Advice on overlaps between the evidence standards framework and medical device regulations for companies with digital health technologies that are also medical devices

|  |  |
| --- | --- |
| **Work package reference** | RX216 phase 1 |
| **Work package name** | Overlap between the medical device regulations and the evidence standards framework |
| **Produced by** | Newcastle upon Tyne Hospitals NHS Foundation Trust External Assessment Centre (EAC) |
| **Main authors** | Ina Guri, Alison Bray, Michael Drinnan, Northern Medical Physics and Clinical Engineering, The Newcastle upon Tyne Hospitals NHS Foundation Trust |
| **Correspondence to** | Alison Bray, [abray3@nhs.net](mailto:abray3@nhs.net) |
| **Publication date** | 23 October 2020 |

Advice on overlaps between the evidence standards framework and medical device regulations for companies with digital health technologies that are also medical devices

**Contents**

[Purpose 2](#_Toc54362492)

[Mapping ESF tiers and MDR classes for DHTs 3](#_Toc54362493)

[NICE ESF Standards and MDR documentation requirements 4](#_Toc54362494)

[Tier B: understanding and communicating 4](#_Toc54362495)

[Tier C: interventions 16](#_Toc54362496)

[Conclusions 30](#_Toc54362497)

[Acknowledgements 30](#_Toc54362498)

[References 30](#_Toc54362499)

# Purpose

NICE has developed an evidence standards framework (ESF) [1] for digital health technologies (DHTs) which defines minimum evidence and best practice standards for DHTs. The NICE ESF is a set of evidence standards which have been developed to help technology developers collect the appropriate evidence to demonstrate clinical effectiveness and economic impact. They aim to promote consistency in the way DHTs are assessed across the NHS by health technology assessment (HTA) organisations and commissioners.

In the UK, medical devices are currently governed by EU law according to the 1993 EU Medical Device Directive (‘MDD’) [2]. Updated legislation, the 2017 EU Regulation on Medical Devices (‘MDR’) [3], entered into force on 25 May 2017, set to replace the MDD according to a transition timetable. The original timetable was for the MDR to fully apply from 26 May 2020 after a 3 year transition period, with a derogation period for some Class I devices under the MDD, including software, to 26 May 2024 [4]. The legislation outlines the technical documentation required for compliance, with the MDR emphasising safety and performance and clarifying the requirements for software that is a medical device compared to the MDD.

In April 2020, a postponement to the full application date of the MDR until 26 May 2021, due to the COVID-19 pandemic, passed through EU parliament. Given that this new date exceeds that when the UK’s legislative-alignment with the EU (transition period) will end (31 December 2020), the MDR will apply in Northern Ireland, but not in the rest of the UK (Great Britain). It was announced on 1 September 2020 [5] that the rest of the UK will continue to be governed by the 2002 UK Medical Device Regulation (the UK implementation of the 1993 EU MDD) from 1st January 2021. Devices placed on the market in Great Britain will require a UK Conformity Assessed (UKCA) mark, with CE marks being recognised until 30 June 2023. The MHRA are currently considering how best to align UK law with regulation in other European counties.

The purpose of this document is to give an overview of the overlap between the 2017 EU Medical Device Regulation (MDR) for software and the NICE evidence standards framework (ESF) for digital health technologies (DHTs), to help developers of DHTs that meet the definition of a medical device to better understand how the information required for the MDR and their CE marking is linked to the evidence levels described in the ESF. The 2017 EU Regulation on In Vitro Diagnostic Medical Devices (IVDR) [6] is out of scope for this work.

# Mapping ESF tiers and MDR classes for DHTs

Medical devices are classified according to risk by Annex VIII of the MDR into one of the following classes: I, IIa, IIb or III. Class IIa, IIb and III devices always require the involvement of a notified body to assess compliance. Some class I devices also require notified body involvement to assess certain aspects (measuring functions, sterility, reusable surgical instruments). In the ESF, DHTs are classified by function and stratified into the following evidence tiers: A (system impact), B (understanding and communicating), C (interventions). The evidence level needed for each tier is proportionate to the potential risk to users presented by the DHTs in that tier. The ESF can apply to DHTs that are not classified as medical devices under the MDR. Table 1 shows the alignment between ESF tiers and MDR classes.

Table : Alignment between ESF tiers and functional classification and MDR classes for DHTs. It is the responsibility of the developer to check whether the DHT is a medical device under the MDR.

| **Tier** | **Functional classification** | **Likelihood of DHT being a medical device** |
| --- | --- | --- |
| **Tier A: system impact**: DHTs with potential system benefits but no direct user benefits | System service | CE-marked medical devices excluded  Not classed as medical devices under the MDR |
| **Tier B: understanding and communicating**: DHTs which help users to understand healthy living and illnesses but are unlikely to have measurable user outcomes | Inform | May be classed as medical devices under the MDR |
| **Tier B: understanding and communicating** | Health diaries | May be classed as medical devices under the MDR |
| **Tier B: understanding and communicating** | Communicate | May be classed as medical devices under the MDR |
| **Tier C: interventions**: DHTs for preventing, diagnosing and managing diseases. They may be used alongside treatment and will likely have measurable user benefits | Preventative behaviour change | Likely to be classed as medical devices under the MDR |
| **Tier C: interventions** | Self-manage | Likely to be classed as medical devices under the MDR |
| **Tier C: interventions** | Treat | Highly likely to be classed as medical devices under the MDR |
| **Tier C: interventions** | Active monitoring | Highly likely to be classed as medical devices under the MDR |
| **Tier C: interventions** | Calculate | Highly likely to be classed as medical devices under the MDR |
| **Tier C: interventions** | Diagnose | Highly likely to be classed as medical devices under the MDR |

# NICE ESF standards and MDR documentation requirements

Tables 2-5 show the evidence standards from the ESF and the recommended MDR documents that technology developers may use to meet the ESF criteria for Tier B: understanding and communicating DHTs and Tier C: intervention DHTs[[1]](#footnote-2). Some ESF criteria are not explicitly MDR requirements, although they are likely to feed into the evidence for the technical file. Best practice evidence standards should be used for DHTs that present a potential high risk, as determined by the contextual questions in the ESF document [1].

The MDR best practice guidelines [7] from the British Standards Institution (BSI) give some background about the MDR documentation requirements with links to further information.

## Tier B: understanding and communicating

DHTs which help users to understand healthy living and illnesses but are unlikely to have measurable user outcomes.

**Inform** e.g. DHTs describing a condition and its treatment, apps providing advice for healthy lifestyles (such as recipes), apps that signpost to other services.

**Health diaries** e.g. health tracking information such as from fitness wearables, and symptom or mood diaries.

**Communicate** e.g. instant messaging apps for health and social care, video conference-style consultation software, and platforms for communication with carers or professionals.

**Tier B: understanding and communication** DHTs may be classified as medical devices under MDR.

Table : Tier B: understanding and communicating - Minimum evidence standards

| **Evidence category** | **ESF minimum evidence standard** | **Is this an MDR requirement?** | **Aligned MDR documentation and section** |
| --- | --- | --- | --- |
| Reliable information content | Be able to show that any health information provided by the DHT is valid (aligned to best available sources, such as NICE guidance, relevant professional organisations or recognised UK patient organisations, and appropriate for the target population) | Yes  No explicit requirement to use UK sources, but all claims by the device manufacturer need to be verified/validated. The way in which to verify/ validate is not specified | General safety and performance requirements checklist  Annex I  Validation and verification reports  Annex II (6) |
| Reliable information content | Be able to show that any health information provided by the DHT is accurate | Yes | General safety and performance requirements checklist  Annex I (15)  Validation and verification reports  Annex II (6)  Clinical investigation/evaluation reports  Annex XIV (A)  Annex XV |
| Reliable information content | Be able to show that any health information provided by the DHT is up to date | Yes | Post-market surveillance reports  Article 85  Annex III  Annex XIV (B)  Periodic safety update report  Article 86  Annex III |
| Reliable information content | Be able to show that any health information provided by the DHT is reviewed and updated by relevant experts at defined intervals, such as every year | Yes | Post-market surveillance reports  Article 85  Annex III  Annex XIV (B)  Periodic safety update report  Article 86  Annex III |
| Reliable information content | Be able to show that any health information provided by the DHT is sufficiently comprehensive | Yes  The DHT needs to perform as claimed | General safety and performance requirements  Annex I  Instructions for use  Annex I (Chapter III)  Validation and verification reports  Annex II (6) |
| Ongoing data collection to show usage of the DHT | Commitment to ongoing data collection to show usage of the DHT in the target population | Yes | Post-market surveillance reports  Article 85  Annex III  Annex XIV (B)  Periodic safety update report  Article 86  Annex III |
| Ongoing data collection to show usage of the DHT | Commitment to share, when available, with relevant decision-makers such as commissioners in a clear and useful format | No  While it is a requirement for ongoing data collection, it is not a requirement to report this to commissioners unless triggering specific vigilance reports | Post-market surveillance reports  Article 85  Annex III  Annex XIV (B)  Periodic safety update report  Article 86  Annex III  Vigilance reporting  Chapter VII (Section 2) |
| Ongoing data collection to show value of the DHT | Commitment to ongoing data collection to show user outcomes (if relevant) or user satisfaction (using non-patient identifiable information) to show ongoing value | Yes | Post-market surveillance reports  Article 85  Annex III  Annex XIV (B)  Periodic safety update report  Article 86  Annex III |
| Ongoing data collection to show value of the DHT | Commitment to share, when available, user outcomes (if relevant) or user satisfaction (using non-patient identifiable information), with relevant decision-makers such as commissioners in a clear and useful format | No  While there is a requirement for ongoing data collection, it is not a requirement to report this to commissioners unless triggering specific vigilance reports | Post-market surveillance reports  Article 85  Annex III  Annex XIV (B)  Periodic safety update report  Article 86  Annex III  Vigilance reporting  Chapter VII (Section 2) |
| Quality and safeguarding | Show that appropriate safeguarding measures are in place around peer-support and other communication functions within the platform | Yes | General safety and performance requirements  Annex I  Vigilance reporting  Chapter VII (Section 2) |
| Quality and safeguarding | Describe who has access to the platform and their roles within the platform. Describe why these people or groups are suitable and qualified to have access | Yes | Risk management  Annex I (3) |
| Quality and safeguarding | Describe any measures in place to ensure safety in peer-to-peer communication, for example through user agreements or moderation | Yes | Post-market surveillance reports  Article 85  Annex III  Annex XIV (B) |
| Credibility with UK health and social care professionals | Show that the DHT has a plausible mode of action that is viewed as useful and relevant by professional experts or expert groups in the relevant field | Not explicitly, but likely to feed into establishing and validating user requirements | Instructions for use  Annex I (Chapter III)  Validation and verification reports  Annex II (6) |
| Credibility with UK health and social care professionals | Show that relevant clinical or social care professionals working within the UK health and social care system have been involved in the design, development or testing of the DHT  or  Show that relevant clinical or social care professionals working within the UK health and social care system have been involved in signing-off the DHT, indicating their informed approval of the DHT | Although there are no explicit requirements for health and social professional involvement (UK or otherwise), heath or social care professionals are likely to feed into establishing and validating user requirements  Similarly, this would form part of design and development work | Validation and verification reports  Annex II (6)  Clinical investigation/evaluation reports  Annex XIV (A)  Validation and verification reports  Annex II (6) |
| Relevance to current care pathways in the UK health and social care system | Evidence to show that the DHT has been successfully piloted in the UK health and social care system, showing that it is relevant to current care pathways and service provision in the UK | Yes  Although there are no explicit requirements for health and social professional involvement (UK or otherwise), heath or social care professionals are likely to feed into device validation and clinical evaluation | General safety and performance requirements  Annex I  Validation and verification reports  Annex II (6)  Clinical investigation/evaluation reports  Annex XIV (A) |
| Relevance to current care pathways in the UK health and social care system | Evidence that the DHT is able to perform its intended function to the scale needed (for example, having servers that can scale to manage the expected number of users) | Yes  Devices must meet the relevant safety and performance requirements | General safety and performance requirements - General requirements  Annex I (Chapter I)  Validation and verification reports  Annex II (6)  Clinical investigation/evaluation reports  Annex XIV (A)  Annex XV  Post-market surveillance reports  Article 85  Annex III  Annex XIV (B) |
| Acceptability with users | Be able to show that representatives from relevant user groups were involved in the design, development or testing of the DHT | Not an MDR requirement for representation from user groups but must give consideration to the use environment | General safety and performance requirements  Annex I (5)  Validation and verification reports  Annex II (6) |
| Acceptability with users | Provide data to show user satisfaction with the DHT | Yes | Validation and verification reports  Annex II (6)  Clinical investigation/evaluation reports  Annex XIV (A)  Annex XV  Post-market surveillance reports and post-market clinical follow-up  Article 85/86  Annex III  Annex XIV (B) |
| Equalities considerations | If relevant, the DHT should contribute to challenging health inequalities in the UK health and social care system, or improving access to care among hard-to-reach populations | Not explicitly, but may feed into establishing and validating user requirements, clinical evaluation and post-market surveillance | Validation and verification reports  Annex II (6)  Clinical investigation/evaluation reports  Annex XIV (A)  Annex XV  Post-market surveillance reports and post-market clinical follow-up  Article 85  Annex III  Annex XIV (B) |
| Equalities considerations | If relevant, the DHT should contribute to promoting equality, eliminating unlawful discrimination and fostering good relations between people with protected characteristics (as described in the 2010 Equalities Act) and others | Not explicitly, but may feed into establishing and validating user requirements, clinical evaluation and post-market surveillance | Validation and verification reports  Annex II (6)  Clinical investigation/evaluation reports  Annex XIV (A)  Annex XV  Post-market surveillance reports  Article 85  Annex III  Annex XIV (B) |
| Accurate and reliable measurements (if relevant) | Data or analysis which shows that the data generated or recorded by the DHT is accurate, reproducible and relevant to the range of values expected in the target population  Data showing that the DHT is able to detect clinically relevant changes or responses | Yes  Devices must meet the relevant safety and performance requirements | General safety and performance requirements  Annex I (particularly 15)  Validation and verification reports  Annex II (6)  Clinical investigation/evaluation reports  Annex XIV (A)  Annex XV  Summary of safety and clinical performance (class III)  Article 32 |
| Accurate and reliable transmission of data (if relevant) | Technical data showing that numerical, text, audio, image-based, graphic-based or video information is not changed during the transmission process  Technical data showing that numerical, text, audio, image-based, graphic-based or video information is not biased by the data ‘value’ expected from the target patient population. | Yes  Devices must meet the relevant safety and performance requirements | General safety and performance requirements  Annex I (particularly 15)  Validation and verification reports  Annex II (6)  Clinical investigation/evaluation reports  Annex XIV (A)  Annex XV  Summary of safety and clinical performance (class III)  Article 32 |

Table 3: Tier B: understanding and communicating - Best practice standards

| **Evidence category** | **ESF best practice standard** | **Is this an MDR requirement?** | **Aligned MDR documentation and section** |
| --- | --- | --- | --- |
| Reliable information content | Evidence of endorsement, accreditation or recommendation by NICE, NHS England, a relevant professional body or recognised UK patient organisation or | No  Endorsement is not a requirement | Validation and verification reports  Annex II (6) |
| Reliable information content | Evidence that the information content has been validated though an independent accreditation such as The Information Standard or HONcode certification | Not explicitly, but likely to feed into device validation and clinical evaluation | Validation and verification reports  Annex II (6) |
| Ongoing data collection to show usage of the DHT | Evidence that data on usage is being collected in line with the minimum standards and can be made available to relevant decision-makers | Yes  While it is a requirement for ongoing data collection, it is not a requirement to report this to relevant commissioners, but will be reviewed by notified bodies as part of compliance | Post-market surveillance reports  Article 85  Annex III  Annex XIV (B)  Periodic safety update report  Article 86  Annex III |
| Ongoing data collection to show value of the DHT | Evidence that data on outcomes or user satisfaction is being collected in line with the minimum standard and can be made available to relevant decision-makers | Yes  While it is a requirement for ongoing data collection, it is not a requirement to report this to relevant commissioners, but will be reviewed by notified bodies as part of compliance | Post-market surveillance reports  Article 85  Annex III  Annex XIV (B)  Periodic safety update report  Article 86  Annex III |
| Credibility with UK health and social care professionals | Show that the DHT has a plausible mode of action that is viewed as useful and relevant by professional experts or expert groups in the relevant field | Not explicitly, but likely to feed into establishing and validating user requirements | Instructions for use  Annex I (Chapter III)  Validation and verification reports  Annex II (6) |
| Credibility with UK health and social care professionals | Published or publicly available evidence documenting the role of relevant UK health or social care experts in the design, development, testing or sign-off of the DHT  Published or publicly available evidence documenting the role of relevant UK health or social care experts in signing-off the DHT, indicating their informed approval of the DHT | No  Although there are no explicit requirements for health and social professional involvement (UK or otherwise), heath or social care professionals are likely to feed into establishing and validating user requirements  It is not a requirement for this information to be published or publicly available | Validation and verification reports  Annex II (6)  Clinical investigation/evaluation reports  Annex XIV (A)  Annex XV |
| Relevance to current care pathways in the UK health and social care system | Evidence to show successful implementation of the DHT in the UK health and social care system | No explicit requirement for successful implementation in the health and social care system (UK or otherwise), but likely to be covered by validation, clinical evaluation, clinical investigation if applicable, and post-market surveillance | Validation and verification reports  Annex II (6)  Clinical investigation/evaluation reports  Annex XIV (A)  Annex XV  Post-market surveillance reports  Article 85  Annex III  Annex XIV (B) |
| Acceptability with users | Published or publicly available evidence to show that representatives from relevant user groups were involved in the design, development or testing of the DHT | No  It is not a requirement for this information to be published or publicly available | Validation and verification reports  Annex II (6) |
| Acceptability with users | Published or publicly available evidence to show that users are satisfied with the DHT | No  It is not a requirement for this information to be published or publicly available | Validation and verification reports  Annex II (6)  Clinical investigation/evaluation reports  Annex XIV (A)  Annex XV  Post-market surveillance reports  Article 85  Annex III  Annex XIV (B) |
| Equalities considerations | Show evidence of the DHT being used in hard-to-reach populations | Not explicitly, but may feed into establishing and validating user requirements | Validation and verification reports  Annex II (6)  Clinical investigation/evaluation reports  Annex XIV (A)  Annex XV  Post market surveillance reports  Article 85  Annex III  Annex XIV (B) |
| Accurate and reliable measurements (if relevant) | Quantitative data or analysis which shows that the data generated or recorded by the DHT is accurate, reproducible and relevant to the range of values expected in the target population  Quantitative data showing that the DHT is able to detect clinically relevant changes or responses | Yes  Devices must meet the relevant safety and performance requirements | General safety and performance requirements  Annex I (particularly 15)  Validation and verification reports  Annex II (6)  Clinical investigation/evaluation reports  Annex XIV (A)  Annex XV  Summary of safety and clinical performance (class III)  Article 32 |
| Accurate and reliable transmission of data (if relevant) | Technical data showing that numerical, text, audio, image-based, graphic-based or video information is not changed during the transmission process  Quantitative data showing that numerical, text, audio, image-based, graphic-based or video information is not biased by the data ‘value’ expected from the target patient population | Yes  Devices must meet the relevant safety and performance requirements | General safety and performance requirements checklist  Annex I  Validation and verification reports  Annex II (6)  Clinical investigation/evaluation reports  Annex XIV (A)  Annex XV  Summary of safety and clinical performance (class III)  Article 32 |

## Tier C: interventions

DHTs for preventing, diagnosing and managing diseases. They may be used alongside treatment and will likely have measurable user benefits.

**Preventative behaviour change** e.g. smoking cessation DHTs and those used as part of weight loss programmes, and DHTs marketed as aids to good sleep habits.

**Self-manage** e.g. DHTs that allow users to record, and optionally to send, data to a healthcare professional to improve management of their condition.

**Treat** e.g. DHTs for treating mental health or other conditions, clinician-facing apps that advise on treatments in certain situations and electronic prescribing systems that provide patient-level advice on prescribing.

**Active monitoring** e.g. DHTs linked to devices such as implants, sensors worn on the body or sited in the home or care setting, where data are automatically transmitted through the DHT for remote monitoring. Includes ward-based systems for monitoring and recording patient observations.

**Calculate** e.g. DHTs for use by clinicians, professionals or users to calculate parameters pertaining to care, such as early warning system software.

**Diagnose** e.g. DHTs that diagnose specified clinical conditions using clinical data.

**Tier C preventative behaviour change** and **self-manage** DHTs are likely to be classed as medical devices under the MDR.

**Tier C treat, active monitoring, calculate** and **diagnose** DHTs are highly likely to be classed as medical devices under the MDR.

Table 4: Tier C: interventions - Minimum evidence standards

| **Evidence category** | **ESF minimum evidence standard** | **Is this an MDR requirement?** | **Aligned MDR documentation and section** |
| --- | --- | --- | --- |
| Demonstrating effectiveness for **preventative behaviour change** or **self-manage** DHTs | High quality observational or quasi-experimental studies presenting comparative data demonstrating relevant outcomes. Comparisons could include relevant outcomes in a control group, use of historical controls, routinely collected data. Relevant outcomes may include behavioural or condition-related user outcomes, evidence of positive behaviour change or user satisfaction | A clinical evaluation and in some cases clinical investigation is required to validate device claims. Beyond this the nature of the evidence is not stipulated  Substantial equivalence claims for Medical devices (particularly high risk) is not necessarily seen as being compliant with regulation  As risk increases there is greater need for manufacturer to conduct clinical investigations rather than clinical evaluations | General safety and performance requirements checklist  Annex I  Validation and verification reports  Annex II (6)  Clinical investigation/evaluation reports  Annex XIV (A)  Annex XV  Summary of safety and clinical performance (class III)  Article 32 |
| Demonstrating effectiveness for **treat, active monitoring, calculate** or **diagnose** DHTs | High quality experimental or quasi-experimental studies showing improvements in relevant outcomes (e.g. diagnostic accuracy, patient-reported outcomes, healthy behaviours, physiological measurements, user satisfaction and engagement). Generic outcome measures may also be useful when reported alongside condition-specific outcomes. The comparator should be a care option that is reflective of the current care pathway, such as a commonly used active intervention | A clinical evaluation and in some cases clinical investigation is required to validate device claims. Beyond this the nature of the evidence is not stipulated  Substantial equivalence claims for Medical devices (particularly high risk) is not necessarily seen as being compliant with regulation  As risk increases there is greater need for manufacturer to conduct clinical investigations rather than clinical evaluations | Clinical investigation/evaluation reports  Annex XIV (A)  Annex XV |
| Use of appropriate behaviour change techniques (if relevant | Be able to show that the techniques used in the DHT are consistent with recognised behaviour change theory and recommended practice (aligned to guidance from NICE or relevant professional organisations)  Be able to show that the techniques used in the DHT are appropriate for the target population | Yes | General safety and performance requirements checklist  Annex I  Validation and verification reports  Annex II (6)  Clinical investigation/evaluation reports  Annex XIV (A)  Annex XV |
| Reliable information content | Be able to show that any health information provided by the DHT is valid (aligned to best available sources, such as NICE guidance, relevant professional organisations or recognised UK patient organisations, and appropriate for the target population) | Yes  No explicit requirement to use UK sources, but all claims by the device manufacturer need to be verified/validated. The way in which to verify/ validate is not specified | General safety and performance requirements checklist  Annex I  Validation and verification reports  Annex II (6) |
| Reliable information content | Be able to show that any health information provided by the DHT is accurate | Yes | General safety and performance requirements checklist  Annex I (15)  Validation and verification reports  Annex II (6)  Clinical investigation/evaluation reports  Annex XIV (A)  Annex XV |
| Reliable information content | Be able to show that any health information provided by the DHT is up to date | Yes | Post-market surveillance reports  Article 85  Annex III  Annex XIV (B)  Periodic safety update report  Article 86  Annex III |
| Reliable information content | Be able to show that any health information provided by the DHT is reviewed and updated by relevant experts at defined intervals, such as every year | Yes | Post-market surveillance reports  Article 85  Annex III  Annex XIV (B)  Periodic safety update report  Article 86  Annex III |
| Reliable information content | Be able to show that any health information provided by the DHT is sufficiently comprehensive | Yes  The DHT needs to perform as claimed | General safety and performance requirements  Annex I  Instructions for use  Annex I (Chapter III)  Validation and verification reports  Annex II (6) |
| Ongoing data collection to show usage of the DHT | Commitment to ongoing data collection to show usage of the DHT in the target population | Yes | Post-market surveillance reports  Article 85  Annex III  Annex XIV (B)  Periodic safety update report  Article 86  Annex III |
| Ongoing data collection to show usage of the DHT | Commitment to share, when available, with relevant decision-makers such as commissioners in a clear and useful format | Yes  While it is a requirement for ongoing data collection, it is not a requirement to report this to relevant commissioners, but will be reviewed by notified bodies as part of compliance | Post-market surveillance reports  Article 85  Annex III  Annex XIV (B)  Periodic safety update report  Article 86  Annex III |
| Ongoing data collection to show value of the DHT | Commitment to ongoing data collection to show user outcomes (if relevant) or user satisfaction (using non-patient identifiable information) to show ongoing value | Yes | Post-market surveillance reports  Article 85  Annex III  Annex XIV (B)  Periodic safety update report  Article 86  Annex III |
| Ongoing data collection to show value of the DHT | Commitment to share, when available, user outcomes (if relevant) or user satisfaction (using non-patient identifiable information), with relevant decision-makers such as commissioners in a clear and useful format | Yes  While it is a requirement for ongoing data collection, it is not a requirement to report this to relevant commissioners, but will be reviewed by notified bodies as part of compliance | Post-market surveillance reports  Article 85  Annex III  Annex XIV (B)  Periodic safety update report  Article 86  Annex III |
| Quality and safeguarding | Show that appropriate safeguarding measures are in place around peer-support and other communication functions within the platform | Yes | General safety and performance requirements  Annex I |
| Quality and safeguarding | Describe who has access to the platform and their roles within the platform  Describe why these people or groups are suitable and qualified to have access | Yes | Risk management  Annex I (3) |
| Quality and safeguarding | Describe any measures in place to ensure safety in peer-to-peer communication, for example through user agreements or moderation | Yes | Post-market surveillance reports  Article 85  Annex III  Annex XIV (B) |
| Credibility with UK health and social care professionals | Show that the DHT has a plausible mode of action that is viewed as useful and relevant by professional experts or expert groups in the relevant field | Not explicitly, but likely to feed into establishing and validating user requirements | Instructions for use  Annex I (Chapter III)  Validation and verification reports  Annex II (6) |
| Credibility with UK health and social care professionals | Show that relevant clinical or social care professionals working within the UK health and social care system have been involved in the design, development or testing of the DHT  or  Show that relevant clinical or social care professionals working within the UK health and social care system have been involved in signing-off the DHT, indicating their informed approval of the DHT | Although there are no explicit requirements for health and social professional involvement (UK or otherwise), heath or social care professionals are likely to feed into establishing and validating user requirements | Validation and verification reports  Annex II (6)  Clinical investigation/evaluation reports  Annex XIV (A)  Validation and verification reports  Annex II (6) |
| Relevance to current care pathways in the UK health and social care system | Evidence to show that the DHT has been successfully piloted in the UK health and social care system, showing that it is relevant to current care pathways and service provision in the UK | Although there are no explicit requirements for health and social professional involvement (UK or otherwise), heath or social care professionals are likely to feed into device validation and clinical evaluation | Validation and verification reports  Annex II (6)  Clinical investigation/evaluation reports  Annex XIV (A) |
| Relevance to current care pathways in the UK health and social care system | Evidence that the DHT is able to perform its intended function to the scale needed (for example, having servers that can scale to manage the expected number of users) | Yes  Devices must meet the relevant safety and performance requirements | General safety and performance requirements - General requirements  Annex I (Chapter I)  Validation and verification reports  Annex II (6)  Clinical investigation/evaluation reports  Annex XIV (A)  Annex XV  Post-market surveillance reports  Article 85  Annex III  Annex XIV (B) |
| Acceptability with users | Be able to show that representatives from relevant user groups were involved in the design, development or testing of the DHT | Not an MDR requirement for representation from user groups but must give consideration to the use environment | General safety and performance requirements  Annex I (5)  Validation and verification reports  Annex II (6) |
| Acceptability with users | Provide data to show user satisfaction with the DHT | Yes | Validation and verification reports  Annex II (6)  Clinical investigation/evaluation reports  Annex XIV (A)  Annex XV  Post-market surveillance reports and post-market clinical follow-up  Article 85/86  Annex III  Annex XIV (B) |
| Equalities considerations | If relevant, the DHT should contribute to challenging health inequalities in the UK health and social care system, or improving access to care among hard-to-reach populations | Not explicitly, but may feed into establishing and validating user requirements, clinical evaluation and post-market surveillance | Validation and verification reports  Annex II (6)  Clinical investigation/evaluation reports  Annex XIV (A)  Annex XV  Post-market surveillance reports and post-market clinical follow-up  Article 85  Annex III  Annex XIV (B) |
| Equalities considerations | If relevant, the DHT should contribute to promoting equality, eliminating unlawful discrimination and fostering good relations between people with protected characteristics (as described in the 2010 Equalities Act) and others | Not explicitly, but may feed into establishing and validating user requirements, clinical evaluation and post-market surveillance | Validation and verification reports  Annex II (6)  Clinical investigation/evaluation reports  Annex XIV (A)  Annex XV  Post-market surveillance reports  Article 85  Annex III  Annex XIV (B) |
| Accurate and reliable measurements (if relevant) | Data or analysis which shows that the data generated or recorded by the DHT is accurate, reproducible and relevant to the range of values expected in the target population  Data showing that the DHT is able to detect clinically relevant changes or responses | Yes  Devices must meet the relevant safety and performance requirements | General safety and performance requirements  Annex I (particularly 15)  Validation and verification reports  Annex II (6)  Clinical investigation/evaluation reports  Annex XIV (A)  Annex XV  Summary of safety and clinical performance (class III)  Article 32 |
| Accurate and reliable transmission of data (if relevant) | Technical data showing that numerical, text, audio, image-based, graphic-based or video information is not changed during the transmission process  Technical data showing that numerical, text, audio, image-based, graphic-based or video information is not biased by the data ‘value’ expected from the target patient population | Yes  Devices must meet the relevant safety and performance requirements | General safety and performance requirements  Annex I (particularly 15)  Validation and verification reports  Annex II (6)  Clinical investigation/evaluation reports  Annex XIV (A)  Annex XV  Summary of safety and clinical performance (class III)  Article 32 |

Table 5: Tier C: interventions - Best practice standards

| **Evidence category** | **ESF best practice standard** | **Is this an MDR requirement?** | **Aligned MDR documentation and section** |
| --- | --- | --- | --- |
| Demonstrating effectiveness for **preventative behaviour change** or **self-manage** DHTs | High quality intervention study (quasi-experimental or experimental design) which incorporates a comparison group, showing improvements in relevant outcomes, such as patient-reported outcomes (preferably using validated tools) including symptom severity or quality of life, other clinical measures of disease severity or disability, healthy behaviours, physiological measures, user satisfaction and engagement, health and social care resource use such as admissions or appointments. The comparator should be a care option that is reflective of standard care in the current care pathway, such as a commonly used active intervention | A clinical evaluation and in some cases clinical investigation is required to validate device claims. Beyond this the nature of the evidence is not stipulated  Substantial equivalence claims for Medical devices (particularly high risk) is not necessarily seen as being compliant with regulation  As risk increases there is greater need for manufacturer to conduct clinical investigations rather than clinical evaluations | Validation and verification reports  Annex II (6)  Clinical investigation/evaluation reports  Annex XIV (A)  Annex XV |
| Demonstrating effectiveness for **treat, active monitoring, calculate** or **diagnose** DHTs | High quality randomised controlled study or studies done in a setting relevant to the UK health and social care system, comparing the DHT with a relevant comparator and demonstrating consistent benefit including in clinical outcomes in the target population, using validated condition-specific outcome measures  or  Well-conducted meta-analysis of randomised controlled studies if there are enough available studies on the DHT | A clinical evaluation and in some cases clinical investigation is required to validate device claims. Beyond this the nature of the evidence is not stipulated  Substantial equivalence claims for Medical devices (particularly high risk) is not necessarily seen as being compliant with regulation  As risk increases there is greater need for manufacturer to conduct clinical investigations rather than clinical evaluations  Not explicitly, but likely to feed into device validation if there are enough available studies to conduct a meta-analysis | Clinical investigation/evaluation reports  Annex XIV (A)  Annex XV  Clinical investigation/evaluation reports  Annex XIV (A)  Annex XV  Validation and verification reports  Annex II (6) |
| Use of appropriate behaviour change techniques (if relevant) | Published qualitative or quantitative evidence showing that the techniques used in the DHT are based on published and recognised effective behaviour change techniques | No  It is not a requirement for this information to be published or publicly available | Validation and verification reports  Annex II (6) |
| Use of appropriate behaviour change techniques (if relevant) | Published qualitative or quantitative evidence showing that the techniques used in the DHT are aligned with recommended practice | No  It is not a requirement for this information to be published or publicly available | General safety and performance requirements checklist  Annex I  Validation and verification reports  Annex II (6) |
| Use of appropriate behaviour change techniques (if relevant) | Published qualitative or quantitative evidence showing that the techniques used in the DHT are appropriate for the target population | No  It is not a requirement for this information to be published or publicly available | General safety and performance requirements checklist  Annex I  Validation and verification reports  Annex II (6) |
| Reliable information content | Evidence of endorsement, accreditation or recommendation by NICE, NHS England, a relevant professional body or recognised UK patient organisation or | No  Endorsement is not a requirement | Validation and verification reports  Annex II (6) |
| Reliable information content | Evidence that the information content has been validated though an independent accreditation such as The Information Standard or HONcode certification | Not explicitly, but likely to feed into device validation and clinical evaluation | Validation and verification reports  Annex II (6) |
| Ongoing data collection to show usage of the DHT | Evidence that data on usage is being collected in line with the minimum standards and can be made available to relevant decision-makers | Yes  While it is a requirement for ongoing data collection, it is not a requirement to report this to relevant commissioners, but will be reviewed by notified bodies as part of compliance | Post-market surveillance reports  Article 85  Annex III  Annex XIV (B)  Periodic safety update report  Article 86  Annex III |
| Ongoing data collection to show value of the DHT | Evidence that data on outcomes or user satisfaction is being collected in line with the minimum standard and can be made available to relevant decision-makers | Yes  While it is a requirement for ongoing data collection, it is not a requirement to report this to relevant commissioners, but will be reviewed by notified bodies as part of compliance | Post-market surveillance reports  Article 85  Annex III  Annex XIV (B)  Periodic safety update report  Article 86  Annex III |
| Credibility with UK health and social care professionals | Show that the DHT has a plausible mode of action that is viewed as useful and relevant by professional experts or expert groups in the relevant field | Not explicitly, but likely to feed into establishing and validating user requirements | Instructions for use  Annex I (Chapter III)  Validation and verification reports  Annex II (6) |
| Credibility with UK health and social care professionals | Published or publicly available evidence documenting the role of relevant UK health or social care experts in the design, development, testing or sign-off of the DHT  Published or publicly available evidence documenting the role of relevant UK health or social care experts in signing-off the DHT, indicating their informed approval of the DHT | No  Although there are no explicit requirements for health and social professional involvement (UK or otherwise), heath or social care professionals are likely to feed into establishing and validating user requirements  It is not a requirement for this information to be published or publicly available | Validation and verification reports  Annex II (6)  Clinical investigation/evaluation reports  Annex XIV (A)  Annex XV |
| Relevance to current care pathways in the UK health and social care system | Evidence to show successful implementation of the DHT in the UK health and social care system | No explicit requirement for successful implementation in the health and social care system (UK or otherwise), but likely to be covered by validation, clinical evaluation, clinical investigation if applicable, and post-market surveillance | Validation and verification reports  Annex II (6)  Clinical investigation/evaluation reports  Annex XIV (A)  Annex XV  Post-market surveillance reports  Article 85  Annex III  Annex XIV (B) |
| Acceptability with users | Published or publicly available evidence to show that representatives from relevant user groups were involved in the design, development or testing of the DHT | No  It is not a requirement for this information to be published or publicly available | Validation and verification reports  Annex II (6) |
| Acceptability with users | Published or publicly available evidence to show that users are satisfied with the DHT | No  It is not a requirement for this information to be published or publicly available | Validation and verification reports  Annex II (6)  Clinical investigation/evaluation reports  Annex XIV (A)  Annex XV  Post-market surveillance reports  Article 85  Annex III  Annex XIV (B) |
| Equalities considerations | Show evidence of the DHT being used in hard-to-reach populations | Not explicitly, but may feed into establishing and validating user requirements | Validation and verification reports  Annex II (6)  Clinical investigation/evaluation reports  Annex XIV (A)  Annex XV  Post market surveillance reports  Article 85  Annex III  Annex XIV (B) |
| Accurate and reliable measurements (if relevant) | Quantitative data or analysis which shows that the data generated or recorded by the DHT is accurate, reproducible and relevant to the range of values expected in the target population  Quantitative data showing that the DHT is able to detect clinically relevant changes or responses | Yes  Devices must meet the relevant safety and performance requirements | General safety and performance requirements  Annex I (particularly 15)  Validation and verification reports  Annex II (6)  Clinical investigation/evaluation reports  Annex XIV (A)  Annex XV  Summary of safety and clinical performance (class III)  Article 32 |
| Accurate and reliable transmission of data (if relevant) | Technical data showing that numerical, text, audio, image-based, graphic-based or video information is not changed during the transmission process  Quantitative data showing that numerical, text, audio, image-based, graphic-based or video information is not biased by the data ‘value’ expected from the target patient population | Yes  Devices must meet the relevant safety and performance requirements | General safety and performance requirements checklist  Annex I  Validation and verification reports  Annex II (6)  Clinical investigation/evaluation reports  Annex XIV (A)  Annex XV  Summary of safety and clinical performance (class III)  Article 32 |

# Conclusions

For software regulated as a medical device under the 2017 EU MDR, some of the documentation that is submitted for regulatory purposes and CE marking may also satisfy certain standards of the NICE ESF, as shown in tables 2-5. There may also be some useful standards, guidelines and best practices within the EU MDR framework that assist DHTs that are unlikely to be medical devices (i.e. Tier A: system impact DHTs) to meet the ESF standards, although these would not be used for regulatory compliance purposes.

# Acknowledgements

Newcastle EAC thanks the following contributors for their expert review and comments on a pre-publication draft of this document:

* Robert Turpin. Head of Sector (Healthcare), British Standards Institute
* Mark Salmon. Deputy Director, Evidence Resources, NICE
* David Grainger. Senior Medical Device Specialist, MHRA
* Andrew Davies. Digital Health Lead, ABHI

Comments were also invited from other organisations but unfortunately not received within the timescale for this work. Some initial work by the ABHI explored the possibility of creating a mapping tool between the ESF and different sections of the MDR.

# References

1. The National Institute for Health and Care Excellence, March 2019. *Evidence Standards Framework for Digital Health Technologies*. Accessed 23/10/2020 at <https://www.nice.org.uk/Media/Default/About/what-we-do/our-programmes/evidence-standards-framework/digital-evidence-standards-framework.pdf>.
2. European Economic Community, 14 June 1993. *Council Directive 93/42/EEC of 14 June 1993 concerning medical devices*. Accessed 23/10/2020 at <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:01993L0042-20071011>.
3. European Union, 5 April 2017. *Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices*. Accessed 23/10/2020 at <https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1573142983313&uri=CELEX:32017R0745>.
4. British Standards Institution, 23 January 2020. *Second corrigendum to the MDR and IVDR; Vigilance Reporting – updated Manufacturer Incident Reporting (MIR) forms*. Accessed 23/10/2020 at <https://www.bsigroup.com/en-GB/medical-devices/news-centre/enews/2020-news/second-corrigenda-to-the-mdr-and-ivdr/>.
5. UK Government, 1 September 2020. *Regulating medical devices from 1 January 2021*. Accessed 23/10/2020 at <https://www.gov.uk/guidance/regulating-medical-devices-from-1-january-2021>.
6. European Union, 5 April 2017. *Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices*. Accessed 23/10/2020 at <https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32017R0746&from=EN>.
7. British Standards Institution, May 2020. *MDR Documentation Submissions Best Practices Guidelines Revision 2*. Accessed 23/10/2020 at <https://www.bsigroup.com/globalassets/meddev/localfiles/en-gb/documents/bsi-md-mdr-best-practice-documentation-submissions-en-gb.pdf>.

1. CE-marked devices are excluded from the system impact tier so there is no corresponding table for Tier A – System impact DHTs. [↑](#footnote-ref-2)