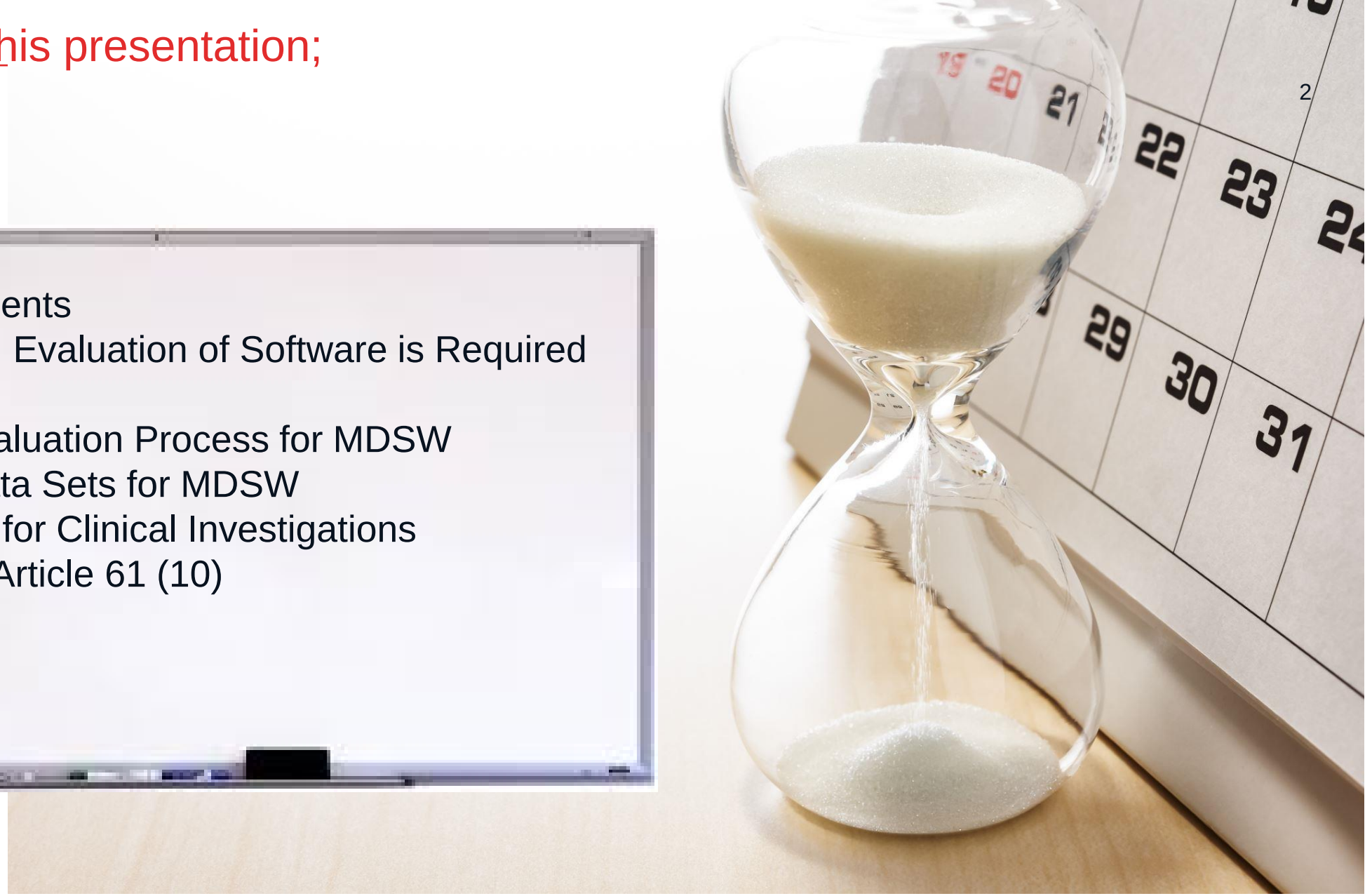
Clinical Evaluation of Software

Considerations for Manufacturers

Topics Covered in this presentation;

- ❑ MDR Requirements
- ❑ When a Clinical Evaluation of Software is Required
- ❑ MDCG 2020-1
- ❑ The Clinical Evaluation Process for MDSW
- ❑ Examples of data Sets for MDSW
- ❑ Considerations for Clinical Investigations
- ❑ Equivalence & Article 61 (10)
- ❑ Questions



MDR Requirements for Clinical Evaluation of Software

Annex II – Technical Documentation. 6.1 Pre Clinical & Clinical Data

— software verification and validation (describing the software design and development process and evidence of the validation of the software, as used in the finished device. This information shall typically include the summary results of all verification, validation and testing performed both in-house and in a simulated or actual user environment prior to final release. It shall also address all of the different hardware configurations and, where applicable, operating systems identified in the information supplied by the manufacturer);

Requirement to consider both pre-clinical and clinical data in the context of software

bsi.

Article 61 & MDSW

- Article 2 (1) definition of *medical device* includes software.
- Software as a Medical Device is still subject to the requirements of Article 61.
- Software is deemed an active device (Article 2 (4))

CHAPTER VI

CLINICAL EVALUATION AND CLINICAL INVESTIGATIONS

Article 61

Clinical evaluation

1. Confirmation of conformity with relevant general safety and performance requirements set out in Annex I under the normal conditions of the intended use of the device, and the evaluation of the undesirable side-effects and of the acceptability of the benefit-risk- ratio referred to in Sections 1 and 8 of Annex I, shall be based on clinical data providing sufficient clinical evidence, including where applicable relevant data as referred to in Annex III.

The manufacturer shall specify and justify the level of clinical evidence necessary to demonstrate conformity with the relevant general safety and performance requirements. That level of clinical evidence shall be appropriate in view of the characteristics of the device and its intended purpose.

To that end, manufacturers shall plan, conduct and document a clinical evaluation in accordance with this Article and Part A of Annex XIV.

2 Important points (To be considered in context of MDCG 2019-11)

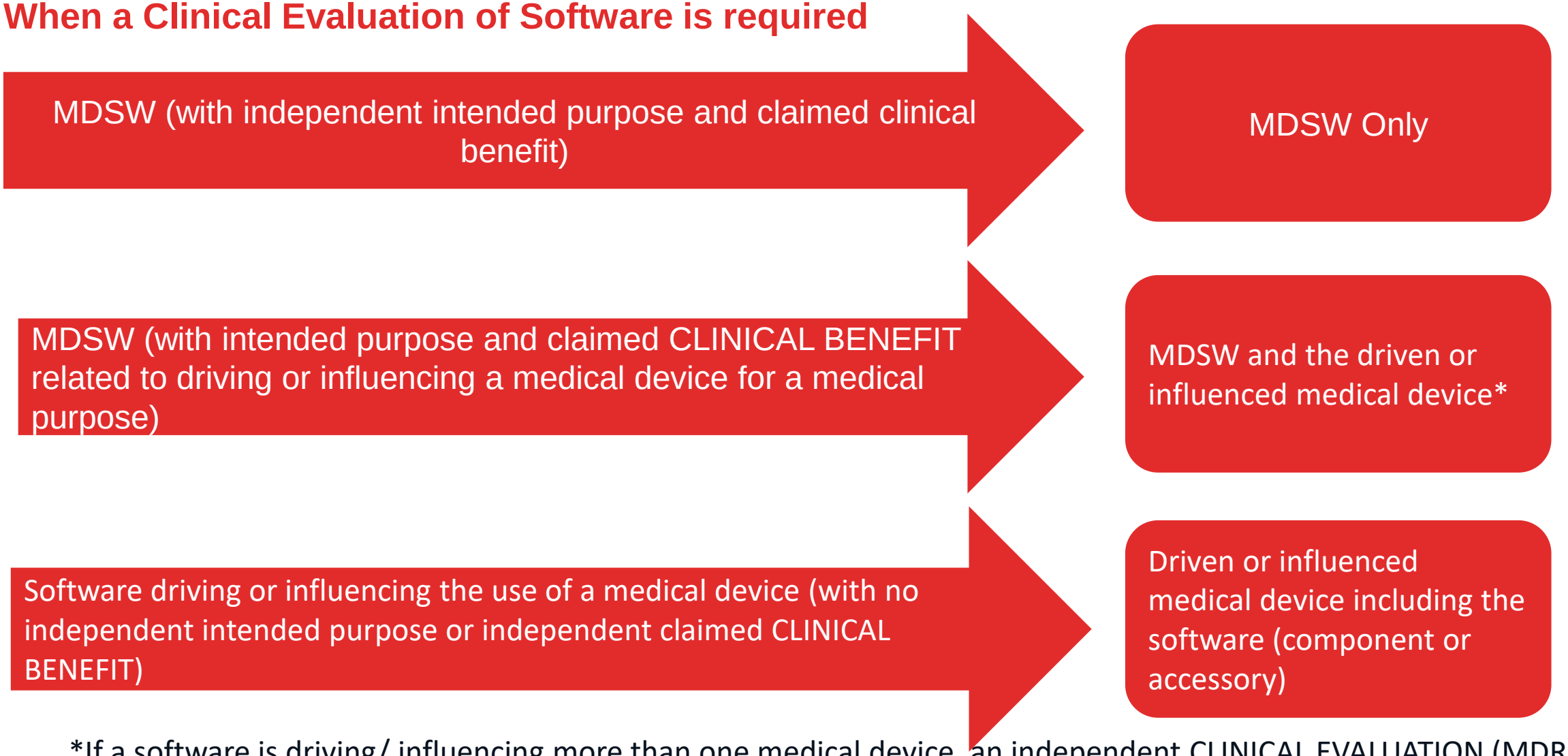
1. Software for which the manufacturer **claims a specific medical intended purpose**. Such software has a **CLINICAL BENEFIT** and requires **CLINICAL EVIDENCE** within its own conformity assessment.

2. Software for which the manufacturer **does not claim any medical intended purpose**. Such software is intended to drive or influence a medical device. The CLINICAL EVIDENCE is provided within the context of the driven or influenced device.

Note: Software that does not have an independent medical intended purpose and/or does not drive or influence another medical device are not considered MDSW.

bsi.

When a Clinical Evaluation of Software is required



*If a software is driving/ influencing more than one medical device, an independent CLINICAL EVALUATION (MDR) / PERFORMANCE EVALUATION (IVDR) is required for each foreseen and clinically viable software – device combination.

bsi.

The importance of your Intended Purpose.

Intended Purpose

- **The intended purpose is instrumental in defining the purpose of the software and should be sufficiently detailed.**

- **Consider the intended purpose in the context of Article 2 (1)**

Article 2

Definitions

For the purposes of this Regulation, the following definitions apply:

(1) 'medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

— diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,

— diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,

— investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,

— providing information by means of *in vitro* examination of specimens derived from the human body, including organ, blood and tissue donations,

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

bsi.

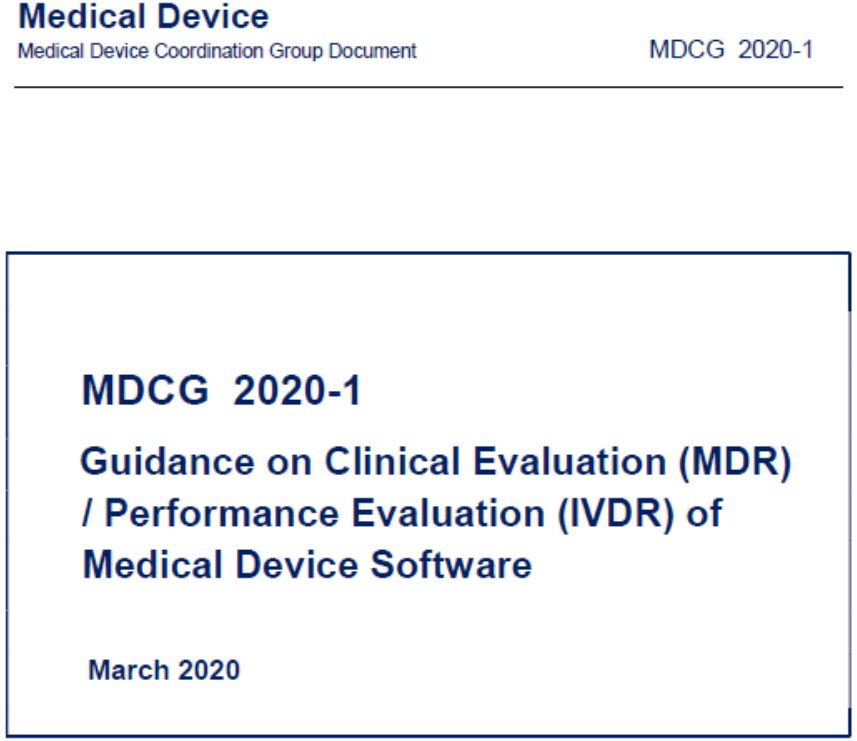
MDCG 2020-1 Guidance on Clinical Evaluation (MDR)/Performance Evaluation (IVDR) of Medical Device Software

MDCG 2020-1 Clinical Evaluation of MDSW

MDCG 2020-1 Guidance on Clinical Evaluation (MDR)/Performance Evaluation (IVDR) of Medical Device Software.

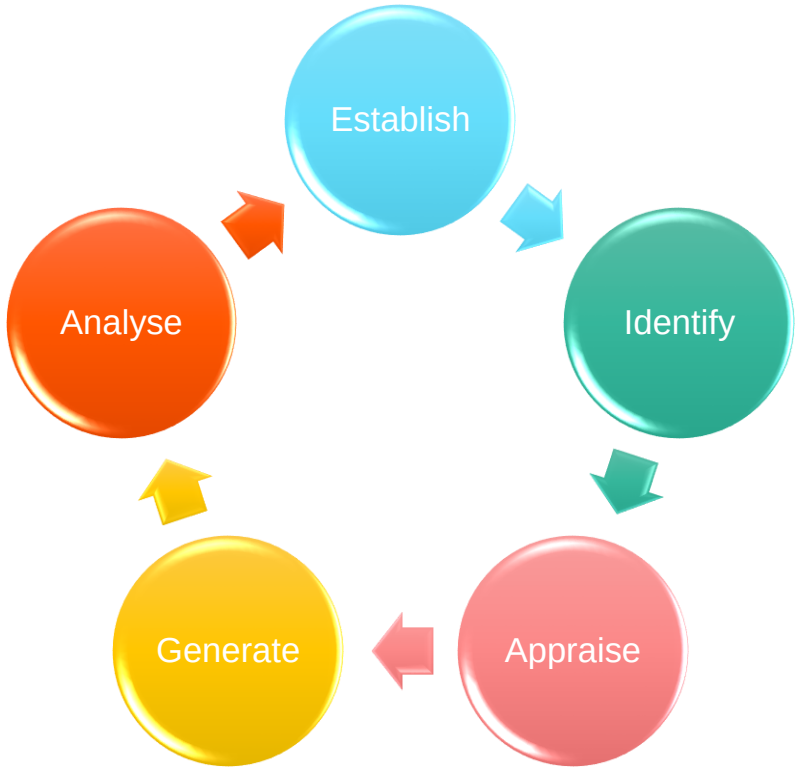
Considerations:

- Released March 2020
- Applicable to IVDR in relation to performance evaluation.
- Considers IMDRF guidance documents to promote global convergence.
- Should be considered in context of MDCG 2019-11



Expectation of the Clinical Evaluation Process for MDSW

Annex XIV Part A (1)



1. To plan, continuously conduct and document a clinical evaluation, manufacturers shall:

(a) establish and update a clinical evaluation plan, which shall include at least:

— an identification of the general safety and performance requirements that require support from relevant clinical data;

— a specification of the intended purpose of the device;

— a clear specification of intended target groups with clear indications and contra-indications;

— a detailed description of intended clinical benefits to patients with relevant and specified clinical outcome parameters;

— a specification of methods to be used for examination of qualitative and quantitative aspects of clinical safety with clear reference to the determination of residual risks and side-effects;

— an indicative list and specification of parameters to be used to determine, based on the state of the art in medicine, the acceptability of the benefit-risk ratio for the various indications and for the intended purpose or purposes of the device;

— an indication how benefit-risk issues relating to specific components such as use of pharmaceutical, non-viable animal or human tissues, are to be addressed; and

— a clinical development plan indicating progression from exploratory investigations, such as first-in-man studies, feasibility and pilot studies, to confirmatory investigations, such as pivotal clinical investigations, and a PMCF as referred to in Part B of this Annex with an indication of milestones and a description of potential acceptance criteria;

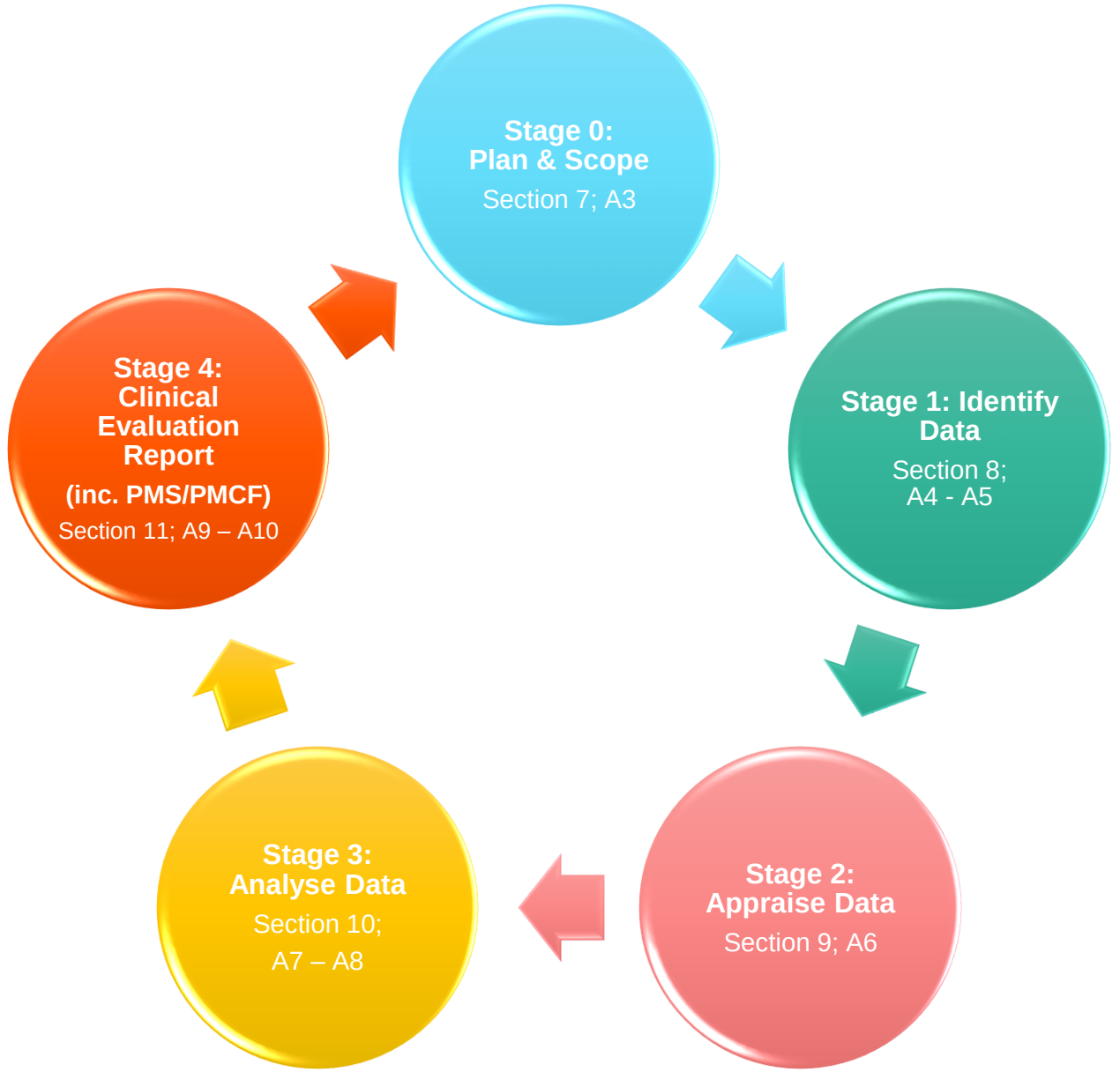
(b) identify available clinical data relevant to the device and its intended purpose and any gaps in clinical evidence through a systematic scientific literature review;

(c) appraise all relevant clinical data by evaluating their suitability for establishing the safety and performance of the device;

(d) generate, through properly designed clinical investigations in accordance with the clinical development plan, any new or additional clinical data necessary to address outstanding issues; and

(e) analyse all relevant clinical data in order to reach conclusions about the safety and clinical performance of the device including its clinical benefits.

The Clinical Evaluation Process, MedDev 2.7/1 Clause 63



Note the commonality with the MDR Text!

bsi.

Stage 0: Plan & Scope/Establish

Defining the scope of the Clinical Evaluation is critical to ensure that the CER reflects appropriate data.

The Scope should be defined to:

- The GSPR's (Annex I) that will require clinical data
- Nature of the Software
- History of the Software

Stage 0: Plan & Scope/Establish

At this stage the manufacturer shall:

- Define the intended purpose of the Software
- Define the intended patient populations
- Define the indications and contraindications of the software
- Detail the intended clinical benefit of the software with relevant & specified clinical outcomes

‘Clinical benefit’
means the positive impact of a device on the health of an individual, expressed in terms of a meaningful, measurable, patient-relevant clinical outcome(s), including outcome(s) related to diagnosis, or a positive impact on patient management or public health.

MDSW and Clinical Benefit

Clinical Benefit (MDR Article 2 (53)):

means the positive impact of a device on the health of an individual, expressed in terms of a meaningful, measurable, patient-relevant clinical outcome(s), including outcome(s) related to diagnosis, or a positive impact on patient management or public health;

Clinical benefit (MDSW) (MDCG 2020-1):

It should be recognised that the concept of a CLINICAL BENEFIT for MDSW may deviate from that which applies in the case of pharmaceuticals or other medical devices, since the benefit of MDSW may lie in providing accurate medical information on patients, where appropriate, assessed against medical information obtained through the use of other diagnostic options and technologies, whereas the final clinical outcome for the patient is dependent on further diagnostic and/or therapeutic options which could be available.

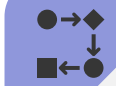
bsi.

A3. Device description – typical contents

1. Device name etc
2. Prior models
3. Device description
4. Device components and technical attributes
5. Principles of operation/mode of action
6. Device group
7. Market status
8. Intended Purpose (or intended use)
9. Target Population
10. Intended Users
11. Lifetime (duration of use) & body contact

Stage 0: Plan & Scope/Establish

The manufacturer should also at this stage:



Describe

Describe the methods it will use to assess the qualitative and quantitative aspects of clinical safety with a clear plan of how it will determine residual risks and side effects.

Define

Define clear objectives, based on state of the art in medicine, that align with the indications and/or intended purpose of the software.

Consider

Give consideration to other high-risk factors and how it will demonstrate benefit/risk e.g. target population, replacement of other interventions

Stage 0: Plan & Scope/Establish

ANNEX XIV

CLINICAL EVALUATION AND POST-MARKET CLINICAL FOLLOW-UP

PART A

CLINICAL EVALUATION

1. To plan, continuously conduct and document a clinical evaluation, manufacturers shall:

(a) establish and update a clinical evaluation plan, which shall include at least:

— a clinical development plan indicating progression from exploratory investigations, such as first-in-man studies, feasibility and pilot studies, to confirmatory investigations, such as pivotal clinical investigations, and a PMCF as referred to in Part B of this Annex with an indication of milestones and a description of potential acceptance criteria;

(d) generate, through properly designed clinical investigations in accordance with the clinical development plan, any new or additional clinical data necessary to address outstanding issues; and

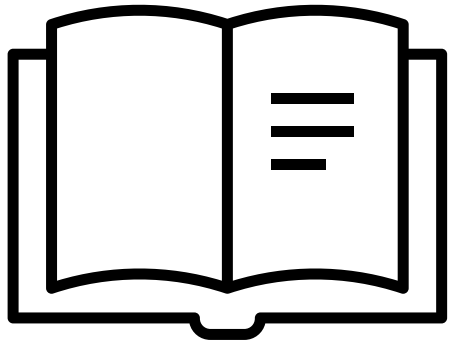
Clinical Development Plan

Data

The clinical development plan defines how you will collect sufficient clinical data for later clinical evaluation. It is the first step of the overall clinical evaluation plan.

Investigations

This may include exploratory investigations, first-in-man studies, feasibility and pilot studies, to confirmatory investigations; an outlook for possible PMCF activities is also possible at this stage.



Outcomes

List all investigations/studies performed from pre-clinical to post market studies, detailing the expected outcomes of these investigations.

Decisions & Actions

If these outcomes are not reached, what **decisions and actions** are required to fulfil those unanswered questions.

‘Off-Label’ Investigations

This may also include information where the manufacturer intends to perform clinical investigations* ‘off-label’ to expand the indications of the medical device in the future.

Acceptance Criteria

The Clinical Development Plan should indicate potential acceptance criteria.

What is a Clinical Development Plan

- ‘Blue Print’ of entire clinical research strategy of a medical device defining the pathway to operational plans
- Define Acceptance Criteria
- Decision Points
- Resources & Documentation Required

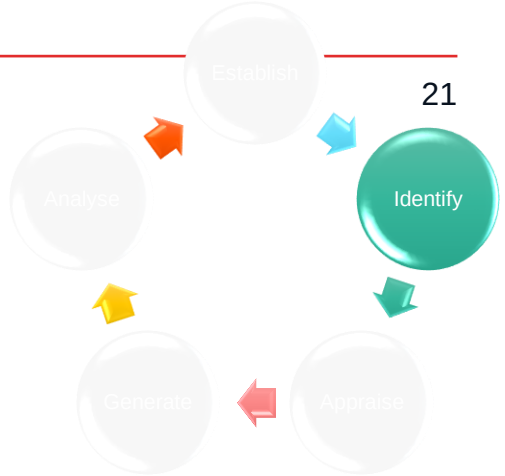
Annex XIV part A

Stage 1: Identify

Annex XIV Part A - (b) identify available clinical data relevant to the device and its intended purpose and any gaps in clinical evidence through a systematic scientific literature review;

- Literature searches should have a comprehensive strategy and cover multiple databases
- Other data should be considered here e.g. Harmonised standards, Medical Society…
- Non published data – Congress data, registry data
- Citations referenced in returned literature should be screened
- Appraise all relevant clinical data by evaluating their suitability for establishing the safety and performance of the device as per MEDDEV 2.7.1/4 Annex XIV Part A Section 1c (MDCG 2020-6 Section 6)
- Literature identified from the search that are in a different language should not be excluded and should be considered relevant

Stage 1: Identify



Identified data sources may include (not exhaustive):

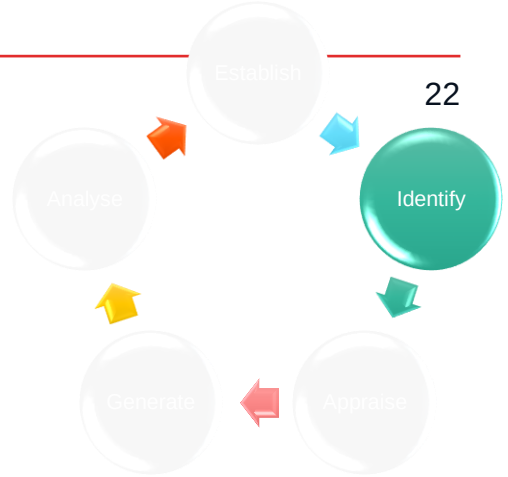
All pre market clinical investigations

All clinical data generated from risk management activities & the PMS programmes which the manufacturer has implemented in Europe & in other countries

Relevant pre-clinical studies (e.g. bench test reports including verification and validation data)

For example: Clinical investigation(s) on the software and published clinical investigations on a demonstrated equivalent software

Stage 1: Identify

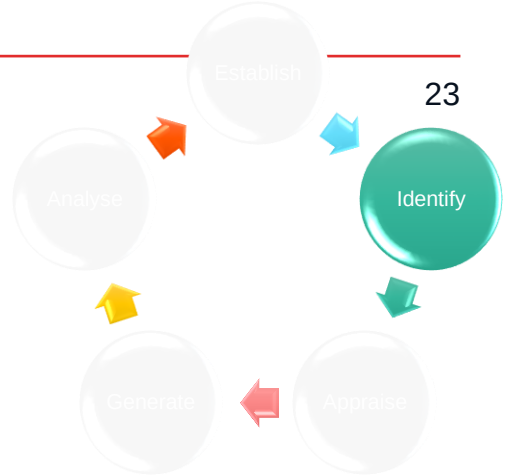


Literature searches need to be conducted:

- Literature on the software in question and the equivalent software. Note: If the manufacturer holds own clinical data for the device in question (e.g. own premarket clinical investigations, PMCF Studies, other PMS data), the literature is considered together with those data for consistent appraisal and overall analysis
- A review of the current knowledge / the state of the art needed for the proper conduct of the appraisal and analysis of the clinical data of the device under evaluation and the equivalent device

bsi.

Stage 1: Identify

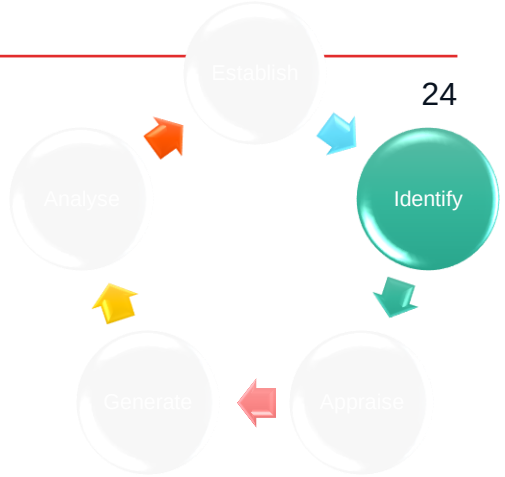


The protocol must provide rationales and be in the scope of the Clinical Evaluation and should use a constructed process such as PICO.

P	**Population**	• Patient characteristics: age, gender, ethnicity • Health issues: diabetes, access to healthcare
I	**Intervention**	What treatment are you looking to explore? • Drugs, surgery, educational program, policy • Setting, geography
C	**Comparison/ Control**	• Comparison is you are comparing multiple interventions • Control if you're comparing an internvention to do nothing
O	**Outcome**	What results will you consider to determine if / how well the intervention is working? • Blood glucose, BMI • Timing

bsi.

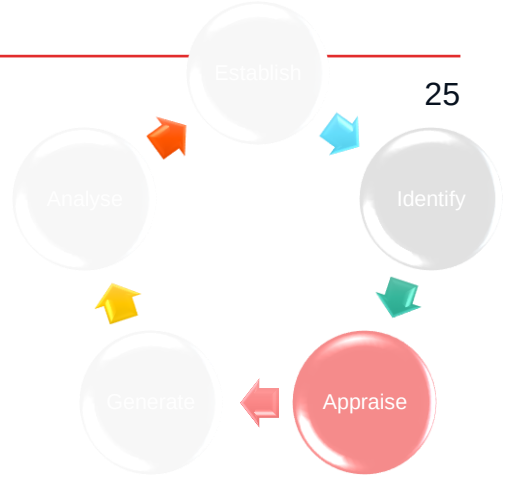
Stage 1: Identify



The literature search output must be:

- Objective and not biased
- Include favourable and unfavourable data
- Repeatable
- Include non English publications where applicable

Stage 2: Appraise



Annex XIV Part A (C) appraise all relevant clinical data by evaluating their suitability for establishing the safety and performance of the device;

To ensure systematic and unbiased appraisal of the data, the evaluators should set up an appraisal plan that describes the procedure and the criteria to be used for the appraisal.

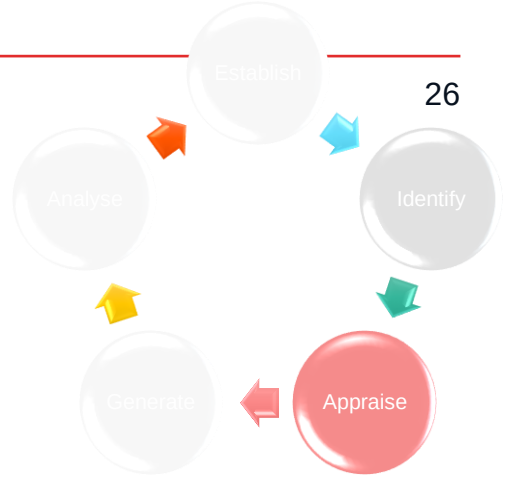
The evaluators should:

- ✓ follow the pre-defined appraisal plan strictly and apply its criteria consistently throughout the appraisal
- ✓ base their appraisal on the full text of publications and of other documents (not abstracts or summaries), so as to review all of the contents, the methodology employed, the reporting of results, the validity of conclusions drawn from the investigation or report, and evaluate any limitations and potential sources of error in the data
- ✓ document the appraisal in the clinical evaluation report to the extent that it can be critically reviewed by others

MDCG-2020-6 reference section A6 of MEDDEV 2.7.1

bsi.

Stage 2: Appraise



Based on their scientific validity and relevance, the data should be weighted according to their relative contributions.

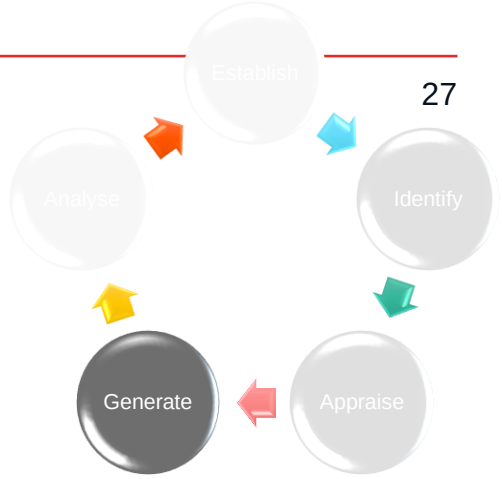
Due to the diversity of medical devices, there is no single, well established method for weighting clinical data:

- the evaluators should identify appropriate criteria to be applied for a specific evaluation
- these pre-defined criteria should be followed strictly by the evaluators

Weighting factor	Weighting classification	Score
Research type	Restoration	1.00
	Empirical research	0.50
Scientific rigor	Peer-reviewed journal article	1.00
	Peer-reviewed book chapter	0.66
	Conference proceeding	0.66
	Gov. report / gray literature	0.66
	Stakeholder webpage	0.33
Year completed	2005 – ongoing	1.00

Data Contribution Criteria	Description		Grading System
Data source type	Was the design of the study appropriate?	T1 T2	Yes No
Outcome measures	Do the outcome measures reported reflect the intended performance of the device?	O1 O2	Yes No
Follow up	Is the duration of follow-up long enough to assess whether duration of treatment effects and identify complications?	F1 F2	Yes No
Statistical significance	Has a statistical analysis of the data been provided and is it appropriate?	S1 S2	Yes No
Clinical significance	Was the magnitude of the treatment effect observed clinically significant?	C1 C2	Yes No

Stage 3: Analyse Data

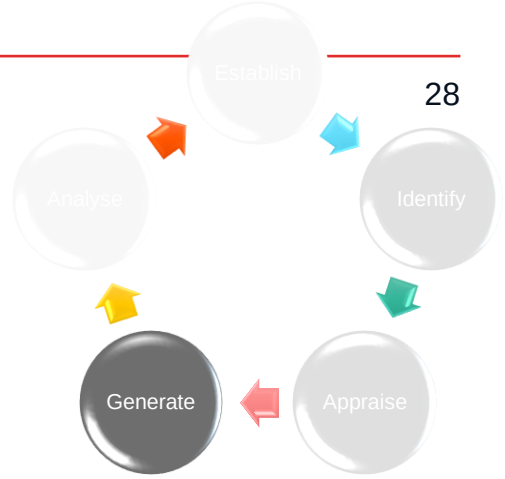


The goal of the analysis stage is to determine if the appraised data sets available for a medical device collectively demonstrate compliance with each of the GSPRs pertaining to the clinical performance and clinical safety of the device, when the device is used according to its intended purpose.

In order to demonstrate compliance, the evaluators should:

- Use sound methods
- Make a comprehensive analysis
- Determine if additional clinical investigations or other measures are necessary
- Determine PMCF needs

Stage 3: Analyse Data



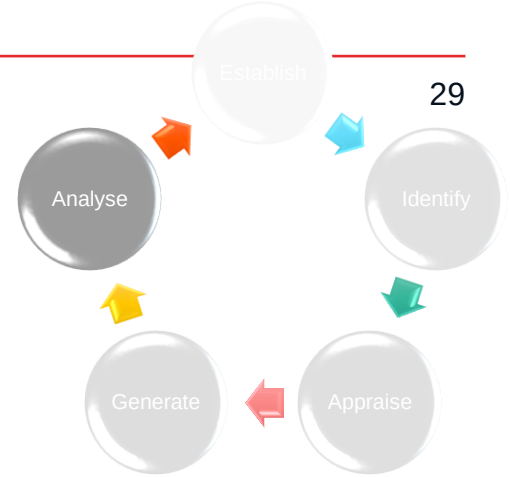
Annex XIV (d) generate, through properly designed clinical investigations in accordance with the clinical development plan, any new or additional clinical data necessary to address outstanding issues.

After analysis to GSPRs, any gaps in the data identified should be taken into consideration and activities initiated for collection of clinical data to bridge those gaps.

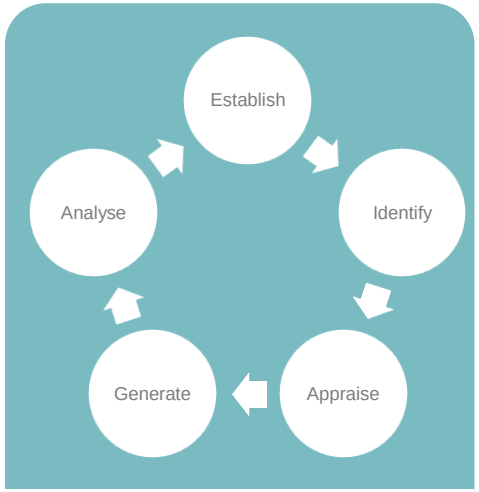
This is also the stage that the manufacturer will initiate clinical investigations per the Clinical Development Plan.

Finally, the evaluators should describe residual risks & any uncertainties or unanswered questions. The evaluators should also include aspects such as rare complications, uncertainties regarding medium- & long-term performance, or safety under wide-spread use.

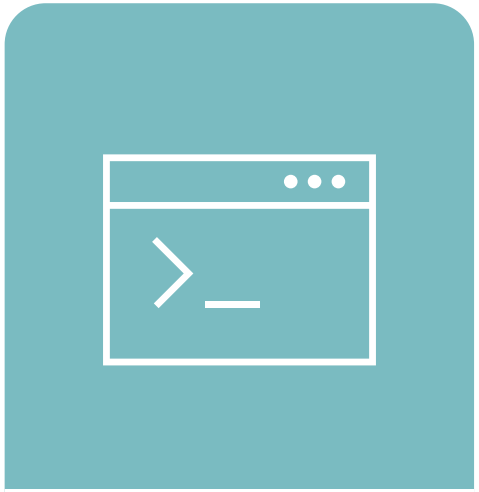
Stage 4 – Clinical Evaluation



Annex XIV Part A (e) analyse all relevant clinical data in order to reach conclusions about the safety and clinical performance of the device including its clinical benefits.



It is important that the report outlines the different stages of the Clinical Evaluation.



The Clinical Evaluation Report should be dated and version controlled.

CVs and DOI should be presented.

Manufacturers should also consider the gaps that remain & consider appropriate activities for the PMCF Plan.

The Clinical Evaluation Report (CER)

The results of the Clinical Evaluation and the clinical evidence on which it is based shall be documented in a **Clinical Evaluation Report** which shall support the assessment of the conformity of the device.

The Clinical Evaluation Report (CER)

Conclusion:
Signatures/dates/version
References
Appendices

Executive summary

Scope

Clinical background, current knowledge, state of the art

Device under evaluation

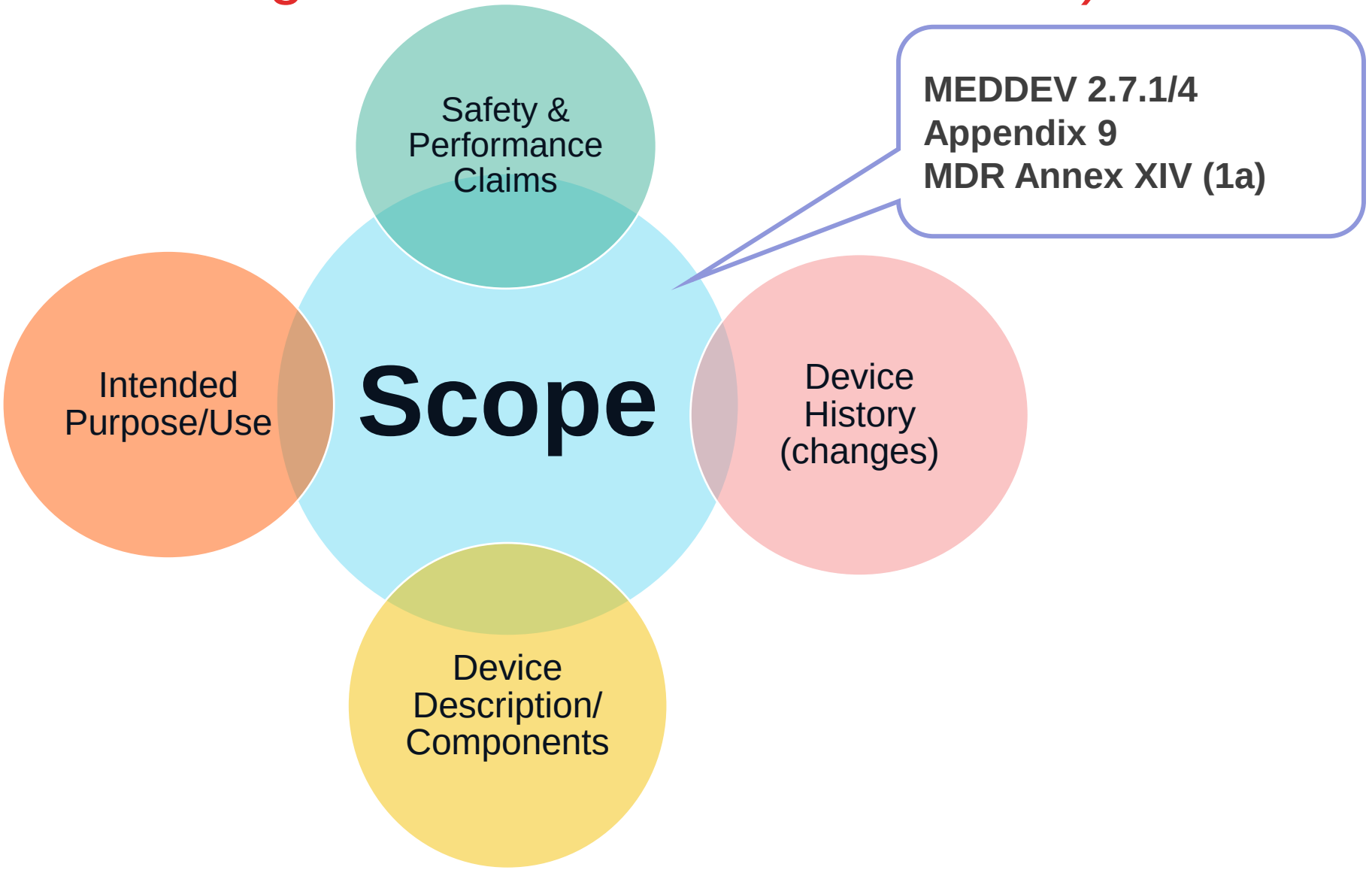
Clinical data generated and held by manufacturer

Clinical data from literature

Summary and appraisal of clinical data

Analysis of clinical data

The Clinical Evaluation Report
(MEDDEV 2.7.1/4 Stage 4/ MDR Annex XIV Part 4)



3 Important considerations when performing a Clinical Evaluation of Software

- **Valid Clinical Association/ Scientific Validity**
- Important to demonstrate a good founded relationship or clinically accepted corresponding to the clinical condition, indication or parameters defined in the intended purpose.

- **Technical/Analytical Performance**
- Demonstration of the MDSW's ability to accurately, reliably and precisely generate the intended output, from the input data.

- **Validation of the clinical Performance**
- Demonstration of a MDSW's ability to yield clinically relevant output in accordance with the intended purpose. The clinical relevance of a MDSW's output is a positive impact

bsi.

Article 61 & MDSW

CHAPTER VI

CLINICAL EVALUATION AND CLINICAL INVESTIGATIONS

Article 61

Clinical evaluation

1. Confirmation of conformity with relevant general safety and performance requirements set out in Annex I under the normal conditions of the intended use of the device, and the evaluation of the undesirable side-effects and of the acceptability of the benefit-risk- ratio referred to in Sections 1 and 8 of Annex I, shall be based on clinical data providing sufficient clinical evidence, including where applicable relevant data as referred to in Annex III.

The manufacturer shall specify and justify the level of clinical evidence necessary to demonstrate conformity with the relevant general safety and performance requirements. That level of clinical evidence shall be appropriate in view of the characteristics of the device and its intended purpose.

To that end, manufacturers shall plan, conduct and document a clinical evaluation in accordance with this Article and Part A of Annex XIV.

What is Sufficient?
(Amount & Quality)

Amount

- Does the data support the intended use, indications, target groups, clinical claims and contraindications?
- Have the clinical risks and analytical performance/ clinical performance been investigated?
- Have relevant MDSW's characteristics, such as the data input and output, the applied algorithms or type of interconnection been considered when generating the data to support the performance of the device?
- What is the grade of innovation/ history on the market (how big is the body of scientific evidence)?
- Other, as applicable.

Quality

- Were the type and the design of the study/ test appropriate to meet the research objectives?
- Was the data set appropriate and actual (state of the art)?
- Was the statistical approach appropriate to reach a valid conclusion?
- Were all ethical, legal and regulatory considerations/ requirements taken into account?
- Is there any conflict of interest?
- Other, as Applicable

bsi.

Examples of Data Sets & Clinical Investigations

Example of Data Sets

Examples of existing data (in no particular order)

- Technical standards

- Professional medical society guidelines

- Systematic scientific literature review

- CLINICAL INVESTIGATIONs/ CLINICAL PERFORMANCE STUDIES

- Published CLINICAL DATA (e.g. Summary of Safety and Clinical Performance (SSCP) / Summary of Safety and Performance (SSP), Registries and databases from authorities)

Examples of generating new evidence (in no particular order)

- Secondary data analysis (Analysis of real-world data)

- Perform CLINICAL INVESTIGATION / CLINICAL PERFORMANCE STUDY

Clinical Investigations

MDSW Class III & Implantable (MDR)

Clinical Investigations Applicable*
(*Unless Article 61 (4), (5) or (6) are fulfilled)

MDSW (IVDR)

Performance Studies Applicable**
(**Unless due justification provided for reliance on other sources of clinical performance data)

MDR – For other classifications (IIa/IIb Non-implantable) clinical investigations should still be considered based on the device's intended purpose, sufficiency of existing data etc.

bsi.

What type of Clinical Investigation/Performance Study is required?

Example: MDSW that is used for patients presenting for chest pain to analyse blood results with an ECG (EKG) and make a decision whether the patient is having a myocardial infarction (Heart Attack) and should be escalated for routine, urgent or emergency treatment.

What type of Clinical Investigation/Performance Study is required?

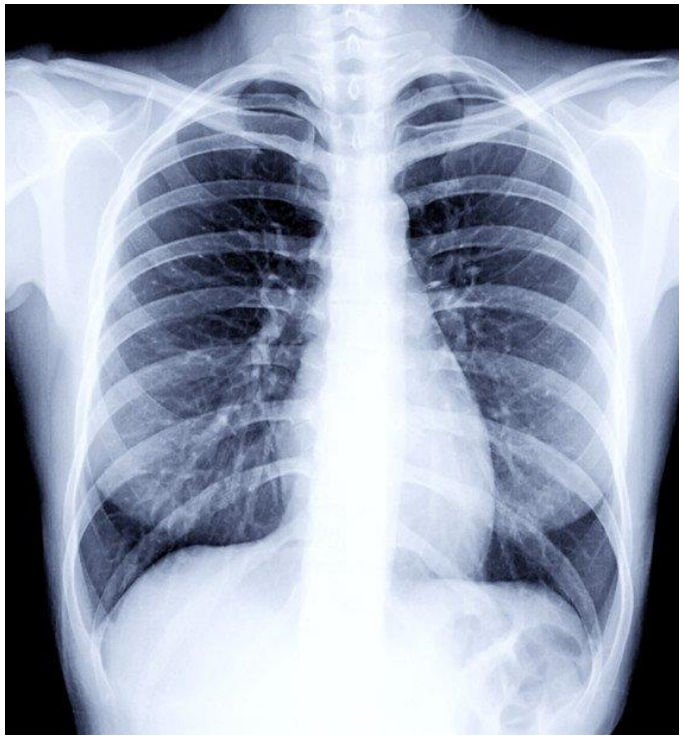
Example: MDSW that is used for patients presenting for chest pain to analyse blood results with an ECG (EKG) and make a decision whether the patient is having a myocardial infarction (Heart Attack) and should be escalated for routine, urgent or emergency treatment.

- The claimed intended purpose of this software is significant enough to determine the a patients future state *i.e. are they having a heart attack?*
- *The claimed intended purpose is also determining patient management i.e. should they get immediate care or can they be seen less urgently.*

Conclusion: Based on these points and that new risk are introduced it would be expected that a prospective study is performed.

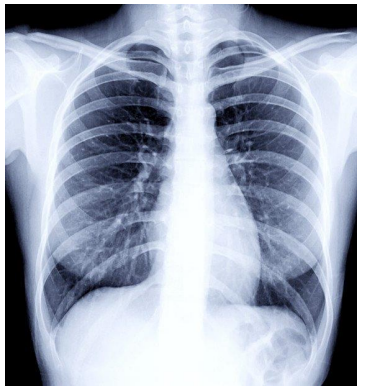
What type of Clinical Investigation/Performance Study is required?

Example: Software that screens outpatient chest X-Rays to determine whether they are normal or abnormal prior to radiologist review. All X-rays (abnormal or normal) are still screened by a radiologist.



What type of Clinical Investigation/Performance Study is required?

Example: Software that screens outpatient chest X-Rays to determine whether they are normal or abnormal prior to radiologist review. All X-rays (abnormal or normal) are still screened by a radiologist.



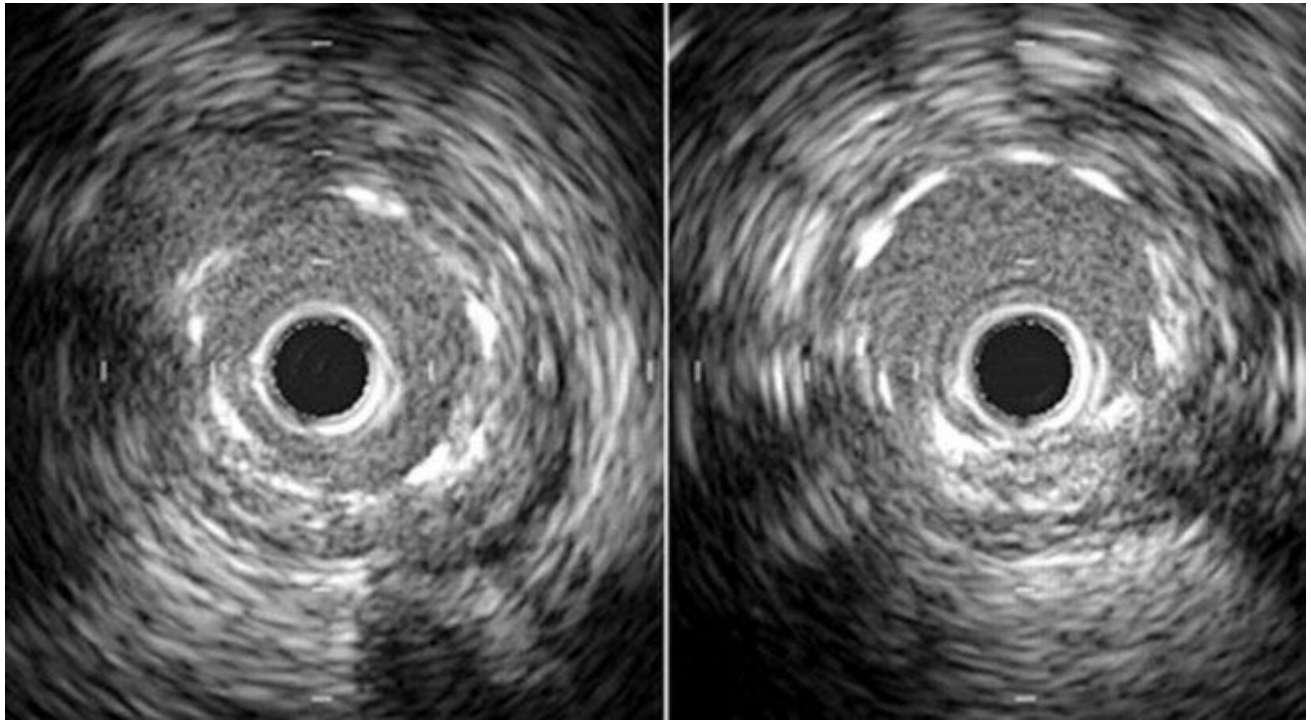
- The claimed intended purpose of this software does not change of impact the patients future state. – ***Caution!***
- *The claimed intended purpose is not determining patient management.*

<u>Conclusion: No new risks are introduced (The software supports the radiology department current clinical practice) a retrospective study could be considered acceptable in the scenario.</u>

bsi.

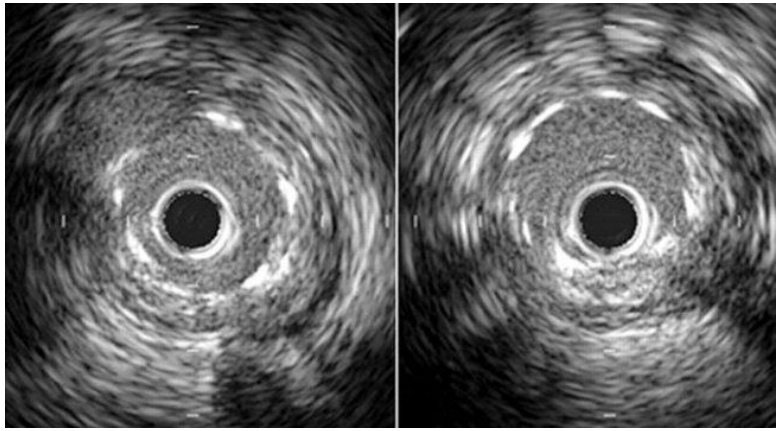
What type of Clinical Investigation/Performance Study is required?

Example: Software that drives the function of an intravascular ultrasound (IVUS) imaging probe for detection of atherosclerotic plaques or stent apposition.



What type of Clinical Investigation/Performance Study is required?

Example: Software that drives the function of an intravascular ultrasound (IVUS) imaging probe for detection of atherosclerotic plaques or stent apposition.



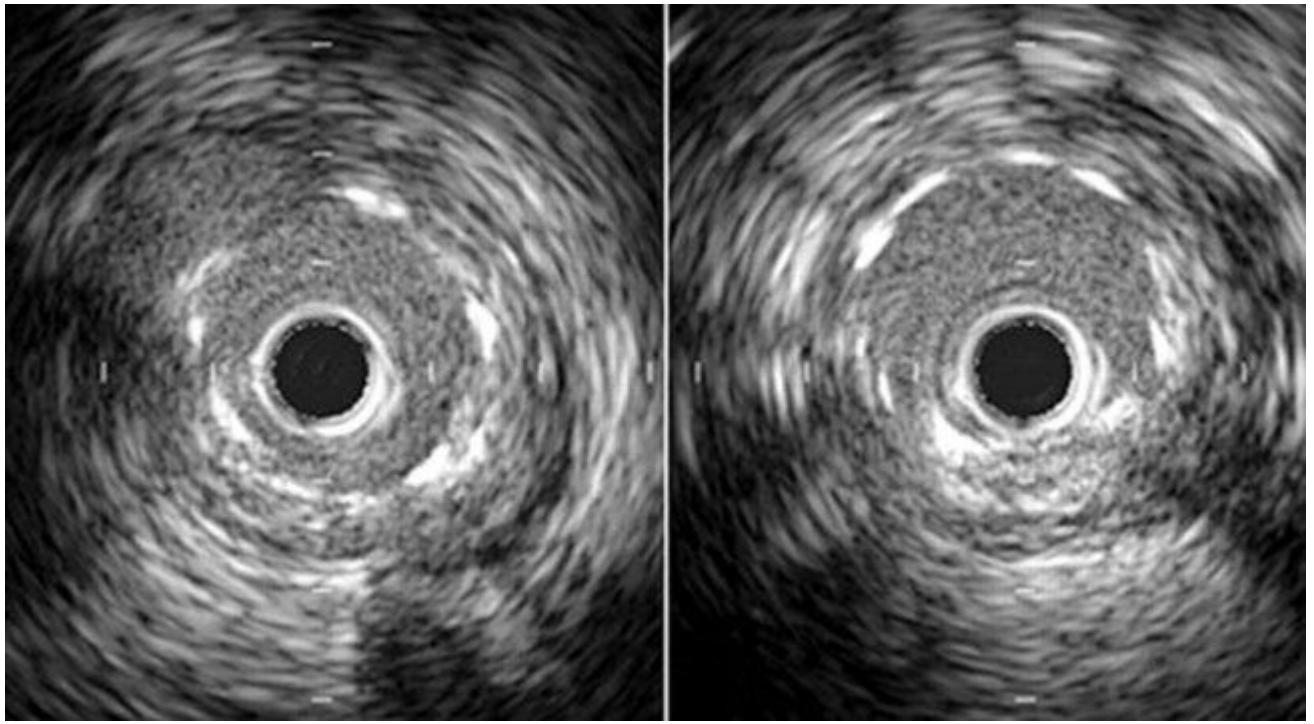
Considered Class III Medical Device.

- *The claimed intended purpose* When used with the medical device *is determining patient management.*

Conclusion: Clinical Investigations would be needed (normally prospective) but these investigations should consider the software as part of the medical device.

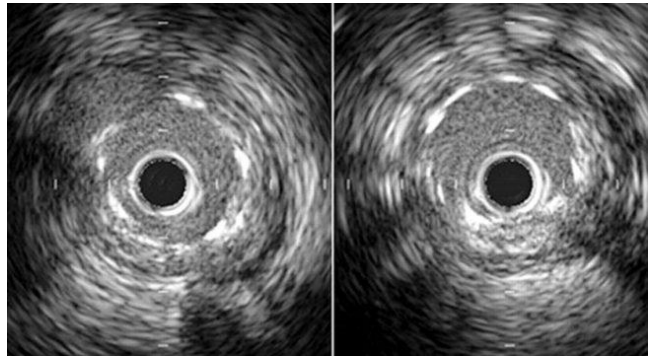
What type of Clinical Investigation/Performance Study is required?

Example: Additional software to the Intravascular Ultrasound that determines whether the plaques are '*hot*' and subject to rupture and thrombosis.



What type of Clinical Investigation/Performance Study is required?

Example: Additional software to the Intravascular Ultrasound that determines whether the plaques are '*hot*' and subject to rupture and thrombosis.



- The claimed intended purpose of this software is significant enough to determine the a patients future state *i.e. are they susceptible to a plaque rupture?*
- *The claimed intended purpose is also determining patient management i.e. should they receive intervention*

Conclusion: Based on these points and that new risk are introduced it would be expected that a prospective study is performed.

Clinical Investigations in the context of MDSW

Prospective Studies

- Predisposition
- Prognosis
- Prediction
- Treatment efficacy
- Patient Management Decision

Retrospective Studies*

- No impact to patient management
- Research does not introduce new risks

** Based on the assumption there is sufficient access to obtain the data for purposes of conformity to GSPRs*

All Pre-Market Clinical investigations irrespective of prospective/retrospective will need to comply as far as appropriate with Article 62 -82

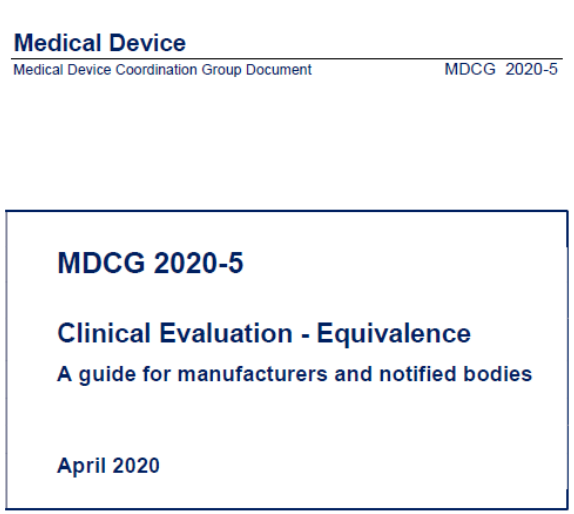
Or if conducted outside of the EU will need to meet the required standards of ISO14155

bsi.

Equivalence and MDSW

Software

- Algorithms should be ‘Similar’ including driving/influencing or MDSW intended to be used alone.
- *It is the functional principle of the software algorithm, as well as the clinical performance(s) and intended purpose(s) of the software algorithm, that shall be considered when demonstrating the equivalence of a software algorithm*
- Software solely intended for configuration of a device (e.g. graphical user interface an not related to a medical purpose doe not need to be similar providing there are no negative impacts to usability, safety or clinical performance.



Is Article 61 (10) Applicable to Software?

This cannot Apply to Class III or Implantable Devices

'**Clinical Performance & Claims**'
Article 2 (52)

CHAPTER VI

CLINICAL EVALUATION AND CLINICAL INVESTIGATIONS

Article 61

Clinical evaluation

10. Without prejudice to paragraph 4, where the demonstration of conformity with general safety and performance requirements based on clinical data is not deemed appropriate, adequate justification for any such exception shall be given based on the results of the manufacturer's risk management and on consideration of the specifics of the interaction between the device and the human body, the clinical performance intended and the claims of the manufacturer. In such a case, the manufacturer shall duly substantiate in the technical documentation referred to in Annex II why it considers a demonstration of conformity with general safety and performance requirements that is based on the results of non-clinical testing methods alone, including performance evaluation, bench testing and pre-clinical evaluation, to be adequate.

Consideration should be given to the risk(s) of the device and the interaction with the human body.

Manufacturer should justify why it is acceptable to use this route to conformity

Allowance for non-clinical data to be considered (Article 2 (48))

Article 61 (10)

- A clinical evaluation is still required with a documented justification and demonstration of how the pre-clinical data can support conformity with the GSPRs

- This should be documented within the Clinical Evaluation Report.

BSI Medical Devices – Use Our Resources

https://www.bsigroup.com/en-GB/medical-devices/resources

Brochures, Guides and Documents

MDR guidance

MDD Best Practice Guidelines >
MDR Best Practice Guidelines >
MDR Mapping Guide >
MedDev 2.7.1 Rev 4 changes >
MDR Conformity Routes >
MDR Readiness Review >

Webinars

MDR Conformity Assessment Routes webinar

MDR - What we know

Download the presentation >

Join and follow us on LinkedIn

Share your knowledge, challenges and news with others on LinkedIn.

White Papers and Articles

Person responsible for regulatory compliance (PRRC) - MDR/IVDR Article 15

With the MDR and IVDR, European regulators aim to ensure companies have a regulatory expert – a Person Responsible for Regulatory Compliance (PRRC) – at their disposal, to ensure that the company is meeting certain specific EU requirements.

Software as a medical device - A comparison of the EU's approach with the US's approach

The International Medical Device Regulators Forum (IMDRF) aims to accelerate international medical device regulatory convergence. Through the IMDRF, regulators reached consensus on what software is considered a medical device. Regulators call it 'software as a medical device' (SaMD). This paper provides a comparison of how SaMD is regulated in the US and in the EU.

Machine learning AI in medical devices

How is AI different from traditional medical devices and medical software and what are the implications of those differences? What controls are necessary to ensure AI in healthcare is safe and effective?

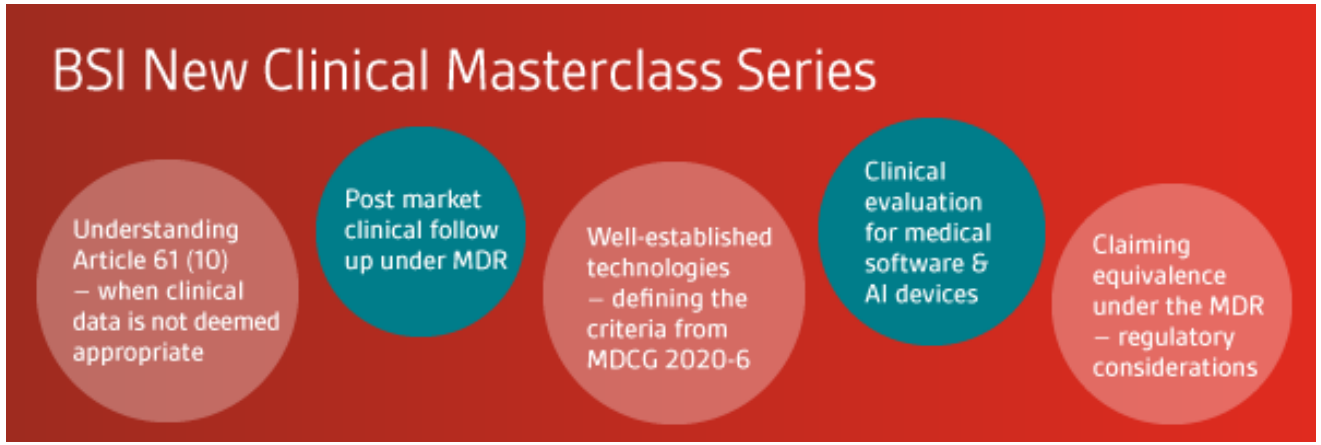
Medical device clinical investigations – What's new under the MDR?

The conduct of a clinical investigation is one of the most time consuming and resource intensive activities that a medical device manufacturer can face. This paper discusses important new requirements for pre-market and post-market clinical investigations under the European MDR.

Training Resources

Medical devices regulation (MDR)	
Transition from MDD to MDR	1 day
Technical Documentation for CE - Marking	1 day
Requirements of MDR for CE - Marking	1 day
Implementing of MDR for CE- Marking	3 days

Further courses for medical devices manifacturers	
Medical Device Single Audit Program (MDSAP)	2 days
ISO 14971 Risk Management	1 day
Creating and Maintaining Technical Files	1 day
Post-market Surveillance and Vigilance	1 day
Clinical Evaluation for Medical Devices	1 day
Process Validation for the Medical Device Industry	1 day
Introduction to Medical Device Software	1 day



We have more webinars available in our Clinical Masterclass series.

The next webinar available is:

16th March 2022 – Post Market Clinical Follow Up under MDR

Use the link to sign up to this webinar and any other webinar(s) in the series:

https://www.bsigroup.com/en-GB/medical-devices/resources/webinars/2022/mdr/clinical-masterclass/

bsi.

Questions