The Clinical Evaluation Plan

BSI Clinical Masterclass 2023
Session 1

What can you expect from the Clinical Masterclass 2023 series?

5 sessions focusing on the best practice for detailing your key clinical evaluation documents including:

- The Clinical Evaluation Plan
- The Clinical Evaluation Report
- The Post Market Clinical Follow Up Plan
- The Post Market Clinical Follow Up Report
- The Summary of Safety and Clinical Performance

At the end of these sessions, we will be providing you with a specific best practice guide for documenting your clinical evaluation.

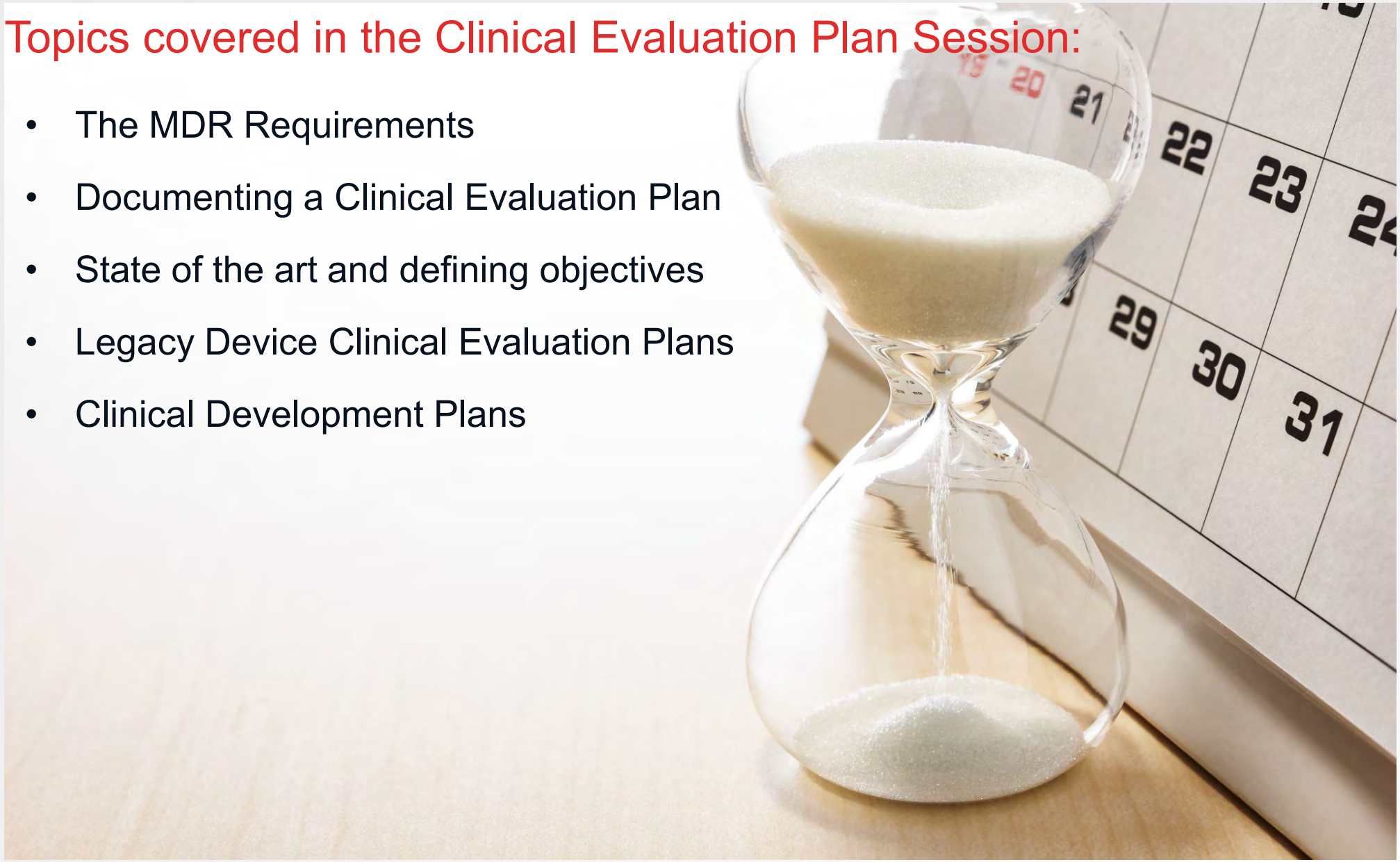
bsi.

Documenting a Clinical Evaluation Plan. (CEP)

Annex XIV Part A

Topics covered in the Clinical Evaluation Plan Session:

- The MDR Requirements
- Documenting a Clinical Evaluation Plan
- State of the art and defining objectives
- Legacy Device Clinical Evaluation Plans
- Clinical Development Plans

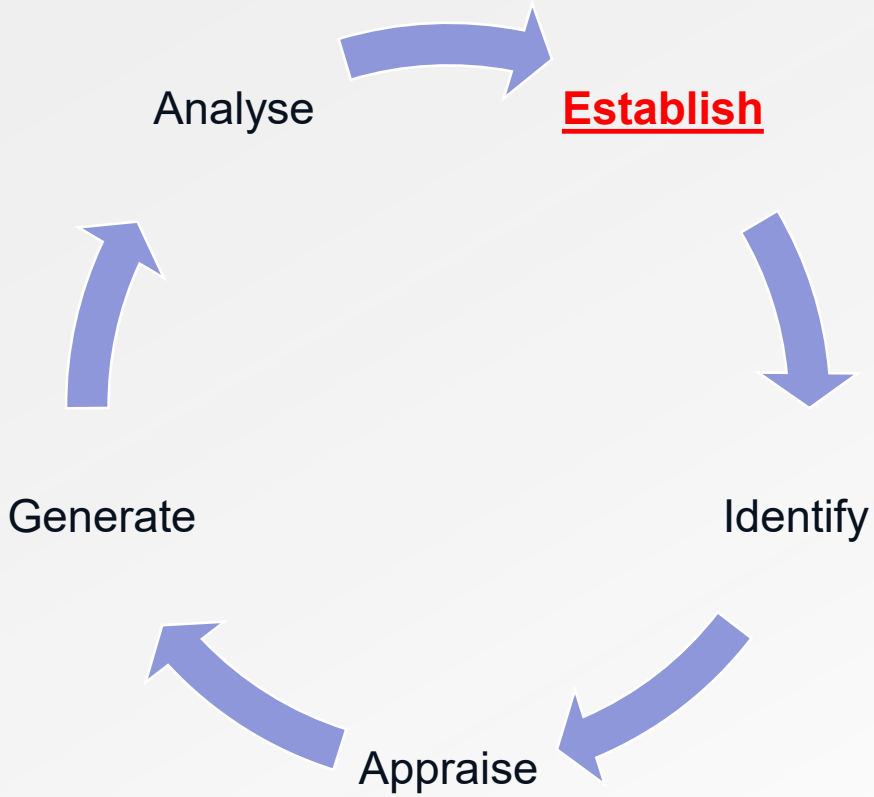


What is the purpose of a Clinical Evaluation Plan?

- The clinical evaluation plan is the foundation of the overall clinical evaluation process and provides the roadmap for the process.

- The clinical evaluation plan sets out the required steps to define the scope, the regulatory pathway and necessary steps to gather the required clinical data in a methodological and systematic approach for the device under evaluation.

'Behind every good clinical evaluation report is a perfect clinical evaluation plan'



The MDR Requirements of the Clinical Evaluation Plan

The MDR is prescriptive on the requirements of the CEP:

GSPR

The CEP needs to identify the general safety and performance requirements that require clinical data

The intended purpose of the device

Intended target groups, clear indications and contra-indications

Intended clinical benefits to patients with relevant and specified clinical outcome parameters

Methods used for qualitative and quantitively aspects of clinical safety to determine residual risk/side effects

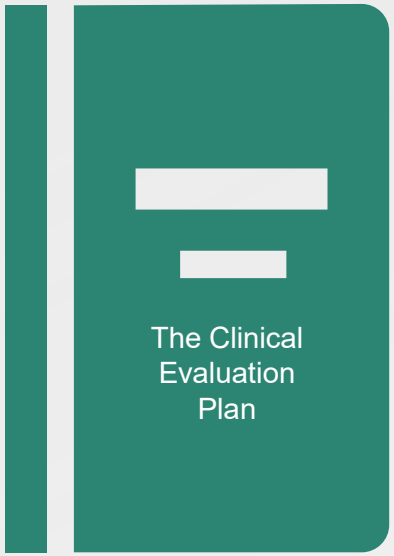
Parameters to be used to determine State of the Art and acceptability of benefit/risk for all indications

Benefit-risk issues relating to specific components such as use of pharmaceutical, non- viable animal or human tissues

A clinical development plan….

bsi.

Where and how should I document my Clinical Evaluation Plan?



The clinical evaluation plan should be clearly highlighted/titled within the technical documentation.

The plan can be presented either as a separate document or as part of the clinical evaluation report. It is essential that wherever the plan is documented the information is easily identifiable, and the complete information is presented.

Considerations when documenting the requirements.

GSPR

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

1. *Devices shall achieve the performance intended by their manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose. They shall be safe and effective and shall not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art.*

5. *In eliminating or reducing risks related to use error, the manufacturer shall: (a) reduce as far as possible the risks related to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and (b) give consideration to the technical knowledge, experience, education, training and use environment, where applicable, and the medical and physical conditions of intended users (design for lay, professional, disabled or other users).*

8. *All known and foreseeable risks, and any undesirable side-effects, shall be minimised and be acceptable when weighed against the evaluated benefits to the patient and/or user arising from the achieved performance of the device during normal conditions of use.*

bsi.

Tips when documenting the GSPRs that will require clinical data.

- Document the GSPRs clearly with consideration of a table format to identify and where possible explain the rationale for clinical data.
- This rationale will help understand the thought process and can assist the Notified Body in determining whether the manufacturer has adequately identified all the applicable GSPRs that require support from relevant clinical data for the device under assessment.

GSPR #	Requirement	Justification
14.5	Devices that are intended to be operated together with other devices or products shall be designed and manufactured in such a way that the interoperability and compatibility are reliable and safe.	The implantable device may be used with other manufacturer configurations. The is a lack of data on longer term safety and performance for these combinations. Longer term clinical data from investigations is required to support claims of compatibility with other devices for the lifetime.

Tips when documenting the GSPRs that will require clinical data.

- Avoid generalised statements covering all GSPRs. – This potentially demonstrates that the manufacturer is not applying an appropriate thought process to the device under evaluation.
- Understand the definition of **Clinical Data – Article 2(48)**
- Clinical data is not:
  - **Animal studies**
  - **Toxicology testing**
  - **Bench testing**
  - **Expert opinion not related to clinical experience**
  - **Compliance with CS or standards**
  - **Clinical experience not published in peer-reviewed or scientific literature**.

(48) 'clinical data' means information concerning safety or performance that is generated from the use of a device and is sourced from the following:

— clinical investigation(s) of the device concerned,

— clinical investigation(s) or other studies reported in scientific literature, of a device for which equivalence to the device in question can be demonstrated,

— reports published in peer reviewed scientific literature on other clinical experience of either the device in question or a device for which equivalence to the device in question can be demonstrated,

— clinically relevant information coming from post-market surveillance, in particular the post-market clinical follow-up;

Considerations when documenting the Intended Purpose.

Requirement: a specification of the intended purpose of the device;

Intended Purpose:

means the use for which a device is intended according to the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or statements and as specified by the manufacturer in the 'intended purpose' clinical evaluation; (Article 2 (12))

In the clinical evaluation planning phase, it can be difficult to determine your intended purpose before your collection of clinical data.

The intended purpose should be reflective of what you intend the device to achieve.

N.B: Intended purpose is synonymous with intended use (MDCG 2020-6 (1)) and is different to a device's indication.

bsi.

Considerations when documenting the Intended Purpose

Requirement: a specification of the intended purpose of the device;

The following information should be considered within the *Intended purpose* of the device:

- ✓ exact medical indications (if applicable)
- ✓ name of disease or condition/ clinical form, stage, severity/ symptoms or aspects to be
- ✓ treated, managed or diagnosed
- ✓ patient populations (adults / children / infants, other aspects)
- ✓ intended user (use by health care professional / lay person)
- ✓ organs / parts of the body / tissues or body fluids contacted by the device
- ✓ duration of use or contact with the body
- ✓ repeat applications, including any restrictions as to the number or duration of reapplications
- ✓ contact with mucosal membranes/ invasiveness/ implantation
- ✓ contraindications
- ✓ precautions required by the manufacturer
- ✓ single use / reusable
- ✓ other aspects

Meddev 2.7/1 rev 4 Section A3 Device Description

Example

- *The Notified Body device is a permanent implant situated in either the right or left atrium, intended to treat the symptoms of stage 4 heart failure and unstable angina, in adults over the age of 80 years, by improving coronary vasodilatation and should only be implanted by those trained in interventional cardiology procedures with on-site surgical facilities.*

- *The device is contraindicated in patients with a systolic blood pressure <90mmHg. Patients should be suitable for anticoagulation therapy to be eligible for implant.*

bsi.

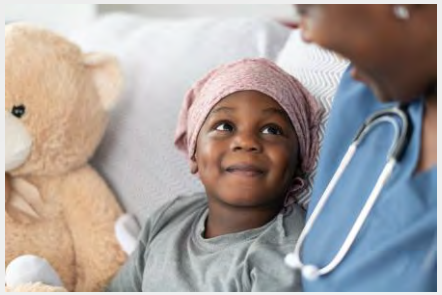
Tips when documenting the Intended Purpose within the CEP

- The intended purpose of the device should be clear and unambiguous. Statements that are vague or nebulous will invite scrutiny from the Notified Body and so it is important to be concise, specific and accurate.
- Ensure that, in all instances in which the intended purpose is cited within the technical documentation, the wording exactly matches what is stated within the CEP.
- If during the clinical evaluation process, the intended purpose changes then it is important to document this and explain the rationale for changing the intended purpose of the device.

Considerations when documenting Intended Target groups

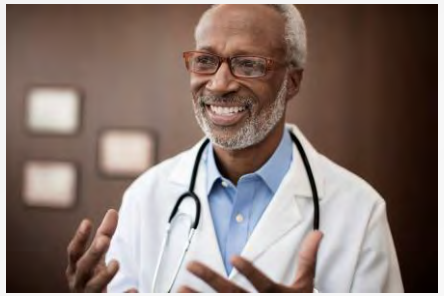
Requirement: — a clear specification of intended target groups with clear indications and contra-indications;

‘Patients’



Gender, Age, Stage/severity of disease, mobility

‘Users’



Healthcare professionals, nurses, scientists, doctors, stage of seniority, sub-specialities

Indications

'indication', 'indication for use': refers to the clinical condition that is to be diagnosed, prevented, monitored, treated, alleviated, compensated for, replaced, modified or controlled by the medical device. ***It should be distinguished*** *from 'intended purpose/intended use', which describes the effect of a device. All devices have an intended purpose/intended use. (MDCG 2020-6 Section 1)*

When considering writing indications for the device, they should be thought of as a checklist of eligible criteria that qualifies the patient to receive the device. This means they should be specific and unambiguous.

Not all devices have an indication, but these are typically devices such as sterilisers or disinfectants. Any absence of an indication should always be strongly justified

Poll Question

Q: Can the indications be identical to the intended purpose?

- Yes
- No

Poll Question

Q: Can the indications be identical to the intended purpose?

- **It Depends…**

Contraindications

Tell when a device should not be used (contraindications). Contraindications are conditions under which the device should not be used because the risk of use clearly outweighs any possible benefit. There may be persons in whom the device should not be used because of their health status. For example, the device may be contraindicated for pregnant women.

Contraindications typically are where this is clear evidence of known harm to patients/users.

Warnings and precautions tell the reader about hazards, other than those that are contraindications to device use. Warnings and precautions provide information on how to avoid these hazards, i.e., sources of harm in the use of the device.

Guidance on Medical Device Patient Labelling; Final Guidance for Industry and FDA Reviewers Document issued on: April 19, 2001

bsi.

Considerations when documenting the clinical benefit

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

'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; (Article 2(53))

- The MDR requires that manufacturers describe the intended clinical benefits to patients in the CEP. In many cases, these will align with the intended purpose statement.

- However, manufacturers can sometimes have difficulty expressing the clinical benefits as benefits afforded to the patient. It is useful therefore to ask the following questions:

    - *How does the use of the device improve the health of the patient?*
    - *What is the positive outcome of using the device, from the perspective of the patient?*

bsi.

Considerations when documenting the clinical benefit

Further, the MDR expects that manufacturers specify the relevant outcome parameters that enable them to demonstrate that these benefits are delivered by the device. It can be thought of in the following way:

If device *x* is going to have positive outcome *y* on the patient, what aspect of *y* can be measured to confirm that the outcome is achieved?

By way of example, a relevant outcome parameter for an orthopaedic device could be an improvement in mobility score reported at x weeks post-surgery.

Tips when documenting the clinical benefits

- ✓ The intended target group may be specific in the case of some devices and broad in the case of others. In either case, it is important that manufacturers demonstrate an awareness of the groups of patients that will benefit from the use of the device.
- ✓ When appropriate the target population should also be clarified considering, gender, age, co-morbidities and other clinical aspects of which the data reflects.
- ✓ Users of the device should also be defined. This should be accompanied with the expected education, grade and experience of the users that can use the device safely as demonstrated by the clinical data. Consideration should also be given when devices are to be used under certain supervision.
- ✓ Where appropriate, the specification should include details such as the grade/stage of disease that the device is indicated for, as well as any limitations that apply. For example, there may be (sub)groups of patients for which use of the device would not be appropriate and this should be clearly stated within the CEP.
- ✓ Where the use of a device by particular group(s) and/or circumstances is deemed hazardous, the manufacturer is expected to include a list of contra-indications *along with warnings and precautions*.

bsi.

Tips when documenting the clinical benefits

- ✓ When clinical benefit scoring systems are to be used, where possible these should ideally be validated national/international agreed scoring systems. E.g. WHOQOL
- ✓ For many devices, the relevant outcome parameters will be obvious. However, for some devices - for example, those used for imaging patients for a variety of purposes - it may be challenging for manufacturers to define relevant outcome parameters. In this case, other performance parameters may be indirectly related to patient benefit. Where the clinical benefit is not directly afforded to the patient, manufacturers should clearly state this and provide a justification as to why the specified clinical performance parameters were selected.

bsi.

Considerations when documenting aspects of safety

Requirement: 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;

- The MDR expects manufacturers to specify, within the CEP, the methods they will use to evaluate the risks posed by use of the device. It is important, therefore, to describe in detail the methods by which information relating to the risks posed by use of the device will be gathered and analysed – both qualitatively and quantitatively.
- This requirement is related to the risk assessment, which should include risks that are identified as part of the clinical evaluation of the device. Manufacturers should include details of how they intend to identify clinical risks as part of the clinical evaluation and should also make clear their intention to determine the residual risks (i.e., post-mitigation) and side-effects associated with the device.

Considerations when documenting the parameters based on State of the Art .

Requirement: 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;

'**state of the art**': IMDRF/GRRP WG/N47 provides the following definition:

*Developed stage of **current technical capability** and/or **accepted clinical practice** in regard to products, processes and patient management, based on the relevant consolidated findings of science, technology and experience.*

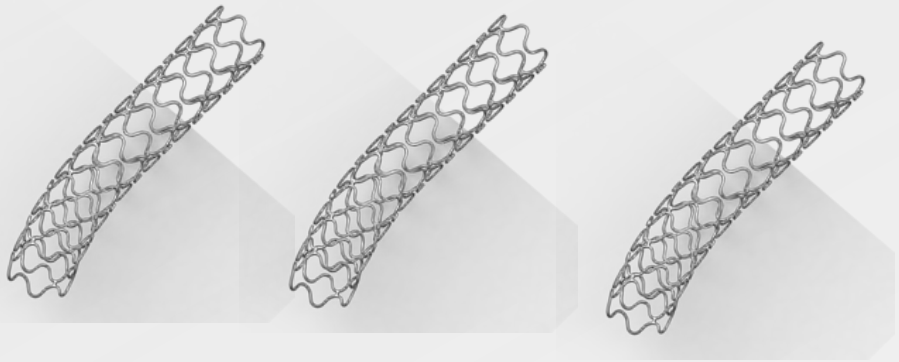
*Note: The state-of-the-art embodies what is currently and generally accepted as **good practice in technology** and **medicine**. The state-of-the-art does not necessarily imply the most technologically advanced solution. The state-of-the-art described here is sometimes referred to as the "generally acknowledged state-of-the-art'*

Reproduced from MDCG 2020-6 (1. Definitions)

bsi.

State of the Art & Defining Objectives

3 Stents identified from State-of-the-Art Search



Stent under Evaluation

State of the Art Results should drive the Safety and Performance objectives for the device under evaluation

Results of SoTA Search

Risk identified - Thrombosis at 12 months – 6-9%
Performance identified – Patency at 5 years – 82-86%

Objectives for Device under Evaluation

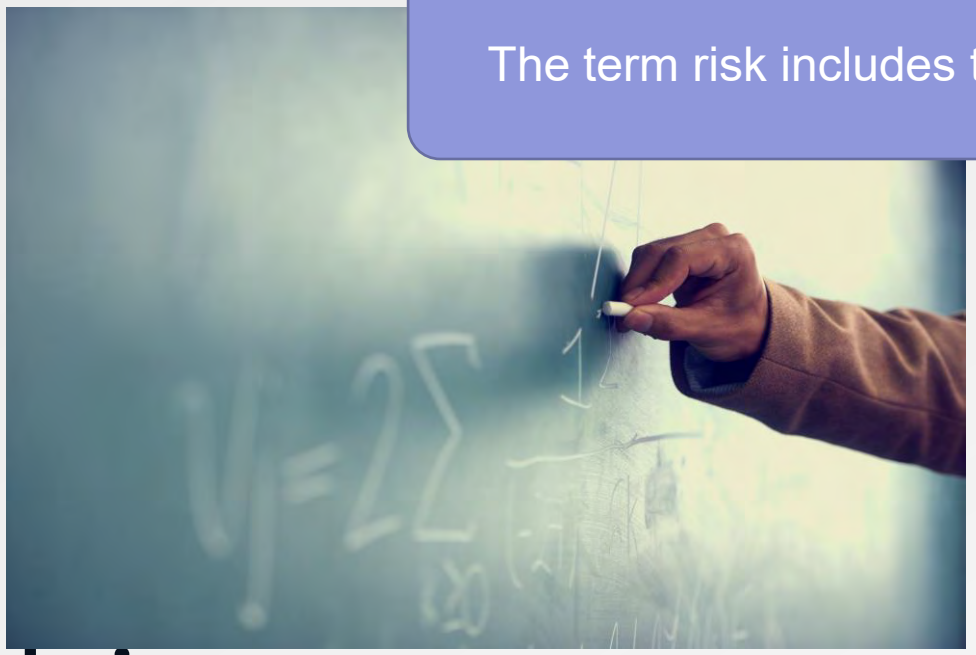
Safety Objective - Thrombosis at 12 months – < 9%
Performance Objective – Patency at 5 years – >82%

Understanding the safety and performance profile of similar devices from State of the Art allows the manufacturer to develop an acceptable safety and performance profile for the device under evaluation. This allows the manufacturer to compare its data against those other technologies to confirm its safety and performance is equal or better than those available devices and ultimately its right to have a position on the market

bsi.

MDR 2017/745 Article 2 (23) – Safety Objectives

(23) 'risk' means the combination of the probability of occurrence of harm and the severity of that harm;

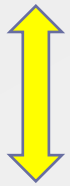


The term risk includes the words probability, so there is always a need for quantification.

Safety Objectives

Outcomes of Risk Management Activities the input for clinical evaluation.
Clinical risks are identified:

- During development process from clinical experts
- Relating to foreseeable misuse (or assessing questions of EN ISO 14971 Annex C)
- Post Market Surveillance Activities



Outcomes of clinical evaluation activities the input for Risk Management.
Clinical risks are identified through:

- literature reviews
- Clinical investigations,
- PMCF related activities

Safety Objectives should be quantified according to;

1. magnitude, (extent, amount, intensity) this should be measurable and patient group specific

2. Probability based on patient populations should be considered. Statements to reflect general population may not be appropriate.

3. Duration - Think quantity!

Safety Objectives.

The main task of the clinical evaluation activities is now to strengthen the confidence of these assumptions through the targeted identification of clinical data e.g. search terms or safety endpoints which relate to specific clinical risks.

MDR 2017/745 – Measurable Objectives.

(52) 'clinical performance' means the ability of a device, resulting from any direct or indirect medical effects which stem from its technical or functional characteristics, including diagnostic characteristics, to achieve its intended purpose as claimed by the manufacturer, thereby leading to a clinical benefit for patients, when used as intended by the manufacturer;

(53) '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;

Clinical Performance Objectives look at 'clinical benefit' and here is the expectation that clinical benefit is measurable and meaningful.

Article 2 (53)

Performance Objectives

Performance objectives should be clinically meaningful:

- **Positive impact on clinical outcomes such as reduced probability of adverse events or improvement of impaired body function,**
- **Patients Quality of Life (freedom from symptoms). Considering international recognized scoring systems**
- **Outcomes related to Diagnosis (Earlier detection, Sensitivity and specificity of diagnosis)**
- **Positive impact from diagnostic devices on clinical outcomes, (Pharmacological intervention sooner).**
- **Public Health Impact (Ability of a diagnostic tool to prevent spread of disease).**
- **Valid Surrogate endpoints can be used if there is a validated predictor. (e.g. measurements of biochemical markers)**

Performance Objectives should be quantified according to;

1. magnitude, (extent, amount intensity) this should be measurable and patient specific

2. Probability based on patient populations should be considered. Statements to reflect the general population may not be appropriate. *(Think Meaningful!)*

3. Duration - Think quantity!

Considerations when documenting specific components

Requirement: 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

Some medical devices feature hazardous components such as pharmaceutical, viable animal or human tissues. Since the action(s) of these may need to be considered separately from the overall device, the manufacturer should explain how they intend to assess the benefits and risks posed by these components as part of the overall clinical evaluation of the device. Where the long-term exposure of the drug or material in its particular application is not fully known, this may also point to a requirement for follow-up studies within the PMCF Plan (Annex XIV, 6.1a)

Clinical Evaluation Plans for Legacy Device

MDCG 2020-6 Appendix A

Expectations of clinical evaluation plans for legacy devices

Appendix II – Clinical Evaluation Plan for Legacy Devices[54]

A modified Clinical Evaluation Plan for legacy devices should include at least:[55]

- An identification of the GSPR that require support from relevant clinical data.
- A specification of the intended purpose of the device.[56]
- 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 strategy to identify, analyse and assess alternative treatments[57].
- 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.
- A strategy and methodology to identify, analyse and appraise all relevant available clinical data in light of the changed definition for clinical data.
- Evidence for equivalence, if clinical data from an equivalent device is included in the clinical evaluation.
- A definition of the required level of clinical evidence, which shall be appropriate in view of the characteristics of the device and its intended purpose.[58 59 60]
- A strategy and methodology to systematically collect, summarise and assess post market surveillance data to demonstrate continuing safety and performance, and to what extent complaints with regards to safety and performance have been observed with the legacy devices.[61]

There is no justification for an absence of a CEP for a legacy device – remember the CEP is the foundation of your clinical evaluation and this is a continuous process.

MDCG 2020-6 Appendix II provides the minimum information expected for legacy device CEP.

Remember this is for devices that have not had design modifications or expansion of indications.

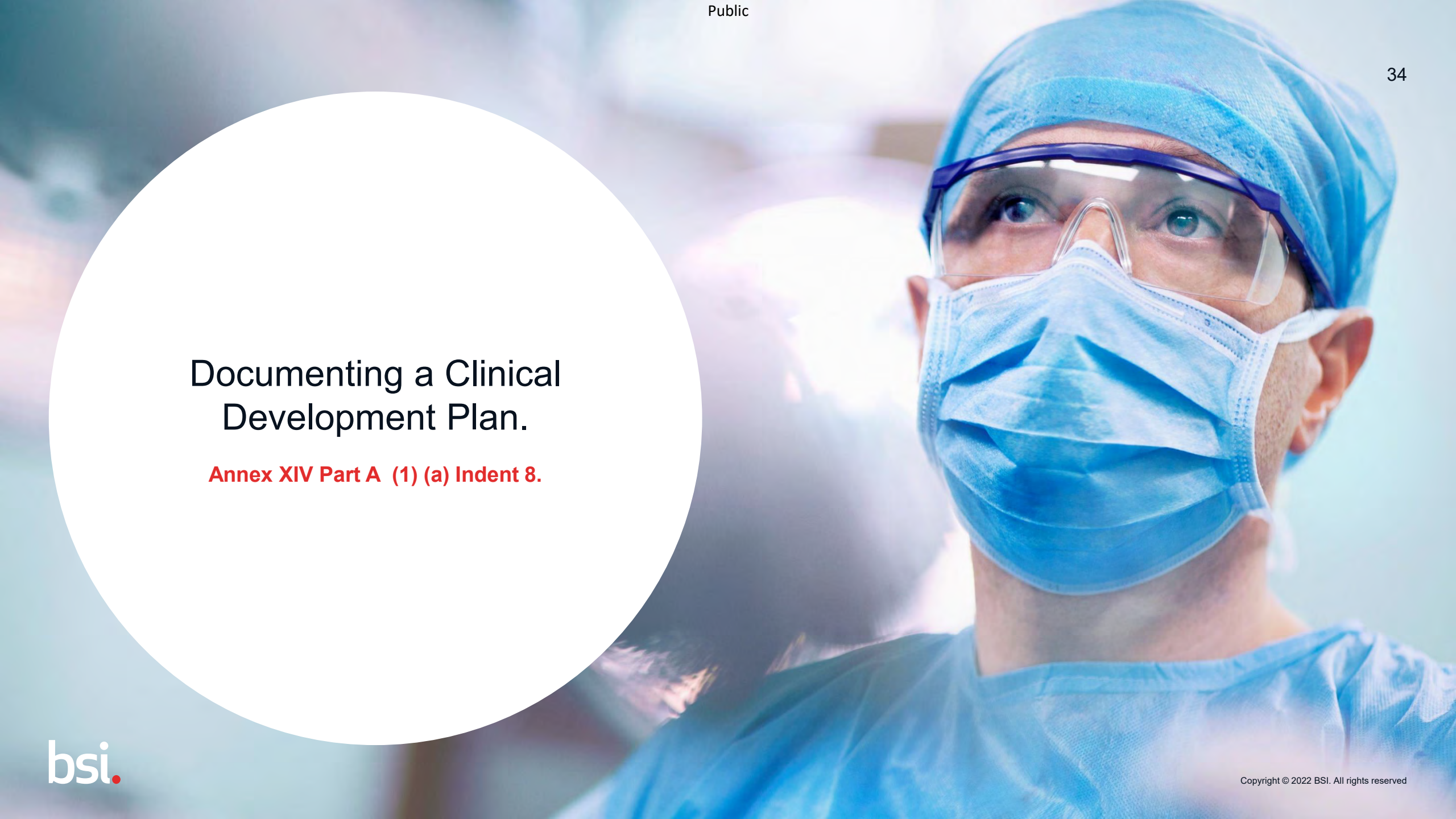
This list can form the titles for the various sections of your CEP, allowing the notified body to locate information easily and quickly.

Don't forget the clinical development plan!

bsi.

Documenting a Clinical Development Plan.

Annex XIV Part A (1) (a) Indent 8.



The Requirement (MDR 2017/745)

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

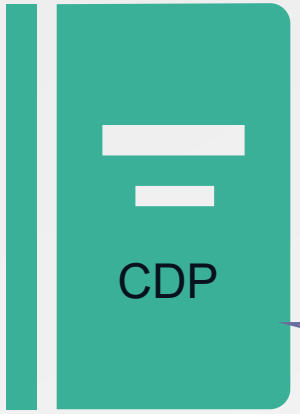
bsi.

Clinical Development Plan in 1 Slide (Annex XIV Part A)

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.

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

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



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.

The Clinical Development Plan should indicate potential acceptance criteria.

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.

**Off label studies are not PMCF studies and are subject to the same scrutiny and processes of the Competent Authority as non-CE marked investigations.*

bsi.

Documenting a Clinical Development Plan **for New MDR Devices**.

Annex XIV Part A (1) (a) Indent 8.

Key Components of a CDP

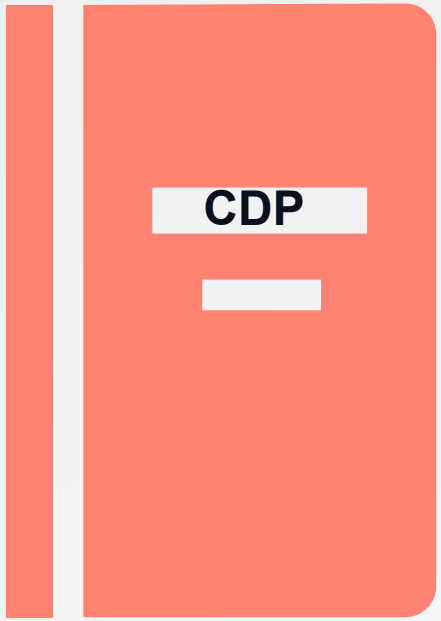
Prospective Patients

Scientific Rationale for Development

Commercial Rationale for Development

Clinical Data (Emphasis on Clinical Investigations)

Strategic Planning



Scientific Rationale for Development

Unmet Clinical Needs/Expansion of Clinical Indications

Limitations of Current Therapies/Diagnostics

Drug/Device Interaction

Commercial Rationale for Development

Unmet Market Need(s) – Unmet Clinical Need(s)

Market Size Assumption and Projections

International Considerations

Competitive Situation

bsi.

Clinical Investigations

The MDCG have published a Clinical Investigations Reporting Template (MDCG 2021-8)

Consider Compliance of CIP to ISO14155 Annex A & MDR Annex XV

Clearly Document within the CDP:

- *Study design.*
- *Devices identified. – Think Accessories!!!*
- *Patient population.*
- *Patient numbers.*
- *Objectives and endpoints.*
- *Length of follow up and intervals.*
- *Study locations.*

Consider potential deviations.

MDCG 2020-13 encourages NBs to review all this information. MDCG 2019-9 also provides a list of detailed information in relation to reporting clinical investigations.

bsi.

Strategic Planning

- Milestones
- Longer term plans (PMCF)
- Market Access (Controlled Roll Out?)
- No-go Criteria
- Risk assessment & Contingency Plans
- Regulatory Aspects

Poll Question

Q: Is a Clinical Development Plan Required for Legacy Devices?

- Yes
- No

Poll Question

Q: Is a Clinical Development Plan Required for Legacy Devices?

- **Yes**
- **No**

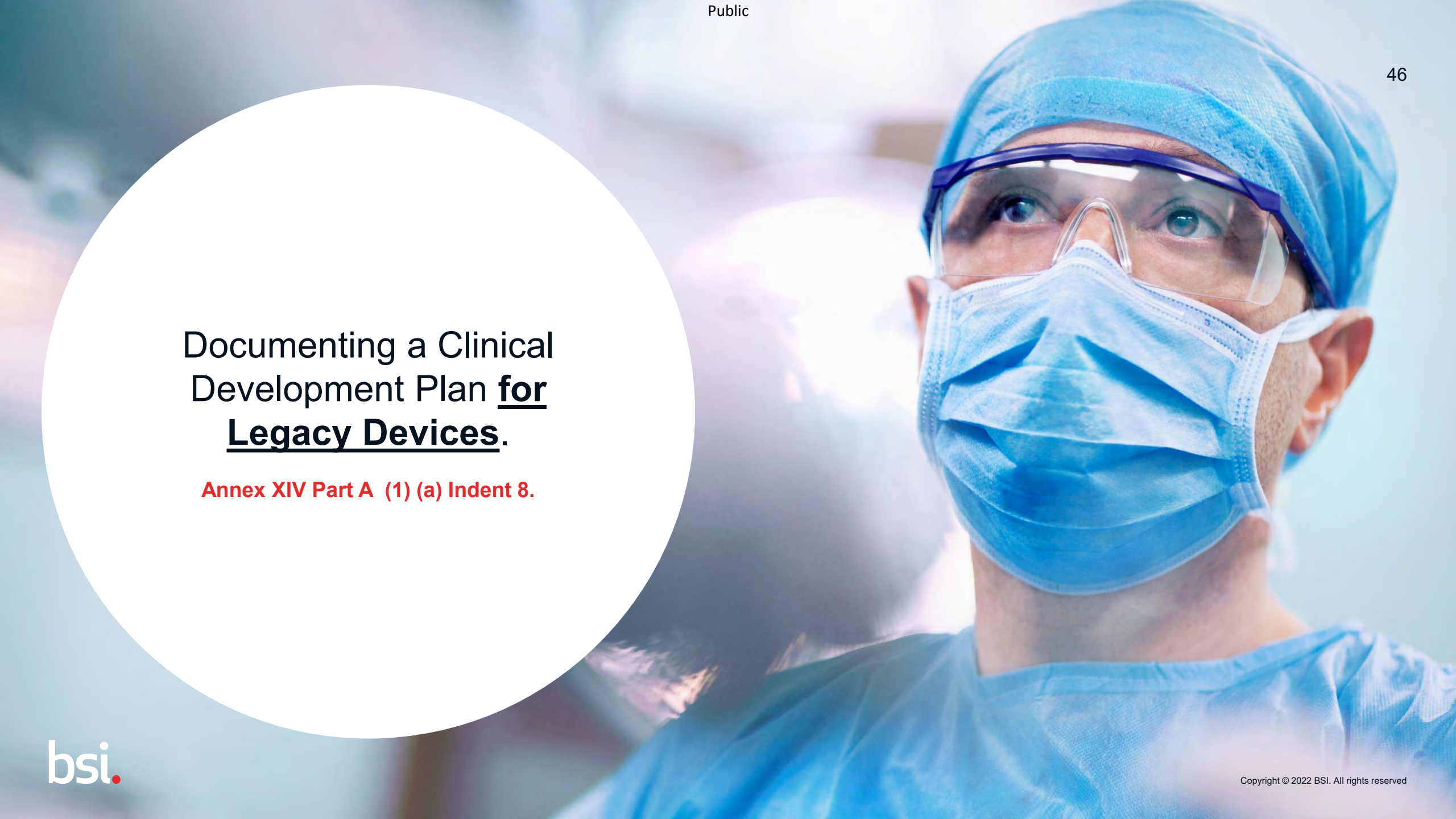
Considerations

The Clinical Development Plan is a critical document for those wishing to gain consultation from the Expert Panels as described in Article 61 (2) – *Class III and Class IIb Rule 12 Administer or Remove Medicinal Substances.*

Consultation Process is likely to be available 2023 for a limited number of devices – Further information is likely early 2023.

Documenting a Clinical Development Plan **for Legacy Devices**.

Annex XIV Part A (1) (a) Indent 8.



Legacy Devices and the CDP

ALL manufacturers are required to document a clinical development plan to meet the requirements of MDR Annex XIV Section 1a.

Premarket elements of the plan as described in the final indent of MDR Annex XIV Section1a (first-in-man studies, feasibility and pilot studies) are not generally relevant to legacy devices ***which are unchanged in design or indications****.*

However, the context for the plan as described in indents 1-7 and the basis for the PMCF as described in indent 8 of MDR Annex XIV Section 1a are ***considered relevant and necessary for demonstration of compliance to the MDR.***

Medical Device

Medical Device Coordination Group Document MDCG 2020-6

MDCG 2020-6

Regulation (EU) 2017/745: Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC

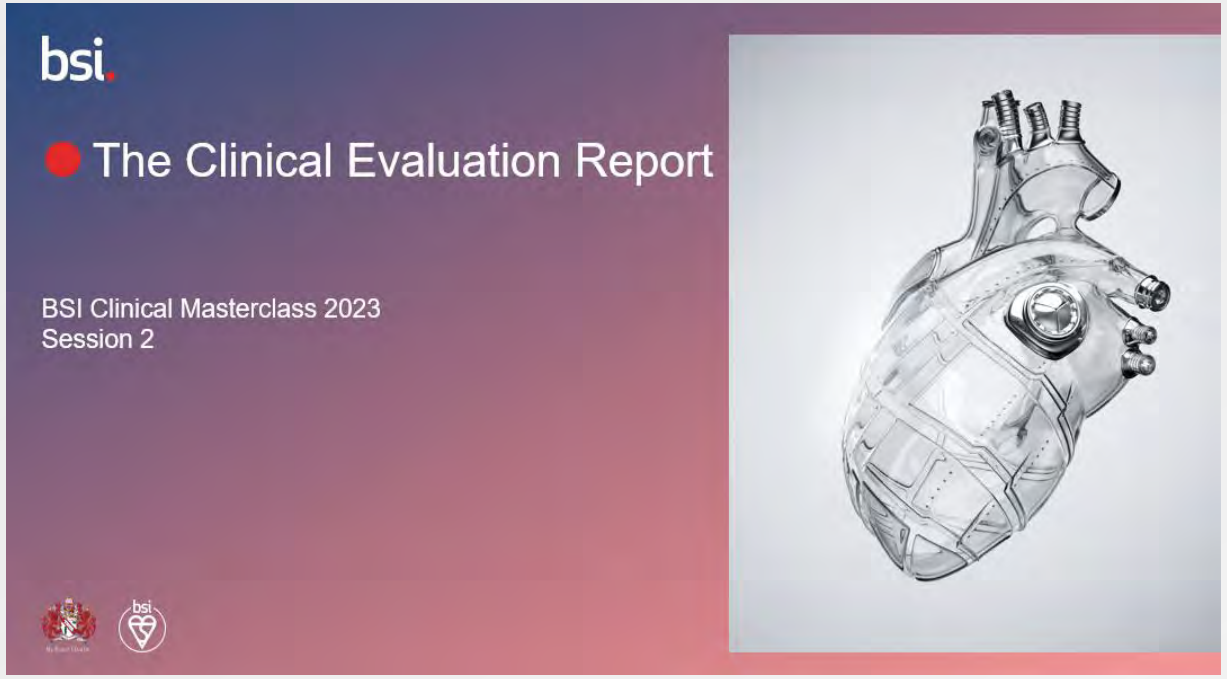
A guide for manufacturers and notified bodies

April 2020

This document has been endorsed by the Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/745. The MDCG is composed of representatives of all Member States and it is chaired by a representative of the European Commission.The document is not a European Commission document and it cannot be regarded as reflecting the official position of the European Commission. Any views expressed in this document are not legally binding and only the Court of Justice of the European Union can give binding interpretations of Union law.

bsi.

Next Session Slide:



How to document:

- ✓ Device Description
- ✓ Equivalence
- ✓ Similar Device Data
- ✓ Clinical Claims
- ✓ Literature Searches
- ✓ Updates and Competency

Next Session: **Wednesday 25th January 2023**
Clinical Evaluation Report Part I

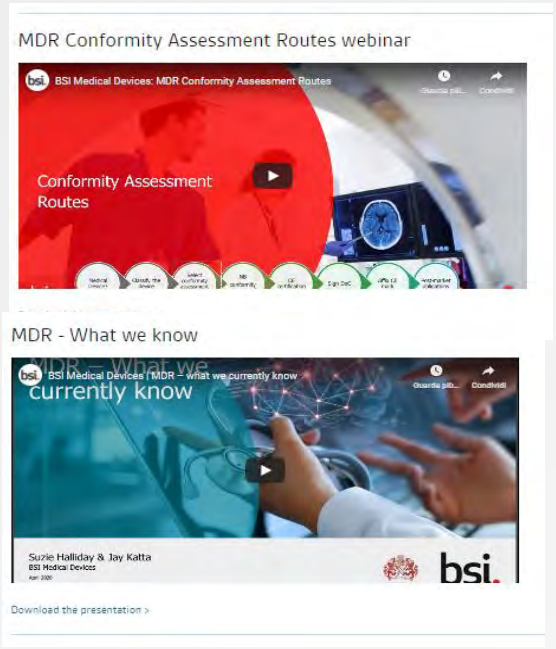
bsi.

BSI Medical Devices – Use Our Resources

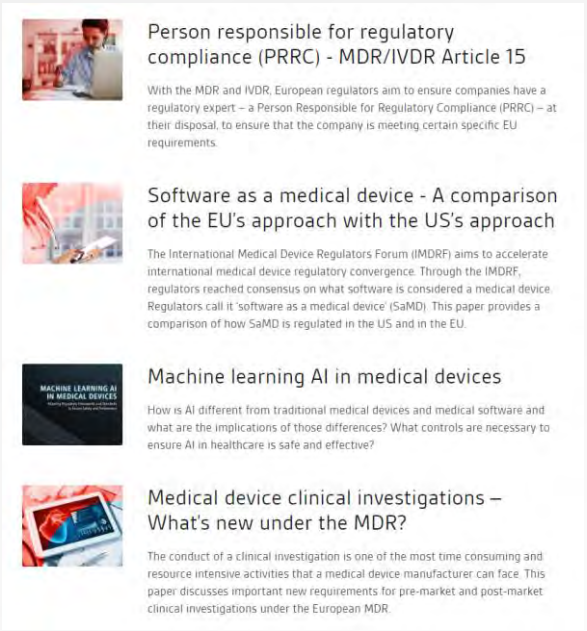
https://www.bsigroup.com/en-GB/medical-devices/resources

Brochures, Guides and Documents

Webinars

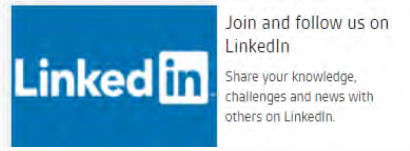


White Papers and Articles



Follow us on LinkedIn:

https://www.linkedin.com/showcase/bsi-medical-devices/



bsi.

End slide