonised standards for medical devices. Health software is not separately listed from other mainstream device standards.

[*EU list of harmonised standards*](#)

We have also provided links to the MHRA and FDA websites where guidance specifically for digital health resides, including the steps you need to take to become compliant.

[*MHRA guidance for software \(apps\)*](#)

[*FDA guidance for Digital Health*](#)

The principles of the NHS Digital, data and technology standards framework:

To determine that the right standards are used across the health and care system, the principles listed below have been applied.

- These standards are open standards
- These standards address the user-needs of patients and care professionals
- We have a clear evidence base of these standards being useful, usable and used
- We have considered how these standards apply across health and care

Link to the standards:

[*Principles of the NHS digital, data and technology standards framework*](#)

They are based on international standards and only specialised where it is necessary for them to be adopted. An example of this would be using the NHS Number as the primary identifier.

NICE Guidance

The National Institute for Health and Care Excellence (NICE) framework makes it easier for innovators and commissioners to understand what good levels of evidence for digital healthcare technologies look like from NICE perspective. Digital healthcare technologies must also meet the needs of the health and care system, patients, and users.

Links to Guidance

[Evidence standards framework for digital health technologies](#)

Security standards and sources for guidance:

[Data security knowledge library](#)

[National Cyber Security Centre](#)

Identity Verification and Authentication Standard for Digital Health and Care Services:

[Authentication Standards](#)

It is worth highlighting a recent publication by a renowned research organisation, funded by industry/corporate sponsorships (REFORM), that focusses on the data driven digital health regulatory landscape. It is interesting to read this document as it provides a summary of guidance and standards-based information used by manufacturers, regulators and commissioners in this sector.

[Data-driven healthcare: regulation & regulators](#)

We hope this information is useful and provides a light touch overview of where you should look for guidance when manufacturing health related digital innovations.

For more information about ETHOS safety and innovation work please find us on:



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