Article 61 (6) & MDCG 2020-6

Clinical Masterclass - Well Established Technologies

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By Royal Charter

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Poll Question

Do you consider yourself a manufacturer of a Well-Established Technology?

- Yes
- No

Topics Covered in this presentation;

- ❑ What is meant by the term 'WET'? (Article 52 (5))
- ❑ What devices can be considered WET according to the MDR?
- ❑ MDCG 2020-6 & the term 'WET'
- ❑ 4 Criteria of WET from MDCG 2020-6
- ❑ MDCG 2020-6 Key Messages
- ❑ When to consider sufficient levels of evidence?
- ❑ Questions

Poll Question

Do you agree with the following statement –

Any legacy device be considered a WET because it has been previously marketed.

a. Agree
b. Disagree

A certain group of devices…(Article 52)

4. Manufacturers of class IIb devices, other than custom-made or investigational devices, shall be subject to a conformity assessment as specified in Chapters I and III of Annex IX, and including an assessment of the technical documentation as specified in Section 4 of that Annex of at least one representative device per generic device group.

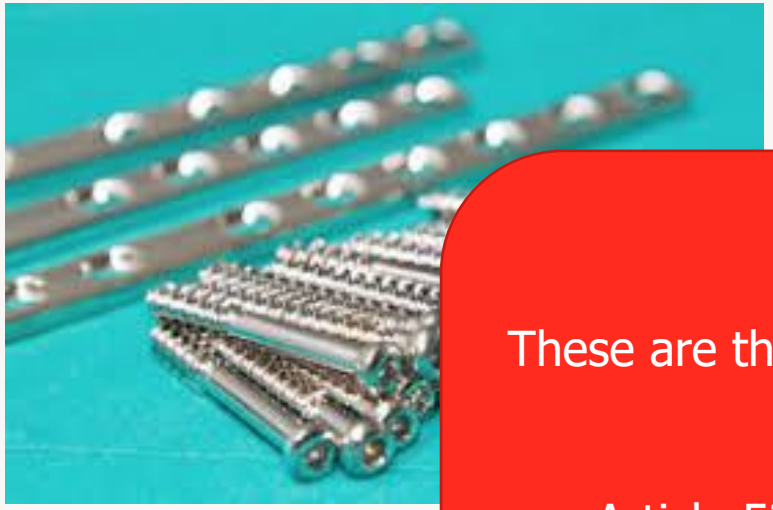
However, for class IIb implantable devices, except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors, the assessment of the technical documentation as specified in Section 4 of Annex IX shall apply for every device.

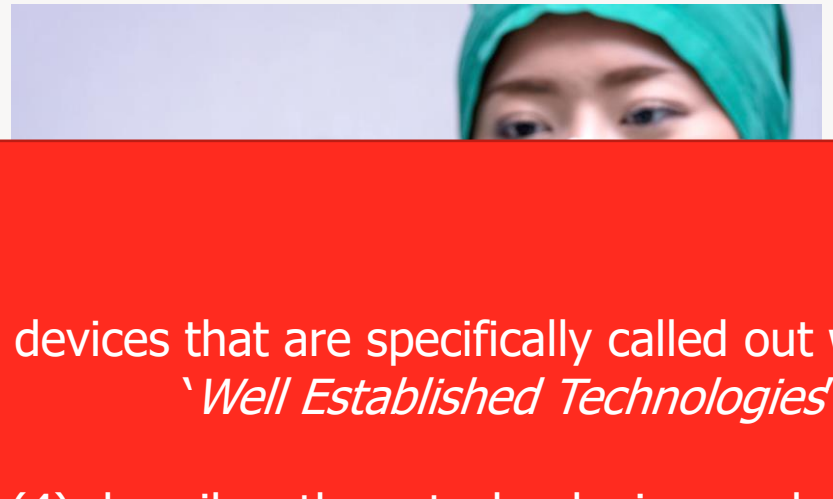
Alternatively, the manufacturer may choose to apply a conformity assessment based on type examination as specified in Annex X coupled with a conformity assessment based on product conformity verification as specified in Annex XI.

Article 52 (4) of the MDR allows for a certain group of Class IIb implantable devices to be 'sampled' through the certificate cycle.

This group of class IIb implantable devices are permitted to allow for technical sampling' through the certificate cycle because they are low risk implantable devices with an established safety and performance profile for their generic device group.

Well Established Technologies

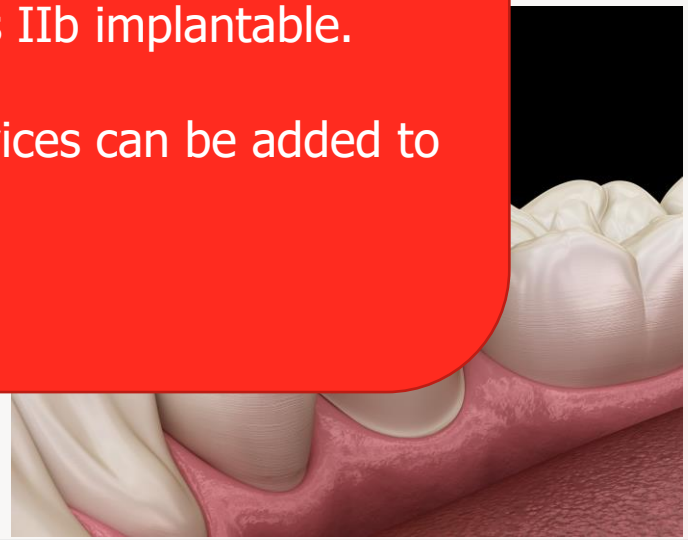




These are the devices that are specifically called out within the MDR text as '*Well Established Technologies*'

Article 52 (4) describes these technologies as class IIb implantable.

Article 52 (5) of the MDR makes it clear how other devices can be added to this list.



Article 52 (5)

Article 52 (5) refers to this certain group of devices as '*well established technologies*'

5. Where justified in view of well-established technologies, similar to those used in the exempted devices listed in the second subparagraph of paragraph 4 of this Article, being used in other class IIb implantable devices, or where justified in order to protect the health and safety of patients, users or other persons or other aspects of public health, the Commission is empowered to adopt delegated acts in accordance with Article 115 to amend that list by adding other types of class IIb implantable devices to that list or removing devices therefrom.

The MDR is clear that the conformity assessment route for this group of class IIb devices cannot be changed unless by a delegated act in accordance to Article 115.

A delegated act means that the European Parliament must approve this change.

What does this have to do with Clinical Evaluation and Clinical Evidence?

MDR Article 61 (6)

This paragraph within Article 61 is related to types of Class III and Implantable devices that do not require clinical investigations

Clause (a) allows for class III /Implantable legacy devices not to perform clinical investigations and to move to MDR - but should have sufficient clinical data

6. The requirement to perform clinical investigations pursuant to paragraph 4 shall not apply to implantable devices and class III devices:

(a) which have been lawfully placed on the market or put into service in accordance with Directive 90/385/EEC or Directive 93/42/EEC and for which the clinical evaluation:

— is based on sufficient clinical data, and

— is in compliance with the relevant product-specific CS for the clinical evaluation of that kind of device, where such a CS is available; or

(b) that are sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips or connectors for which the clinical evaluation is based on sufficient clinical data and is in compliance with the relevant product-specific CS, where such a CS is available.

Clause (b) lists a group of devices but how do we know these are Well Established Technologies(WET) as referred to in Article 52 (5) ?

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Article 61 (8)

Here is the term 'WET' again and provides the legal link to those devices we have just seen in Article 61 (6) (b)

8. Where justified in view of well-established technologies, similar to those used in the exempted devices listed in point (b) of paragraph 6 of this Article, being used in other devices, or where justified in order to protect the health and safety of patients, users or other persons or other aspects of public health, the Commission is empowered to adopt delegated acts in accordance with Article 115 to amend the list of exempted devices referred to in the second subparagraph of Article 52(4) and in point (b) of paragraph 6 of this Article, by adding other types of implantable or class III devices to that list or removing devices therefrom.

That list can only be amended by a delegated Act i.e. that is a new law and not guidance.

Article 52 (4) refers to the conformity assessment route for WET – *this was on slide 5*

This confirms that WET can be class III or Implantable

So….

According to the MDR it is clear that a new device never previously marketed under Directives can be considered a Well Established Technology if;

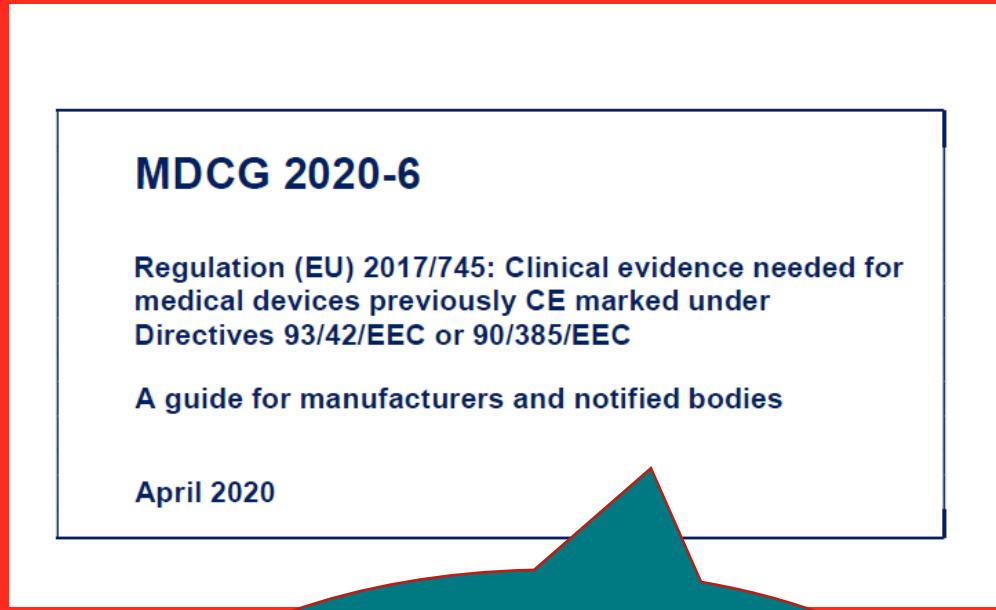
- It is sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors.* and
- is Class III or Implantable

*This list can only change if the MDCG release a delegated Act i.e. a new law amending the list.

Ok, well what about legacy devices? What is classed as a WET for legacy devices?

MDCG 2020-6

- This guidance was created to look at sufficiency of data for legacy devices.
- The MDCG group wanted to ensure that '**standard of care**' devices would be allowed entry under the MDR.
- Obvious but **Important** point: This guidance was created for legacy devices certified under MDD/AIMDD



This document also mentions the term 'Well Established Technology'. But does this have the meaning as we see in the MDR text?

So what does the guidance say about W.E.T?

'well-established technology': this terminology is used in Article 52(5) and Article 61(8) of the MDR, but is not defined in these articles. The term is not restricted to the devices listed in Article 61(6b); Article 61(8) explicitly states that this includes devices similar to the exempted devices listed in Article 61(6b), which might be added to that list in future.

The common features of the devices which are well established technologies are that they all have:

- relatively simple, common and stable designs with little evolution;
- their generic device group has well-known safety and has not been associated with safety issues in the past;
- well-known clinical performance characteristics and their generic device group **are standard of care devices** where there is little evolution in indications and the state of the art;
- a long history on the market.

Therefore, any devices that meet all these criteria may be considered "well established technologies".

These 4 bullet points need to be considered to demonstrate that they are a ***standard of care device***.

Standard of Care Device

~~Well Established Technology~~

The interpretation of WET from MDCG 2020-6 is trying to align with article 61 (6) (a) that for legacy devices sufficent evidence is required and that it may be acceptable that these 'standard of care devices' may have lower levels of evidence if they meet the 4 criteria mentioned previously.

The MDR has to take precedence and the list of WET as mentioned in Article 61 (6) (b) cannot be changed unless by an implement act according to article 115.

MDCG 2020-6: "Sufficient clinical evidence" for legacy devices

Appendix III – Suggested hierarchy of clinical evidence for confirmation of conformity with relevant GSPRs under the MDR

Rank	Types of clinical data and evidence	Considerations / comments
1	Results of high quality[62] clinical investigations covering all device variants,	This may not feasible or necessary for certain well-established devices with broad indications (eg Class IIb legacy sutures, which could be
		Assuming the gaps can be justified, there should be an appropriate PMCF plan to address residual risks. Otherwise, manufacturers shall narrow the intended purpose of the device until sufficient clinical data has also been generated.

But is this really new information or different from the MDR?

Appendix III of MDCG 2020-6 provides a suggested hierarchy of clinical evidence for legacy devices.

The level of evidence may be less for standard of care devices that meet the four criteria points as defined in this guidance

MDR Article 61 (6)

Remember this point that exempts Class III and Implantable legacy devices from clinical investigations?

6. The requirement to perform clinical investigations pursuant to paragraph 4 shall not apply to implantable devices and class III devices:

(a) which have been lawfully placed on the market or put into service in accordance with Directive 90/385/EEC or Directive 93/42/EEC and for which the clinical evaluation:

— is based on sufficient clinical data, and

— is in compliance with the relevant product-specific CS for the clinical evaluation of that kind of device, where such a CS is available; or

(b) that are sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips or connectors for which the clinical evaluation is based on sufficient clinical data and is in compliance with the relevant product-specific CS, where such a CS is available.

Full Circle…Principles of Clinical Evaluation

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.

Class III and Implantable Legacy devices that are '*Standard of care devices'* maybe exempt from performing a clinical investigation if it can be demonstrated that sufficient levels of data exist, the manufacturer should justify what evidence they have to support conformity to the GSPRs.

We should look at the data presented for a legacy device and ask is it sufficient for the device under evaluation and not be too concerned about whether it is WET according to MDCG 2020-6

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The four criteria in MDCG 2020-6 can be helpful to determine the characteristics of what can be considered a 'standard of care' device:

- relatively simple, common and stable designs with little evolution;
- their generic device group has well-known safety and has not been associated with safety issues in the past;
- well-known clinical performance characteristics and their generic device group are standard of care devices where there is little evolution in indications and the state of the art;
- a long history on the market.

Point 1 - relatively simple, common and stable designs with little evolution;

Simple, Common and Stable Designs –

Simple designs should be considered as uncomplicated well known designs with commonly used materials.

Devices that involve additional supporting medical equipment or have specific medicinal or animal tissue properties may not be considered simple.

Commonly used designs could be evident from SoTA literature searches of generic device groups– if the device has novel aspects these may be unacceptable.

Small changes to improve usability could be acceptable. However significant design developments that change how the device is used or functions may not be acceptable.

Little Evolution –

This should consider not only design developments but also consider any developments to other devices in the generic device group.

Point 2 - their generic device group has well-known safety and has not been associated with safety issues in the past;

This could be evidenced by post market surveillance history of the device itself and coupled with known state of the art risk profile for these groups of devices.

MAUDE database searches can also demonstrate the safety profile of the generic device group.

Consider any evidence that the generic device groups have not identified any new residual risks.

Devices that have had Field Safety Notices (FSN) issued in relation to the devices safety or performance may not be able to demonstrate and meet this point.

Point 3 - well-known clinical performance characteristics and their generic device group are standard of care devices where there is little evolution in indications and the state of the art;

'***generic device group***' *means a set of devices having the same or similar intended purposes or a commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics; (Article 2 (7))*

- Manufacturers should demonstrate that their device aligns in relation to safety and performance profile against other devices from that generic group.
- Recommendations of the device or generic device group from medical society or national guidance boards such as NICE can be supportive evidence to demonstrate this point.
- Devices that have changed or unique indications to other generic device groups may not be suitable.

Point 4 - *A long history on the market.*

When was the device first CE Marked?

What is the claimed lifetime of the device?

Has the device achieved its claimed lifetime?

Is there extensive experience of the same users of the device?

Have the indications remained the same through this period?

Does this long history demonstrate that no new residual risks have been identified with the device over recent years?

The market – What markets has the device been placed on? Are there new EU locations? Is there other geographical data to support its long history?

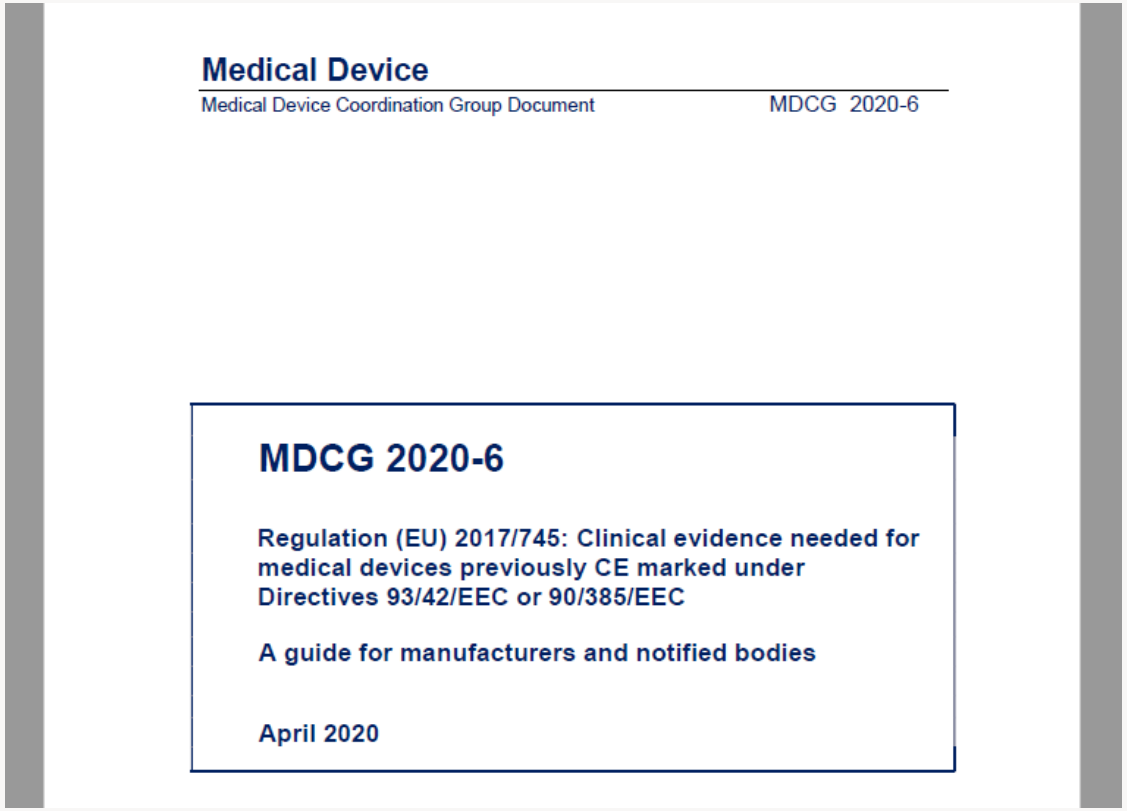
Poll Question

Can a standard of care legacy device rely solely on complaint & vigilance Data?

a. Yes

b. No

What can be considered sufficient clinical data for a legacy device?



MDCG 2020-6 Appendix III provides a helpful list to consider types of data that can be used to support a legacy device.

In line with Article 61 (1) of the MDR:
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.

MDCG 2020-6: "Sufficient clinical evidence" for legacy devices

Key reinforced concepts

- Clinical data generation and evaluation is an ongoing lifecycle process
- Benefit-risk conclusions must be based on consideration of outcomes achievable with other available treatment options
- Benefit-risk conclusions must be based on "sufficient clinical evidence", including PMS data
- The "level of clinical evidence" must be specified and justified by the manufacturer, taking device characteristics and intended purpose into account

MDCG 2020-6: "Sufficient clinical evidence" for legacy devices

Key reinforced concepts

Condensing down page 9:

- Devices previously certified under the Directives might not have "sufficient clinical evidence" under the MDR
- But really, they should have, because they would have been placed on the market on the basis of sufficient clinical data, and they should have been gathering additional clinical evidence as requirements and guidance developed over time
- The clinical evidence used for the initial certification plus data gained from PMS and PMCF will be the basis of MDR applications

But what about the legacy '*Standard of Care*' that may have been placed on the market with little or no clinical evidence, and which are so well-established that little or no clinical evidence was considered to be required?

MDCG 2020-6: "Sufficient clinical evidence" for legacy devices

Key reinforced concepts

Condensing down page 9 (continued):

- Under the Directives, NBs should have required PMCF for devices certified on the basis of equivalence*
- As part of the MDR conformity assessment, NBs should ensure PMCF studies have been undertaken as required under the Directives, and the results incorporated into the manufacturer's clinical evaluation**

* "MEDDEV 2.12/2 regarding PMCF also notes that in the case that clinical evaluation was based exclusively on clinical data from equivalent devices for initial conformity assessment, the certifying notified body shall verify that PMCF studies have been conducted"

** "When assessing the conformity of legacy devices under the MDR, it is important to verify whether PMCF studies considered necessary under the MDD/AIMDD (and where applicable, during the transition period, under the MDR), have been appropriately conducted, and results are taken fully into account for in the clinical evaluation for the conformity assessment under MDR."

Rank #1 of MDCG 2020-6

Rank	Types of clinical data and evidence	Considerations / comments
1	Results of high quality[62] clinical investigations covering all device variants, indications, patient populations, duration of treatment effect, etc	This may not feasible or necessary for certain well-established devices with broad indications (eg Class IIb legacy sutures, which could be used in every conceivable patient population)

This is the ideal level of evidence that would be expected for devices.

This aligns with the MDR requirements for new Class III and implantable devices.

It is known that perhaps older historical devices may not have any data from clinical investigations.

There is also acceptance that clinical investigations may not be practical for some types of devices.

Rank #2 of MDCG 2020-6

Rank	Types of clinical data and evidence	Considerations / comments
2	Results of high quality clinical investigations with some gaps	Gaps must be justified / addressed with other evidence in line with an appropriate risk assessment, and clinical safety, performance, benefit and device claims. Assuming the gaps can be justified, there should be an appropriate PMCF plan to address residual risks. Otherwise, manufacturers shall narrow the intended purpose of the device until sufficient clinical data has also been generated.

Any gaps in clinical investigations will need to be justified or other evidence provided.

We do commonly see lack of evidence to support **ALL** indications.

It can be expected that some indications may have less levels of evidence than others - for example. because it is not as frequently used for that clinical indication.

If this is the case the manufacturer should always justify the level of evidence for each of the indications

Rank #3 of MDCG 2020-6

Rank	Types of clinical data and evidence	Considerations / comments
3	Outcomes from high quality clinical data collection systems such as registries[63]	Is there sufficient evidence of the quality of the data collected by the registry[64, 65]? Are the devices adequately represented? Are the data appropriately stratified? Are the endpoints appropriate to the sa… performances and endpoints identified in the clinical evaluation plan?

This does not specify whether these are national registries or manufacturer registries of data. Both could be acceptable.

National Registries are common for some implantable devices and use of this data could be acceptable. Registries outside of the EU can be supportive but consideration should be given to geographical differences such as clinical practice, patient physiology etc.

Considerations include:

- Can all device variants/indications be identified from this data?
- Comparative data from national/international registries can be supportive to demonstrate state of the art and show that your device aligns to the generic device group.
- Registry data should consider patient outcomes and not market share.

Rank #4 of MDCG 2020-6

Rank	Types of clinical data and evidence	Considerations / comments
4	Outcomes from studies with potential methodological flaws but where data can still be quantified and acceptability justified[66]	Many literature sources fall into this category, due to limitations such as missing information, publication bias, time lag bias, etc. This applies equally to publications in the peer-reviewed scientific literature. However, for legacy devices where no safety or performance concerns have been identified, these sources can be sufficient for confirmation of conformity to the relevant GSPRs if appropriately appraised and the gaps are identified and handled. High quality surveys may also fall into this category.

Data reported form literature on the device under evaluation can be supportive. Note the comment around no safety or performance concerns identified.

High Quality Surveys – We are seeing many manufacturers approach this method. It has any advantages of being able to get data quickly. A ***high quality survey*** should focus on clinical outcomes, indications of which the device has been used and ideally be prospective in its data collection.
Retrospective surveys do have limitations.

Levels 1-4 Statement

Class III legacy devices and implantable legacy devices which are not well-established technologies should have sufficient clinical data as a minimum at level 4. Those devices which are well-established technologies may be able to confirm conformity with the relevant GSPRs via an evaluation of cumulative evidence from additional sources as listed below. Reliance solely on complaints and vigilance is not sufficient.

This statement within Appendix III is important. The message is clear that there is an expectation that Class III and implantable devices have 'high quality clinical data'

The term *'should have'* is there because this is guidance and not legally binding.

There will be some class III devices/Implantable devices where it is impractical to have data levels 1-4 e.g. devices to support an implant, implanted accessories.

The manufacturer should specify and strongly justify the level of evidence if they believe these circumstances apply.

Rank #5 of MDCG 2020-6

Rank	Types of clinical data and evidence	Considerations / comments
5	Equivalence data (reliable / quantifiable)	Equivalence must meet MDR criteria. It is normally expected that manufacturers should gather data on their own devices in the post-market phase, therefore reliance on equivalence should be duly justified, and linked to appropriate PMCF or proactive PMS.

There is an expectation that any devices that claimed equivalence under the MDD should have had appropriate PMCF in place during this time to generate data on their own device.

The regulatory requirements of equivalence must meet the tighter stringent criteria of the MDR if equivalence is claimed.

Rank #6 of MDCG 2020-6

Rank	Types of clinical data and evidence	Considerations / comments
6	Evaluation of state of the art, including evaluation of clinical data from similar devices as defined in Section 1.2 of this document	This is not considered clinical data under the MDR, but for well-established technologies only can be considered supportive of confirmation of conformity to the relevant GSPRs. Data from similar devices may be also important to establish whether the device under evaluation and similar devices belong to the group of devices considered as "well established technologies" (WET). See section 1.2 in this document for the criteria for WET. Data from similar devices may be used, for example, to demonstrate ubiquity of design, lack of novelty, known safety and performance profile of a generic group of devices, etc.

All clinical evaluations should perform a state of the art assessment.

For those groups of devices defined as WET in Article 61 (6) b this can be supportive to demonstrate alignment with the generic device group.

Generally state of the art alone or coupled with PMS and vigilance is not usually sufficient. This guidance suggests that there should be cumulative evidence from additional sources.

Rank #7 of MDCG 2020-6

Rank	Types of clinical data and evidence	Considerations / comments
7	Complaints and vigilance data; curated data	This falls within the definition of clinical data under MDR Article 2(48), but is not generally considered a high quality source of data due to limitations in reporting. It may be useful for identifying safety trends or performance issues. High volume data collected within a robust quality system may provide supportive evidence of device safety.

The guidance does state that compliant and vigilance alone is not sufficient.

All legacy devices should present this data with other sources. If the device has been marketed then this data will exist.

This data can also be helpful in demonstrating alignment with other generic device groups.

Rank #8 of MDCG 2020-6

Rank	Types of clinical data and evidence	Considerations / comments
8	Proactive PMS data, such as that derived from surveys	This falls within the definition of clinical data under MDR Article 2(48), but is not generally considered a high quality source of data due limitations associated with sources of bias and quality of data collection. It may be useful for identifying safety concerns or performance issues.

Proactive PMS data is helpful to confirm or identify existence of any safety concerns or performance issues.

Note: Surveys are mentioned here again, this is assumed to be ***lower quality surveys*** compared to those mentioned in rank #4

Examples of lower quality surveys include:

- Retrospective surveys
- End user surveys focused on experience of device
- Low return rates
- Not focused on PROMS
- Limited to address small gaps in data

Rank #9 of MDCG 2020-6

Rank	Types of clinical data and evidence	Considerations / comments
9	Individual case reports on the subject device	This falls within the definition of clinical data under MDR Article 2(48), but is not considered a high quality source of data due to limitations in generalising findings to a wider patient population, reporting bias, etc. It may provide supportive or illustrative information with respect to specific claims.

Individual Case Reports could be supportive in retaining indications where the device is rarely used.

Case reports may also be helpful to support lower risk devices where larger clinical investigations are impractical or not feasible.

Rank #10 of MDCG 2020-6

Rank	Types of clinical data and evidence	Considerations / comments
10	Compliance to non-clinical elements of common specifications considered relevant to device safety and performance	Common specifications which address clinical investigation or data requirements directly would rank higher in this hierarchy. Common specifications may address clinically relevant endpoints through non-clinical evidence such as mechanical testing for strength and endurance, biological safety, usability, etc.

At this point of the hierarchy we start to see the introduction and acceptability of pre-clinical data.

We are yet to see common specifications published by the EU Commission in relation to clinical evaluation.

However any CS that address clinically relevant endpoints through non-clinical evidence should be presented to support the conformity assessment.

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Rank #11 of MDCG 2020-6

Rank	Types of clinical data and evidence	Considerations / comments
11	Simulated use / animal / cadaveric testing involving healthcare professionals or other end users[67]	This is not clinical data, but may be considered evidence of confirmation of conformity to relevant GSPRs, particularly in terms of usability, such as for accessories or instruments.

This aligns with Rank #10 of the hierarchy. This is not clinical data but for certain devices can be used as cumulative evidence to conform to the relevant GSPRs

If this evidence is ever used then some follow up PMCF or proactive PMS may be required to confirm any claims or to substantiate the evidence provided.

Rank #12 of MDCG 2020-6

Rank	Types of clinical data and evidence	Considerations / comments
12	Pre-clinical and bench testing / compliance to standards[62]	Pre-clinical and bench testing may address clinically relevant endpoints through non-clinical evidence such as mechanical testing for strength and endurance, biological safety, usability, etc.

Again aligning with Ranks #10 and #11.

Not considered clinical data.

Devices that rely on pre-clinical data will typically need to consider some PMCF activities to gather clinical data to support these claims.

For some devices where pre-clinical data is appropriate they should consider Article 61 (10) to see if this is relevant and may be an easier route to conformity.

Tell the Story…

Article 61 (1): *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.***

- **Describe why the evidence you hold can be considered sufficient and why this evidence can meet the relevant GSPR.**
- **Describe why that evidence you hold is appropriate given the devices intended purposes and characteristics of the device.**
- **If there are gaps or flaws in your evidence then be transparent about this and describe how you plan to address these.**

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

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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?

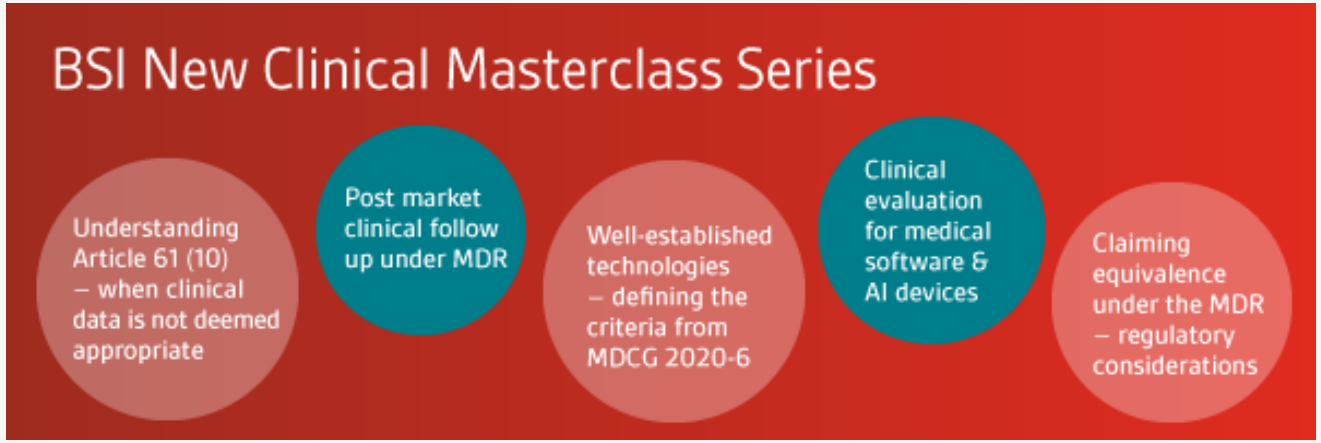
Medical device clinical investigations – What's new under the MDR?

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:

2nd February 2022 - Understanding Article 61 (10) – When Clinical Data is not deemed appropriate

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/

Questions?

By Royal Charter