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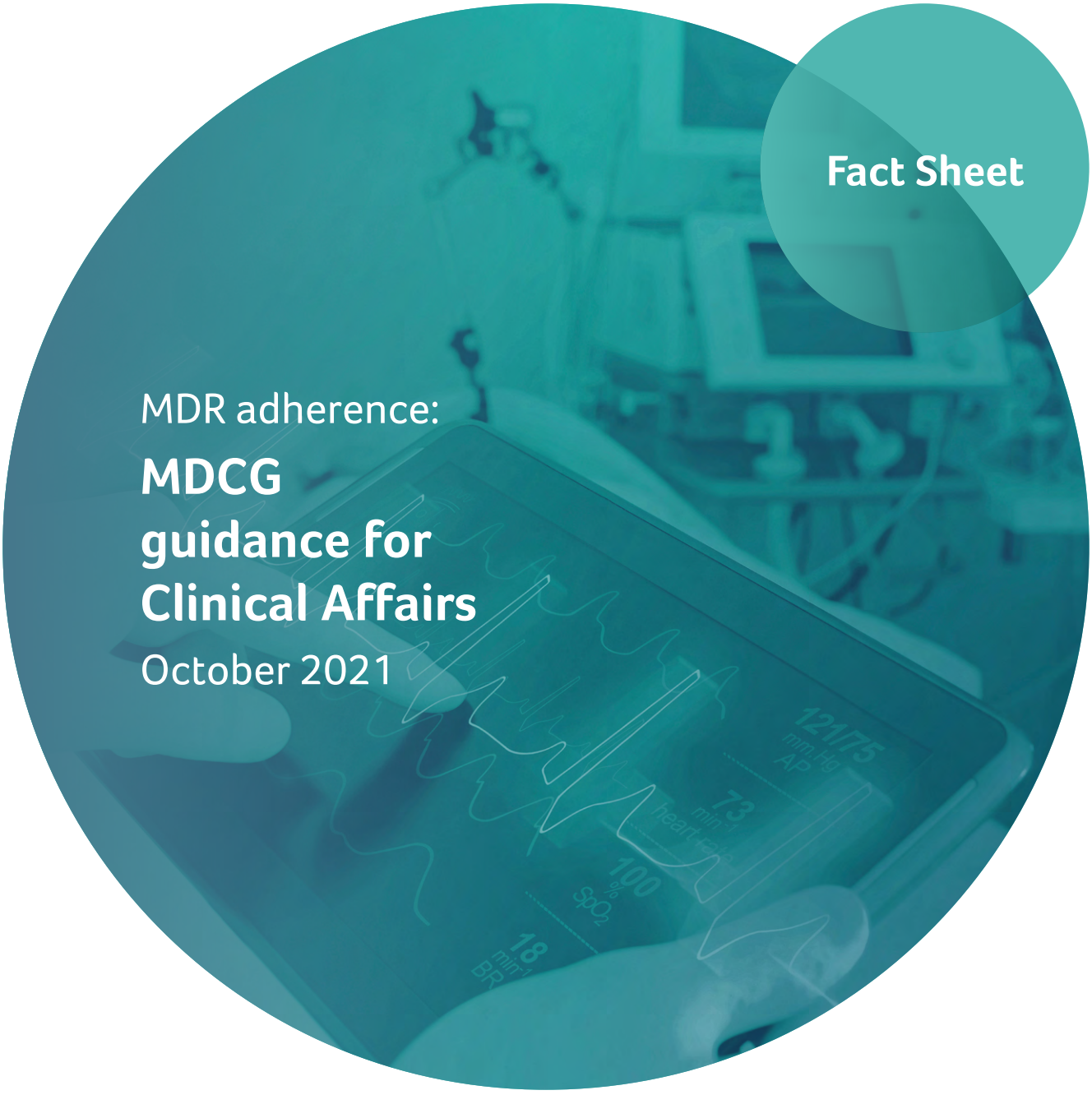

Fact Sheet

MDR adherence:

MDCG guidance for Clinical Affairs

October 2021

Smart consulting,
enhanced medical solutions.

A summary of MDCG guidance regarding MDR & Clinical affairs

What will you find in this fact sheet?

This fact sheet provides a summary of all relevant MDCG guidance regarding MDR adherence relating to:

- Clinical Investigations
- Clinical Evaluation
- Clinical Data

The guidance included spans 2019 - 2021. Some of the guidance documents focus on interpreting MDR, whilst others provide templates and detailed processes for action to be taken. All are helpful in terms of harmonization between Notified Bodies, Competent Authorities and manufacturers regarding MDR implementation in the Clinical field.

The title of each guidance is clickable, to enable easy access to each relevant MDCG document.

MDCG 2020-5 | Clinical evaluation – Equivalence

What does the guidance cover?

Detailed guidance on the evaluation of **equivalence of medical devices,** comparing MDR requirements to the previous Meddev 2.7/1 Rev 4.

Key inclusions

- The different requirements regarding the three equivalence aspects:
    - Technical
    - Biological
    - Clinical
- Considerations for software algorithms with respect to equivalence, which have not been covered by Meddev 2.7/1 Rev 4

Note: The methodology to identify suitable clinical data for a medical device still follows Meddev 2.7/1 Rev 4

MDCG 2020-6 | Clinical evidence needed for medical devices previously CE marked under MDD

What does the guidance cover?

Recommendations on how to **identify the extent of clinical data required** for medical devices that have previously been certified under MDD. It also discusses the requirement of **'sufficient clinical data'** by MDR (Art 61 6a) which is not detailed in the MDR, given that clinical evaluation is a continuous process.

Key inclusions

- Introduction of the new term: 'legacy device', which is a device that has previously been certified under MDD
- Definition for devices that are 'well-established technologies'
- The clarification that for legacy devices, PMCF and PMS need to follow MDR requirements from the date of application
- The outlining of a hierarchy tree of different types of clinical data for demonstration of conformity with relevant GSPRs for legacy devices

Templates & Processes
SSCP & PMCF

MDCG 2019-9 | Summary of Safety and Clinical Performance

The **SSCP** is a new document required by MDR for **implants and Class III products**. It is aimed at the intended user of the device (HCPs and patients where relevant). This guidance document gives a detailed outline of the required content, layout and format for an SSCP.

Key takeouts

An SSCP needs to be:

- ✓ Sourced entirely from the technical documentation
- ✓ Made available in the languages of the EU where the product is on the market, plus English if it's directed to patient / layperson users
- ✓ Uploaded to EUDAMED to enhance transparency to the public

Post-Market Clinical Follow Up

MDCG 2020-7 | PMCF plan template

Provides a **template for a PMCF** plan to guide manufacturers in complying with MDR requirements.

MDCG 2020-8 | PMCF evaluation report template

This guidance proposes **a template for a PMCF evaluation report** that should be part of the CER, in order to provide PMCF data in an organised format to NBs and CAs.

Templates & Processes
Reports, Applications & Notifications

MDCG 2020-10/1&2 | Safety reporting in clinical investigations Appendix: Clinical investigation Summary Safety Report Form

- A detailed guidance on safety reporting in clinical investigations and PMCF clinical investigations as per Art 80(2) MDR and 80(5) and (6) MDR, respectively
- Outlines procedures for safety reporting in the absence of EUDAMED as well as for EUDAMED'S transition period
- Provides completion guidelines for the **Summary Safety Reporting Form** (MDCG 202-10/2)

MDCG 2020-13 | Clinical Evaluation assessment Report template

While this guidance is intended for Notified Bodies, it is a valuable source for manufacturers when **building a CER template.**

MDCG 2021-08 | Clinical investigation application/notification documents

- Provides a set of templates to be used to fulfill the application/notification requirements for clinical investigations under MDR prior to the availability of the EUDAMED clinical investigations and performance studies module
- The data fields mostly overlap with the forms being developed for the clinical investigation module in EUDAMED but you should be sure to check if there are any specific national requirements in each individual Member State

Other information
General Q&A and CIV-ID

MDCG 2021-6 | Regulation (EU) 2017/745 Questions & Answers regarding clinical investigation

This Q&A answers specific questions regarding clinical investigations under MDR. Among other topics, it provides clarification on terminology and regulatory pathways to follow, as well as guidance on what to do in the absence of EUDAMED.

MDCG 2021-20 | Instructions for generating CIV-ID for MDR Clinical Investigations

This guidance provides instructions for generating a CIV-ID for MDR clinical investigations to Competent Authorities with access to EUDAMED2.

Should you require assistance with a clinical challenge, please don't hesitate to get in touch – we'd be happy to help.

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