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Align your Clinical Claims with the Clinical Performance and Safety Endpoints

Helene Quie, CEO

Qmed Consulting A/S

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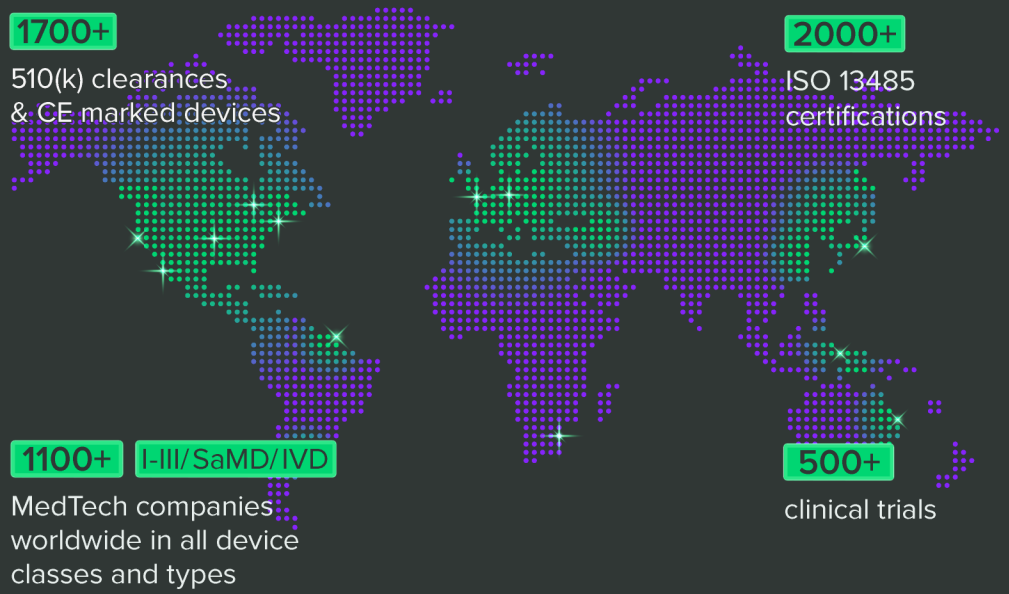

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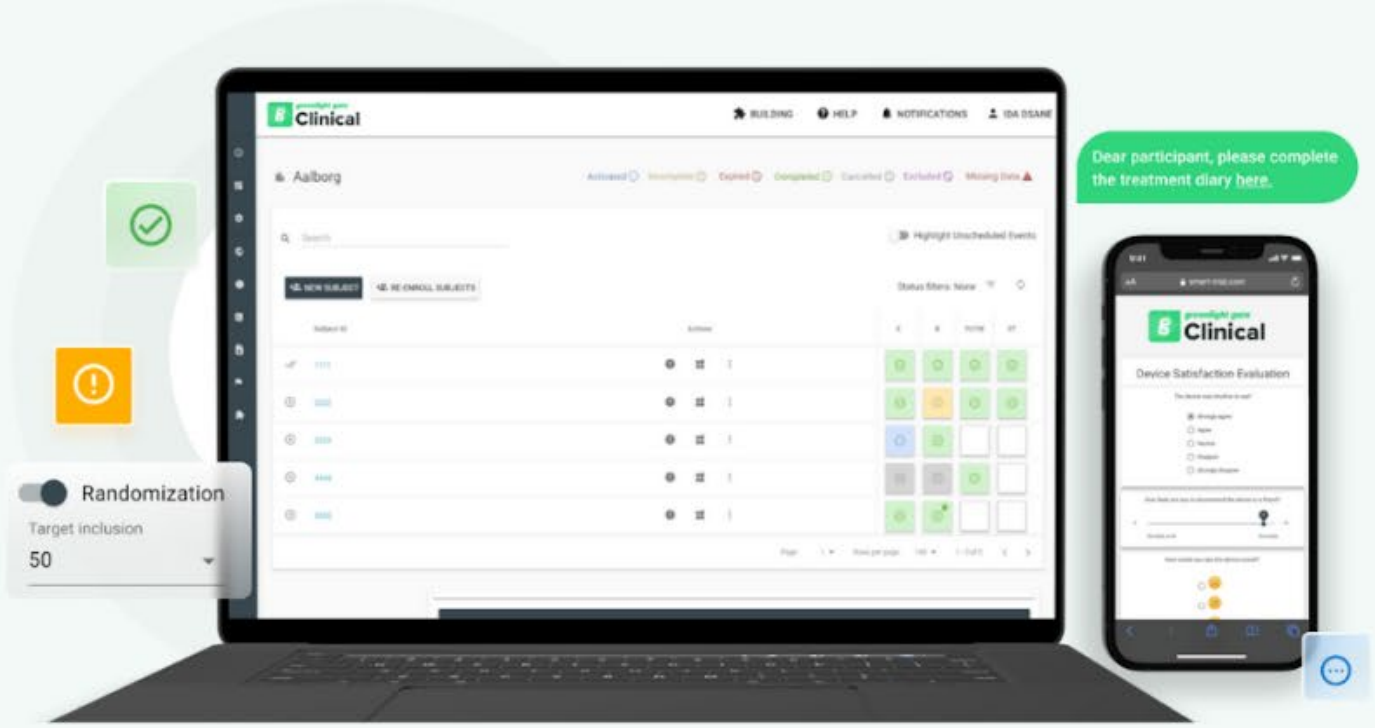

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Setting the stage.....

What are the most common findings we see from the Notified Bodies...

1. Demonstrating compliance will rely on presenting sufficient clinical evidence for the device and its variations under assessment.
2. Presentation of evidence: lack of detailed analysis, tabulation, references.
3. No clear link between conclusions and the SOTA, safety/performance objectives and clinical benefits – Missing the red thread in the analysis!
4. Inconsistency across documentation: CEP, CER, IFU, Risk Management File, etc.
5. PMS data that has not been incorporated into the CER.
6. CEP that does not consider CDP, even when there have been modifications.
7. Lifetime is not considered nor adequately supported by evidence.

MDCG 2021-6

Defining ‘Performance’

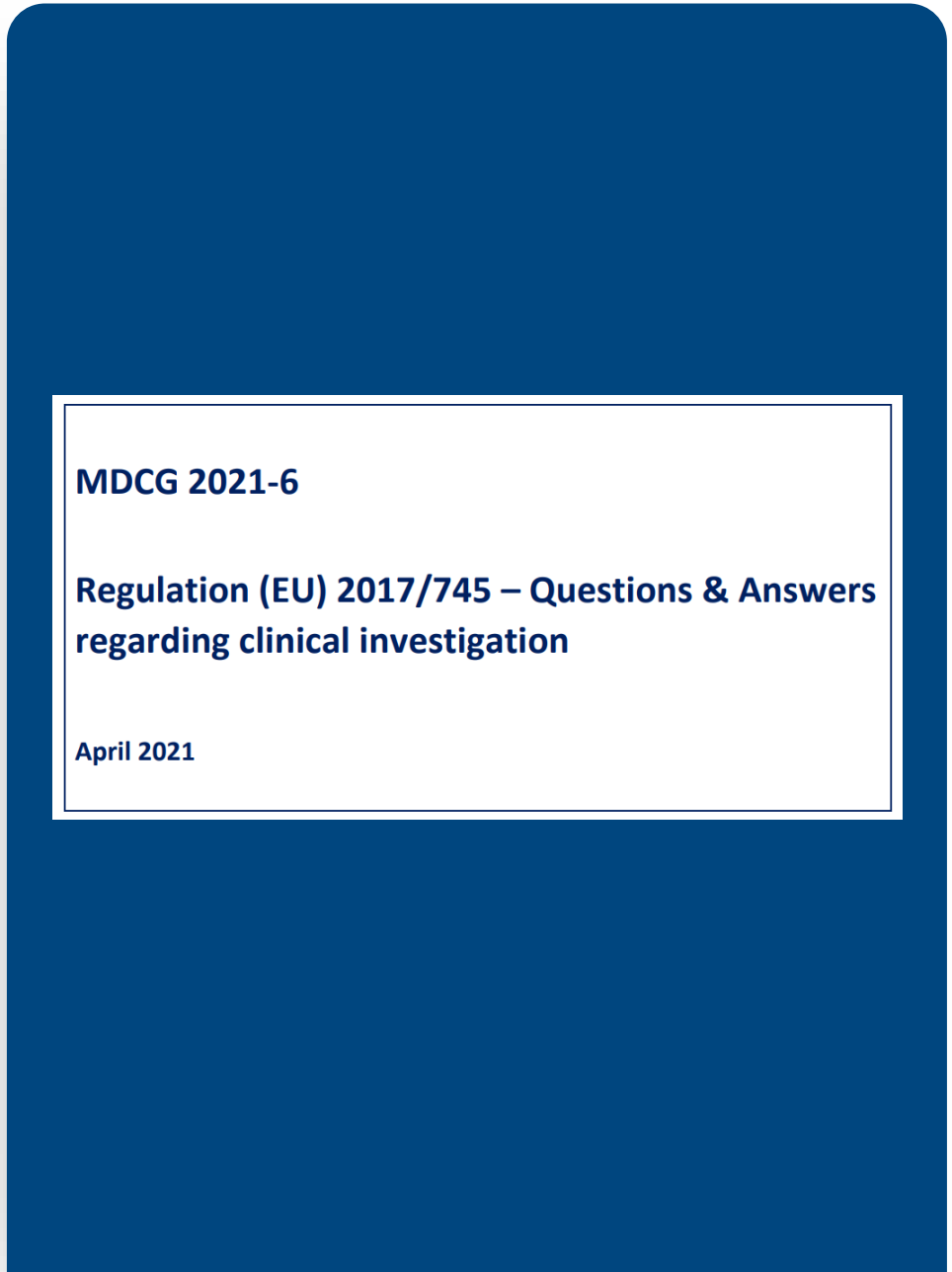
The ability of a device to achieve its intended purpose (NEW MDR term and previously in MDD the ‘intended use’);

Defining ‘Clinical Performance’

The ability of a device to achieve its intended purpose, thereby leading to a clinical benefit;

Defining ‘Clinical Benefit’

The positive impact of a device on the health of an individual, expressed in terms of a meaningful, measurable, patient-relevant clinical outcome(s);



MDR

Article 7 - Claims

In the labelling, instructions for use, making available, putting into service and advertising of devices, it shall be prohibited to use text, names, trademarks, pictures and figurative or other signs that may mislead the user or the patient with regard to the device's intended purpose, safety and performance by:

(a) ascribing functions and properties to the device which the device does not have;

(b) creating a false impression regarding treatment or diagnosis, functions or properties which the device does not have;

(c) failing to inform the user or the patient of a likely risk associated with the use of the device in line with its intended
purpose;

(d) suggesting uses for the device other than those stated to form part of the intended purpose for which the conformity assessment was carried out.

REGULATIONS

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 5 April 2017

on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

(Text with EEA relevance)

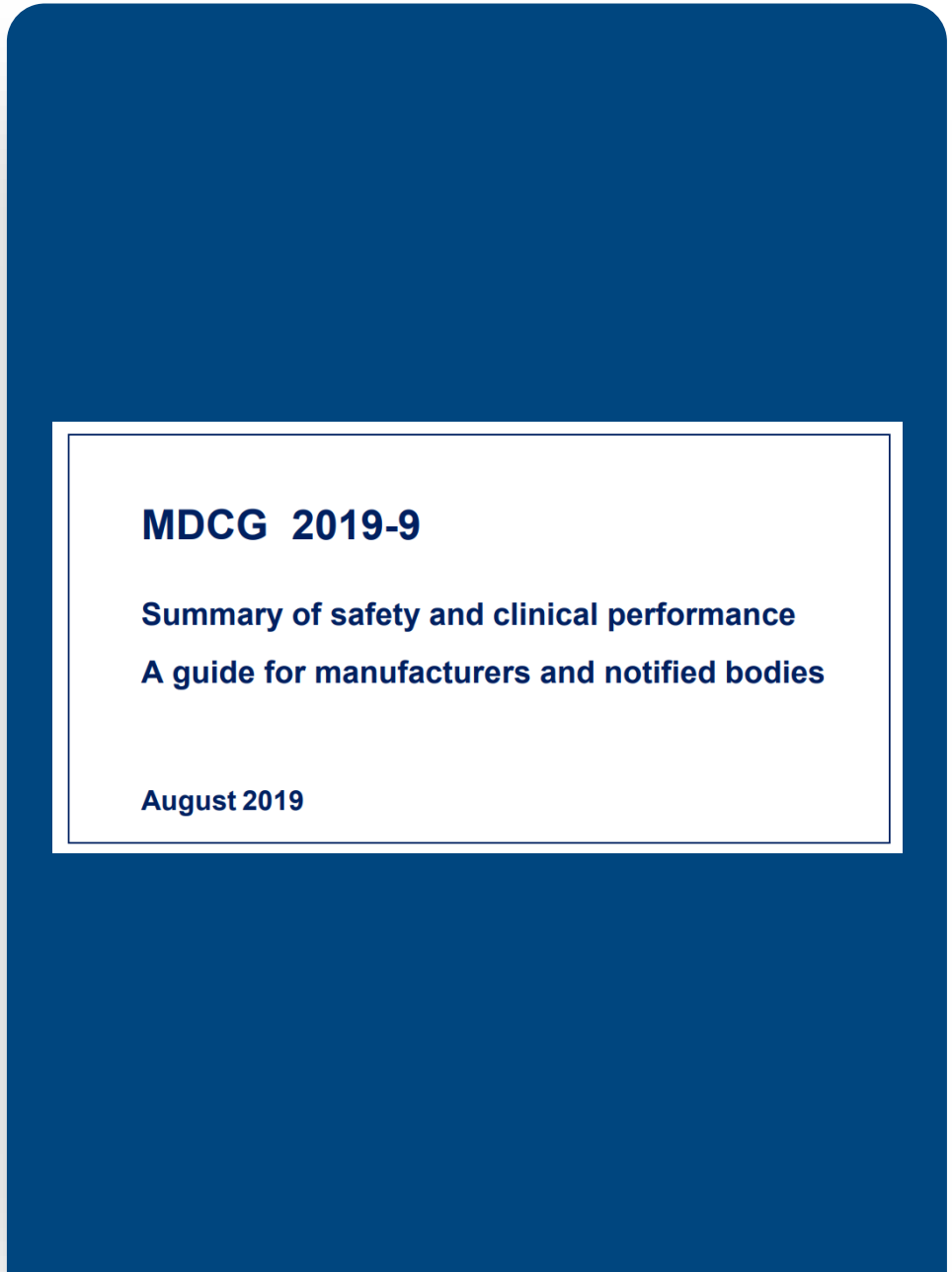
MDCG 2019-9

Link between ‘Clinical Benefit’ and ‘Clinical Claim’

The clinical performance normally leads to clinical benefits for the patient.

In the Summary of Safety and Clinical Performance (SSCP) a description of the documented clinical benefits for patients with relevant and specified clinical outcome measures, and the success rate for achieving the outcome measures shall be described.

This should be described for all clinical claims the manufacturer presents in the IFU, and in any information, marketing, or promotional material that it distributes;



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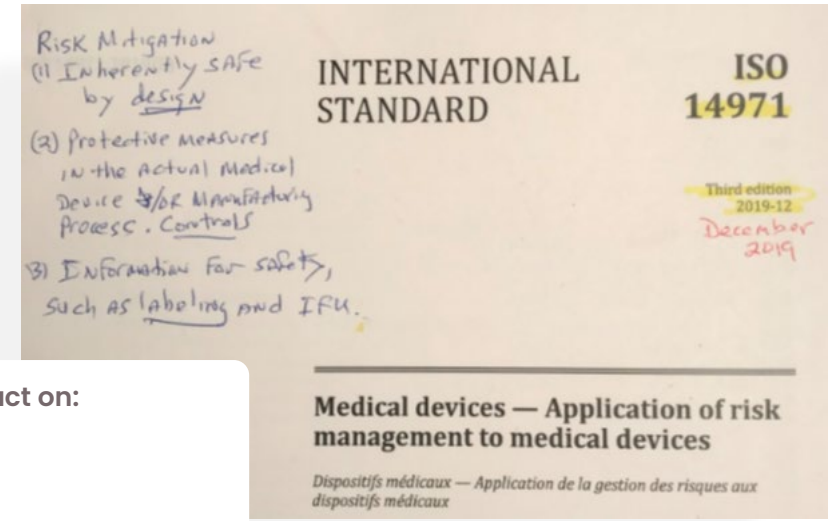
ISO14971:2019 Risk Management for Medical Devices

Defines benefit as having a positive impact or desired outcome of the use of a medical device on the health of an individual, or a positive impact on patient management or public health.


Risk Mitigation
(1) Inherently safe by design
(2) Protective measures in the actual Medical Device &/or Manufacturing Process. Controls
(3) Information for safety, such as labeling and IFU.

INTERNATIONAL STANDARD

ISO 14971

Third edition
2019-12
December 2019

Medical devices — Application of risk management to medical devices

Dispositifs médicaux — Application de la gestion des risques aux dispositifs médicaux

Benefits can include a positive impact on:

a. clinical outcomes

b. the patient's quality of life

c. outcomes related to diagnosis

d. impact from diagnostic devices on clinical outcomes

e. impact on public health

Medical Device Regulation 2017/745

Defining ‘benefit-risk’

(24) ‘benefit-risk determination’ means the analysis of all assessments of benefit and risk of possible relevance for the use of the device for the intended purpose, when used in accordance with the intended purpose given by the manufacturer;

Benefit-risk assessment is an integrated part of key processes in the MDR:

- Design and Development process
- The Technical Documentation (TD)
- Clinical evaluation and investigational processes and reporting
- Post market surveillance (PMS)

5.5.2017 EN Official Journal of the European Union L 117/1

I

(Legislative acts)

REGULATIONS

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 5 April 2017
on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 and Article 168(4)(c) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee (1),

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure (2),

Whereas:

(1) Council Directive 90/385/EEC (3) and Council Directive 93/42/EEC (4) constitute the Union regulatory framework for medical devices, other than *in vitro* diagnostic medical devices. However, a fundamental revision of those Directives is needed to establish a robust, transparent, predictable and sustainable regulatory framework for medical devices which ensures a high level of safety and health whilst supporting innovation.

(2) This Regulation aims to ensure the smooth functioning of the internal market as regards medical devices, taking as a base a high level of protection of health for patients and users, and taking into account the small- and medium-sized enterprises that are active in this sector. At the same time, this Regulation sets high standards of quality and safety for medical devices in order to meet common safety concerns as regards such products. Both objectives are being pursued simultaneously and are inseparably linked whilst one not being secondary to the other. As regards Article 114 of the Treaty on the Functioning of the European Union (TFEU), this Regulation harmonises the rules for the placing on the market and putting into service of medical devices and their accessories on the Union market thus allowing them to benefit from the principle of free movement of goods.

(1) Opinion of 14 February 2013 (OJ C 133, 9.5.2013, p. 52).
(2) Position of the European Parliament of 2 April 2014 (not yet published in the Official Journal) and position of the Council at first reading of 7 March 2017 (not yet published in the Official Journal).
(3) Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (OJ L 189, 20.7.1990, p. 17).
(4) Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1).

Safety data

How to determine the safety claims?

Safety data refers to any data collected to support the safety and safe use of the device for the patient and user (e.g., adverse events, serious adverse events, SADE etc.).

Safety data found in vigilance, literature or pre-clinical & clinical investigations are assessed in the risk assessment according to ISO14 971.

Those risks are used in the benefit risk assessment (after identifying Clinical benefits).

Clinical outcome data

What is clinical outcome data?

Clinical outcome data to support the user (physicians, nurses, etc.), or

Clinical and health economic outcome data for market access (e.g., LOS, Survival to hospital arrival, invasive procedures, ICU stay, etc.), or

Patient-reported outcome to support the end user needs (e.g., neurological outcome i.e., EQ5D questionnaires).

Intended use

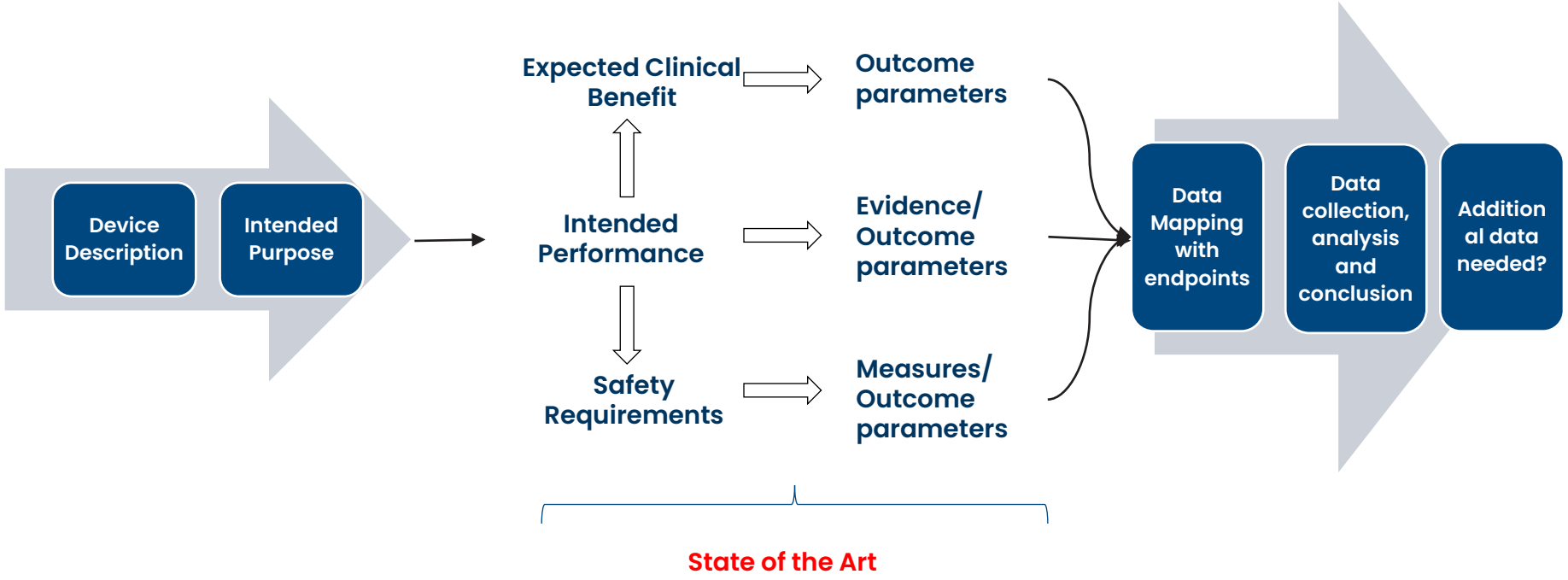
Identification of performance data that supports the intended use

Data no	Performance data to be generated
1	Temperature measurement
2	Ease of use (Likert score)
3	Accuracy of placement
4	Etc.

Performance, Clinical Performance & Clinical Benefits

Performance data no	Performance	Clinical Performance	Clinical Benefit	Supported claim
1	Temperature measurement	Non-invasive, continuous monitoring of accurate body temperature	Prevent hypo- or hyperthermia with a non-invasive device	Accurate continuously, non-invasive temperature monitoring
2	Easy to use	Easy and quick placement	Quick identification of temperature changes	Easy handling

Process Chart



Describe the methods to be used to measuring safety and performance and compare with State of the Art.

Best practice for Defining Outcome Parameters

Involving subject matter experts, clinicians, and patients
-Engaging a multidisciplinary team ensures comprehensive input and consideration of various perspectives in defining outcome parameters and how to measure these.

Conducting pilot studies to refine outcome parameters
-Pilot studies allow iterative refinement of outcome parameters, identifying potential issues and optimizing measurement methodologies.

Incorporating feedback from regulatory agencies
-Seeking feedback from regulatory agencies during the outcome parameter definition process ensures alignment with regulatory requirements and expectations.

Bring a team together

You cannot do this on your own, you need a team!

- Clinical Research
- Risk Management
  Including product/ clinical/software/cybersecurity representation
- Biostatistics
- Clinical Evaluation
- Labelling
- Complaint Handling
- Medical Affairs
- Regulatory Affairs
- Clinical Safety
- Quality
- Engineering
- Others
  (External Healthcare Providers, Patient Advocacy Groups etc.)

Discuss Potential Benefits: Address these 12 issues if they apply

1. Patient perspective, such as quality of life from a validated tool
2. Healthcare professionals and caregivers' perspectives
3. Medical necessity, e.g., What are the other choices to patients/health care practitioners that would make this product a benefit?
4. Types of benefits (remember that claims should automatically be considered types of benefits)
5. Magnitude of benefits in terms of time or scale so a metric can be used here
6. Likelihood or probability of experiencing one or more benefits
7. Reduction in the probability of death
8. Aiding improvement in patient function such as an organ system
9. Reducing the probability of loss of a function
10. Relief of symptoms
11. Duration of benefits in terms of curative, short-term, or long-term
12. Benefits when compared to alternative therapies or state-of-the-art

A Framework For Discussion

1. Types of benefits
2. Magnitude of benefits
3. Likelihood of experiencing one or more benefits
4. Duration of effects
5. Patients' perspective on benefit
6. Benefit factors for health care professionals or caregivers
7. Medical necessity compared to what is currently available, for example

If assumptions are being made, make them clear to the team.

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Benefit Assessment – Template for Brainstorming

Benefit Assessment Criteria	Assessment for Device or Device System*
Types of Benefits	
Magnitude of Benefit	
Likelihood of Experiencing One or More Benefits	
Duration of Effects	
Patients' Perspective on Benefit	
Benefit Factors for Health Care Professionals or Caregivers	
Medical Necessity Compared to What is Currently Available	

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*Add references for scientific measurable evidence here

Discuss Potential Risks: Address these 12 issues if they apply

The concept of risk has two key components:
-the probability of occurrence of harm and
-the consequences of that harm, such as how severe it might be

1. It is the patient who takes the risk for the promise of the potential benefit. How well does the patient understand the risk from the product?
2. Patient tolerance (or intolerance) to the product over time
3. Risks to healthcare professionals and caregivers
4. Severity of risks
5. Type of risks, such as product, clinical, software, and cybersecurity
6. Likelihood of experiencing one or more risks
7. Duration of exposure
8. Mitigation potential such as quantitative and qualitative risk control methods
9. Procedure-related versus device-related risks
10. Disease characteristics that could affect risks
11. Quantitative or qualitative residual risk estimates
12. Risks from false-positive or false-negative results

The discussion should also include how risks might be mitigated or what measures can be in place to lower risks. The key here is to have the team agree on identifying residual risks.

1. Inherently safe by design
2. Protective measures in the actual medical device and/or manufacturing process controls
3. Information for safety, such as labelling and IFU

A Framework For Discussion

1. Types of harms or risks
2. Magnitude or severity of harms or risks
3. Likelihood of experiencing one or more harms or risks
4. Duration of exposure to the population
5. Patients' perspective or tolerance (or intolerance) to harms or risks
6. False-positive or false-negative results

Again, if assumptions are being made, make them clear to the team.

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Address Uncertainties in Potential Risks

Finally, uncertainties in risks need to be addressed and might be related to the following parameters:

- the product,
- the procedure,
- subsequent treatments or tests,
- insufficient number of patients,
- differences in definitions,
- percentage of subjects that were lost-to-follow-up during a clinical investigation,
- protocol deviations, and
- user experience such as being inconsistent or not representative of likely real-world users.

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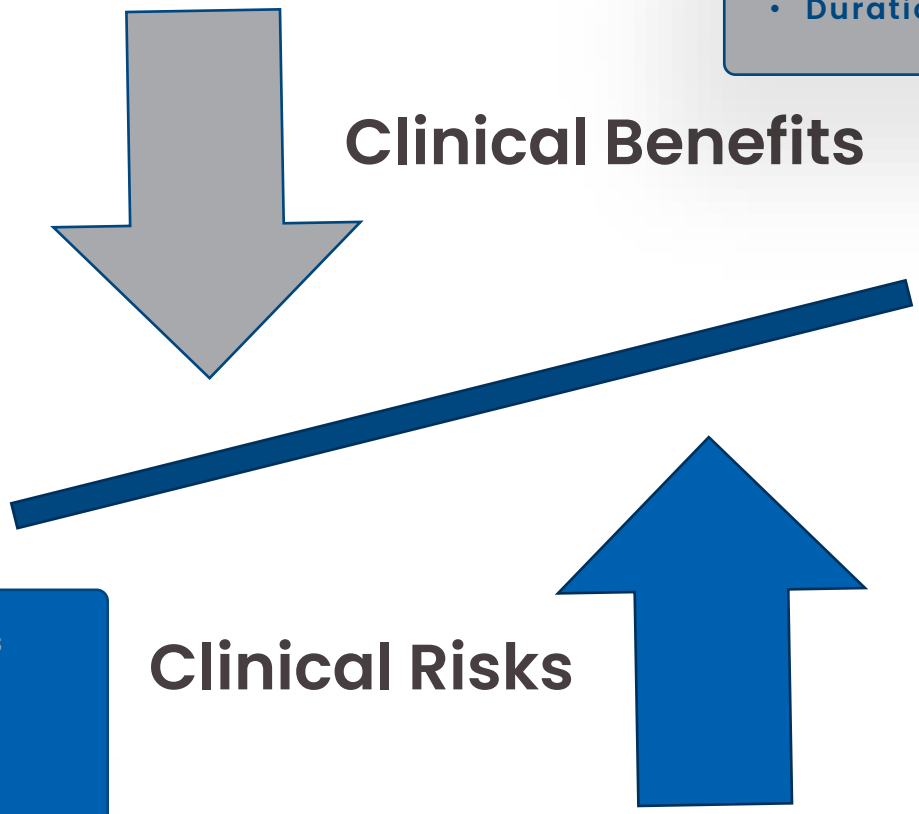
Risk Assessment – Template for Brainstorming

Risk Assessment Criteria	Assessment for Device or Device System*
Types of Harms or Risks	
Magnitude or Severity of Harms or Risks	
Likelihood of Experiencing One or More Harms or Risks	
Duration of Exposure to the Population	
Patients' Perspective or Tolerance (or Intolerance) to Harms or Risks	
False-Positive or False-Negative Results	

*Add references for scientific measurable evidence here

Risk Benefit Assessment

Positive measurable impact on health including:
- Size of benefit to patient
- Probability of benefit
- Duration of benefit



Severity, number and rate harmful events
Probability of harmful event
Duration of harmful event

Technical Documentation and Benefit-Risk Assessment

The benefit-risk assessment is an integrated part of:

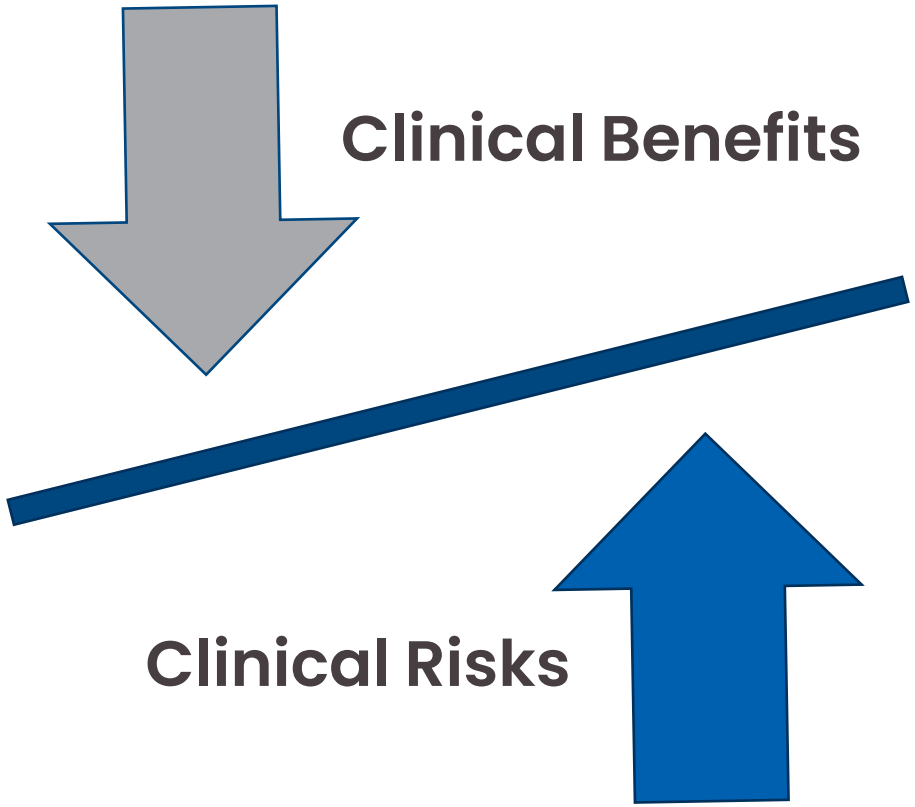
a) Design and Development process,
b) Development of the Technical Documentation, including
c) General Safety and Performance Requirement (GSPR) for example GSPR #2, #3 and #8 and
d) Remember to re-evaluate during Design Changes!

Risk Management and Benefit-Risk Assessment

The documentation shall contain information on:

a) the benefit-risk analysis referred to in Sections 1 and 8 of Annex I, and

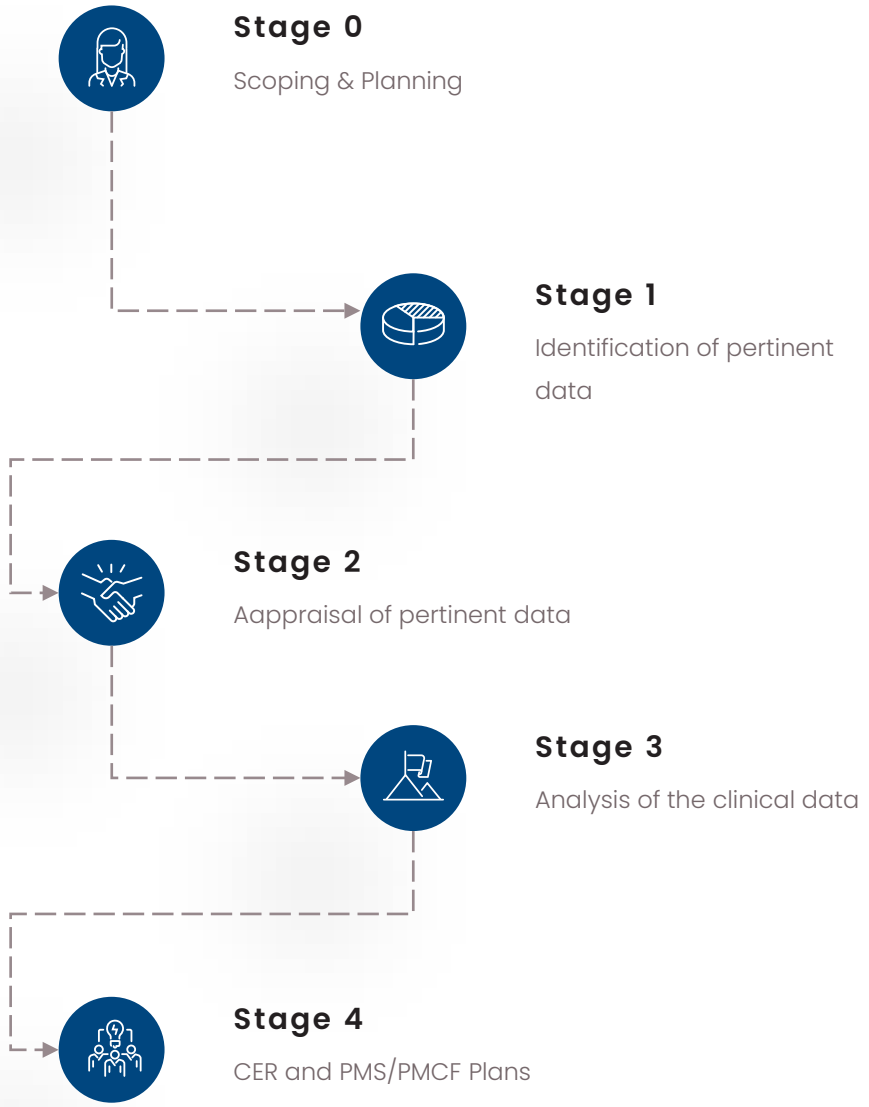
b) the solutions adopted, and the results of the risk management referred to in Section 3 of Annex I.



Clinical evaluation and Benefit-Risk Assessment

- an indicative list and specification of parameters to be used to determine benefits and risks, 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



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When to conduct a Clinical Evaluation/Investigation?

Usually first performed during the development of a medical device in order to identify data that need to be generated to support for market access (risks and benefits/claims)

- ✓ Where to get the data from?
- ✓ Where is real clinical patient data needed?
- ✓ What method to use?
- ✓ What method is applicable?
- ✓ What method has been used for similar or predicate products
- ✓ What methods will the authorities likely accept?

Product	Intended use	Indication for	Document reviewed	Unique claim	Claims per document	Objective evidence	Clinical evidence needed	Supporting data	Evidence level/quality	Comment
Product 1	XX	YY	CEP and State of the Art	1	The device XX enhance the tissue surface structure.	Design V&V protocol …	Yes	User satisfaction measured using a 5-point Likert scale	Pre-clinical study Animal validation study Clinical study	…
Product 1	XX	YY	List of overall claims	2	The software processor shows the tissue structure reflecting natural tissue	Design V&V protocol …	Yes	User satisfaction measured using a 5-point Likert scale	Clinical study	…

How to address clinical benefit in a clinical investigation?

Clinical investigations shall be designed, authorised, conducted, recorded and reported as part of the clinical evaluation for conformity assessment purposes, for one or more of the following purposes:

…

(b) to establish and verify the clinical benefits of a device as specified by its manufacturer;

(c) to establish and verify the clinical safety of the device and to determine any undesirable side-effects, under normal conditions of use of the device, and assess whether they constitute acceptable risks when weighed against the benefits to be achieved by the device.

….

How to address clinical benefit in a clinical investigation?

The investigation shall confirm:

The anticipated benefits to the subjects or to public health justify the foreseeable risks and inconveniences and compliance with this condition is constantly monitored during the investigation.

Sponsor shall ensure that the subject is informed about and understands the nature, objectives, benefits, implications, risks and inconveniences of the clinical investigations.

Including subjects other than habile adults in a clinical investigation shall be justified scientifically.

Post Market Surveillance

PMS data shall be used to give update to the benefit-risk assessment and determination and to improve the risk management of the product.

Input data comes from general vigilance on own and/or equivalent/similar products, trend reporting, incidents and FSCA.

Conclusion of the benefit-risk is included in the Periodic Safety Update Report (PSUR) and Summary of Safety and Clinical Performance (SSCP) to be prepared for class IIa, class IIb and class III devices.

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Find the GAPs?

Clinical evidence tool

Intended Use: Non-invasive TP monitoring		
Supporting data	GuruStudy01	Gurustudy02
	Continuously TP measuring of small piglets as compared with SOTA Primary endpoint: Evaluate TP monitoring function as compared to SOTA Secondary endpoints:	Biocompatibility study of skin reaction Primary endpoint: Evaluate non-invasive placement to monitor skin reaction
Evidence/quality	Animal study- the device is compared to the SOTA - invasive TP measurement device	Biocompatibility study- the device is placed on the xxxx for a period of 6 days to evaluate skin reaction

Indication for use: Indicated for non-invasive monitoring of TP in neonatal patients		
Supporting data	Gurustudy01	Gurustudy02
Evidence quality		

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Clinical evidence tool

Find the GAPs?

		Current clinical investigation Yes or No	Previous PMS or pre-approval Clinical Investigation Yes or No	Propose a New Product(s) Specific PMCF Investigation	PMCF Clinical Study Hospital DB proposed	IIS Potential for aggregated data	PMS International, National, Regional Registry	Propose Proactive Customer Survey(s)	Propose Proactive Product Survey(s)	Propose New Large PMCF Registry for most products
Class III (n=XX devices) XX DKK per year and then decrease	Product 1	Y	Y	N	Y	Y	Y	N		Y
	Product 2	Y	N	N	Y	N	Y	N		N
	Product 3	N	N	N	N	N	N	Y		N
Class IIb (n=XX devices) XX DKK per year and then decrease	Product 1	N	Y	Y	N	Y	N	N		Y
	Product 2	Y	N	N	Y	N	Y	Y		N
	Product 3	N	Y	Y	Y	N	N	N		N
Class IIa and I (n=XX devices) XX DKK per year and then decrease	Product 1	N	N	N	N	N	N	Y		N
	Product 2	N	N	Y	N	Y	N	Y		N
	Product 3	N	N	N	Y	N	Y	Y		N

What is the Medical Device Development Pathway?

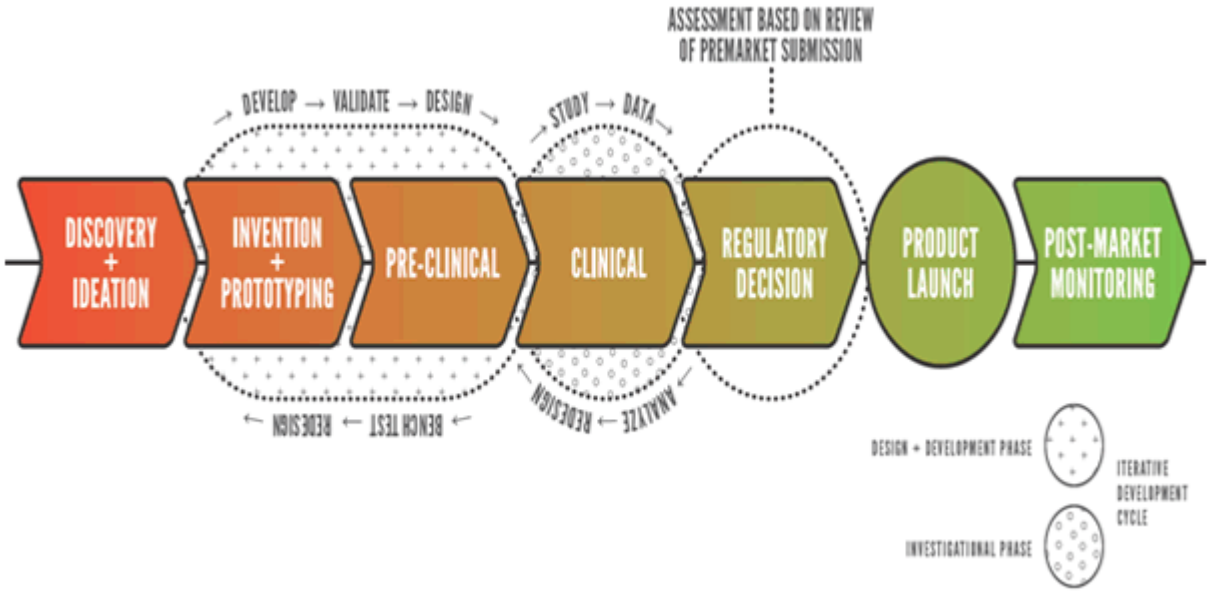
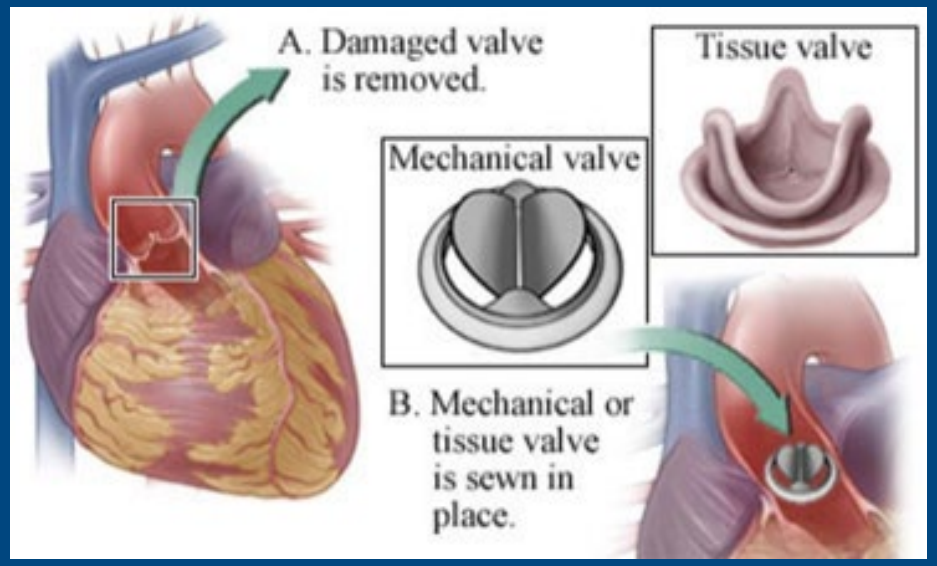


Figure 2. *The medical device development pathway from discovery and ideation to product launch and post market monitoring is shown. The regulatory process affects a significant portion of the device development pathway and should accommodate the iterative, cyclical nature of device design and development.*

Source: https://www.fda.gov/about-fda/cdrh-innovation/medical-device-innovation-initiative-white-paper

Benefit to RiskAssessment: Alternative Therapy Standard Surgical Aortic Valve Replacement



- Open heart surgery
- Diseased valve removed and replaced
- Requires patient to be a surgical candidate

Example borrowed kindly from Global Strategic Solutions, LLC

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Benefit Assessment – Transcatheter Aortic Valve Replacement

Benefit Assessment Criteria	Assessment of Transcatheter Aortic Valve Replacement (High risk, alternative is death
Types of Benefits	Improved mortality, neurological benefits, recovery time, lower rates of atrial fibrillation, vascular complications and bleeding. Longer-term follow-up and additional RCTs have demonstrated that TAVR is equivalent to surgical AVR for severe symptomatic AS when surgical risk is high.
Magnitude of Benefit	All-Cause Mortality 1.1% versus 4.0% at 30 days. Disabling stroke 1.0% versus 4.4% at 30 days. Mean hospital stays of 5.6 days versus 11.9 days for surgery. Mean ICU stays of 2.7 days versus 5.6 days for surgery.
Likelihood of Experiencing ≥1 Benefits	Very high procedural success rates (>90%) with low paravalvular leakage.
Duration of Effect	All-Cause Mortality 7.4% vs. 13.0% at 1 year. Disabling stroke 2.3% vs. 5.9% at 1 year. Effects seen throughout the lifetime of the patient.
Patients' Perspective on Benefit	Short procedure time. Quicker recovery (no sternotomy). Shorter hospital stay. Improve 6-minute walk tests. Improved Quality of Life.
Benefit Factors for Health Care Professionals or Caregivers	Shorter hospital stays and thus frees up hospital resources. Some implants can be re-sheathed and re-deployed, provided that the valve has not been fully released.
Medical Necessity	For patients suffering from symptomatic severe aortic stenosis, the alternative treatment is surgical aortic valve replacement

1. JACC 2017;70(2):252-89. AHA/ACC Focused Update of the 2014 AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease
2. JACC 2014;63:2438-88. 2014 AHA/ACC guideline for the management of patients with valvular heart disease: executive summary;
3. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5317356

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Risk Assessment – Transcatheter Aortic Valve Replacement

Risk Assessment Criteria	Assessment for Transcatheter Aortic Valve Replacement
Types of Harms or Risks in Patients with Aortic Stenosis (AS)	Angina pectoris, dyspnea, or syncope, or repeat hospitalization and/or death.
Magnitude or Severity of Harms or Risks	Annual mortality of 25% in those with moderate-to- severe AS and average survival of only 2 to 3 years. Two-year mortality rates can range from 44.4% for symptomatic AS patients to as high as 79% for predominant AS patients. Following symptomatic patients with severe AS in whom operation was declined, mortality rates of 45%, 63% and 75% at 1 year, 2 year, and 3 year follow-up, respectively. More recently, it has been established that inoperable patients with severe AS had a 1-year mortality rate of 50%.
Likelihood of Experiencing One or More Harms or Risks	30-day risk of new permanent pacemaker was 10.2% versus 7.3% 30-day moderate or severe pulmonary valve regurgitation was 3.7% versus 0.5% 1-year moderate or severe pulmonary valve regurgitation 1.5% versus 0.4%
Duration of Exposure to the Population	Lifetime of the patient.
Patients' Perspective or Tolerance (Intolerance) to Harms or Risks	Very low patient intolerance over the past 15 years.
False-Positive or False-Negative Results	Not applicable.

1. JACC 2017;70(2):252-89. AHA/ACC Focused Update of the 2014 AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease
2. JACC 2014;63:2438-88. 2014 AHA/ACC guideline for the management of patients with valvular heart disease: executive summary;
3. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5317356

Discussion of Benefit to Risk – Transcatheter Aortic Valve Replacement

1. Initially approved in 2011 for high surgical risk patients now being used for lower risk patients due to improved safety and performance of TAVR versus Surgery.
2. Decrease mortality rates over the lifetime of the device.
3. Current-generation devices improve control and accuracy in positioning and placement of the valve, minimizing paravalvular leak (a common complication with first-generation transcatheter valves) and potentially reducing the need for implantation of a permanent pacemaker after the procedure.
4. A separate health economics analysis confirmed that use of xyz is associated with significant cost savings when compared to traditional blood glucose monitoring.
5. This complication is due to the anatomical proximity of the aortic valve to the atrioventricular (AV) node, bundle of His, and major conduction branches. The rate of PPI ranges from 3.4% to 17.3% for BEV and from 15.7% to 37.6% for SEV mostly as a result of complete atrioventricular block.[2
6. Catheter-based delivery of aortic valves avoids the need to place patients on cardiopulmonary bypass, which decrease procedural times and risks.
7. While tissue valves do not require anticoagulation therapy, they also do not la as long as mechanical valves.

1. JACC 2017;70(2):252-89. AHA/ACC Focused Update of the 2014 AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease
2. JACC 2014;63:2438-88. 2014 AHA/ACC guideline for the management of patients with valvular heart disease: executive summary;
3. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5317356

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Q&A

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Anette Kristiansen, Senior Clinical & Scientific Affairs Director, Neurescue Aps
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Søren Underbjerg, Sr. Principal Advisor, Qmed Consulting A/S
David Rutledge, President & CEO, Global Strategic Solutions, LLC

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