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Your Trusted Knowledge Partner

QAdvis group 2023-03-21

Nils-Åke Lindberg

nils-ake.lindberg@qadvis.com

+46 707 994190

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QAdvis Team

LUND

STOCKHOLM

Management at QAdvis

Emma Axelsson
CEO

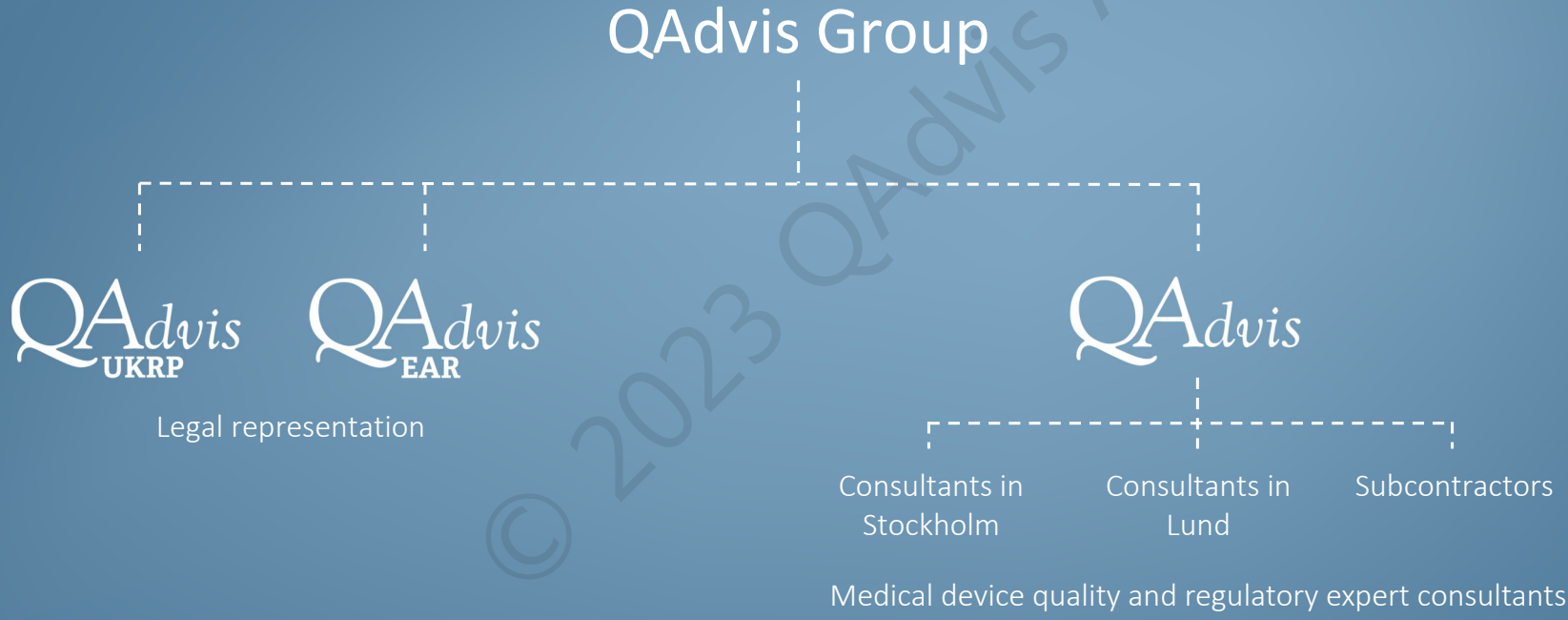
Per Sundström
CSO
Deputy CEO QAdvis EAR
Director QAdvis UK

Bing Wu
EAR Manager

Annelie Hagström
Site Manager, Lund
UKRP Manager

Nils-Åke Lindberg
Founder
Sr Principal Consultant

Organisation



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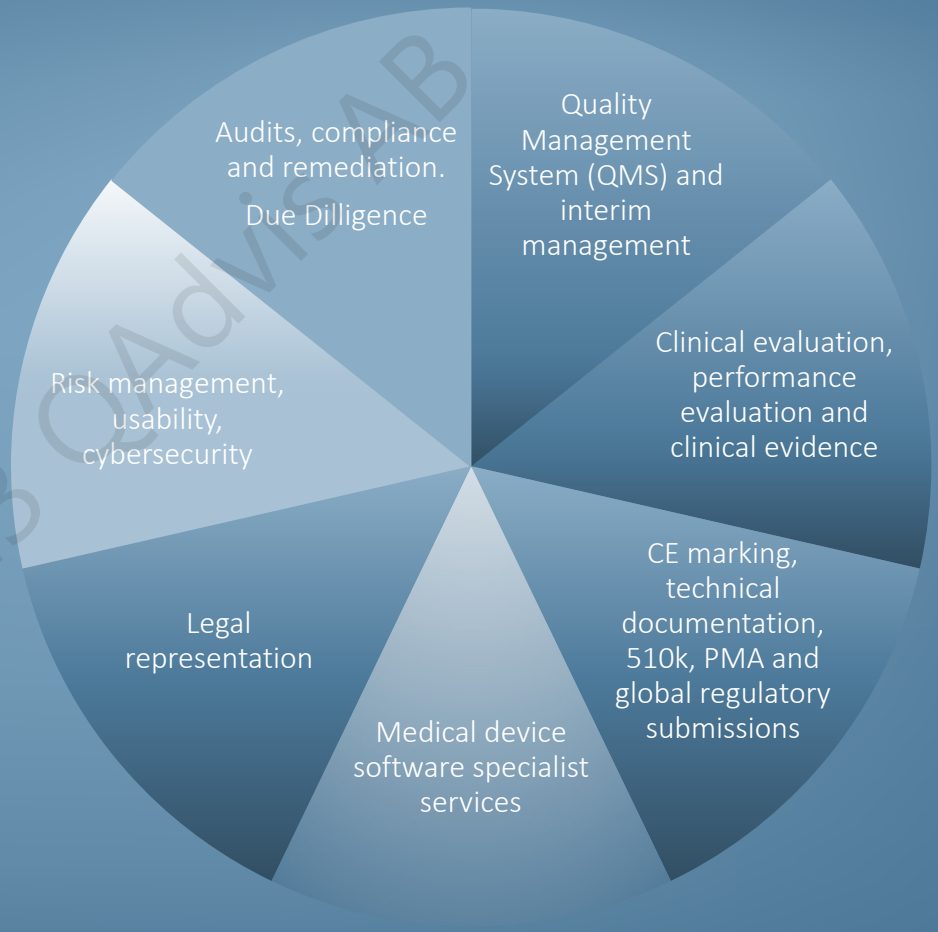
Our services within quality, regulatory and clinical evidence



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QAdvis Academy

Open and company specific training courses:

- CE-marking
- Risk management for medical devices
- Usability according to IEC 62366-1
- Technical Documentation for medical devices
- Clinical evaluation/clinical performance evaluation
- Cybersecurity for medical devices
- ISO 13485:2016
- EU In-Vitro Diagnostic Regulation (IVDR)
- EU Medical Device Regulation (MDR)
- Good Manufacturing Practice for Medical Devices and IVD devices
- Internal audits based on ISO 13485
- Medical device software process design based on IEC 62304

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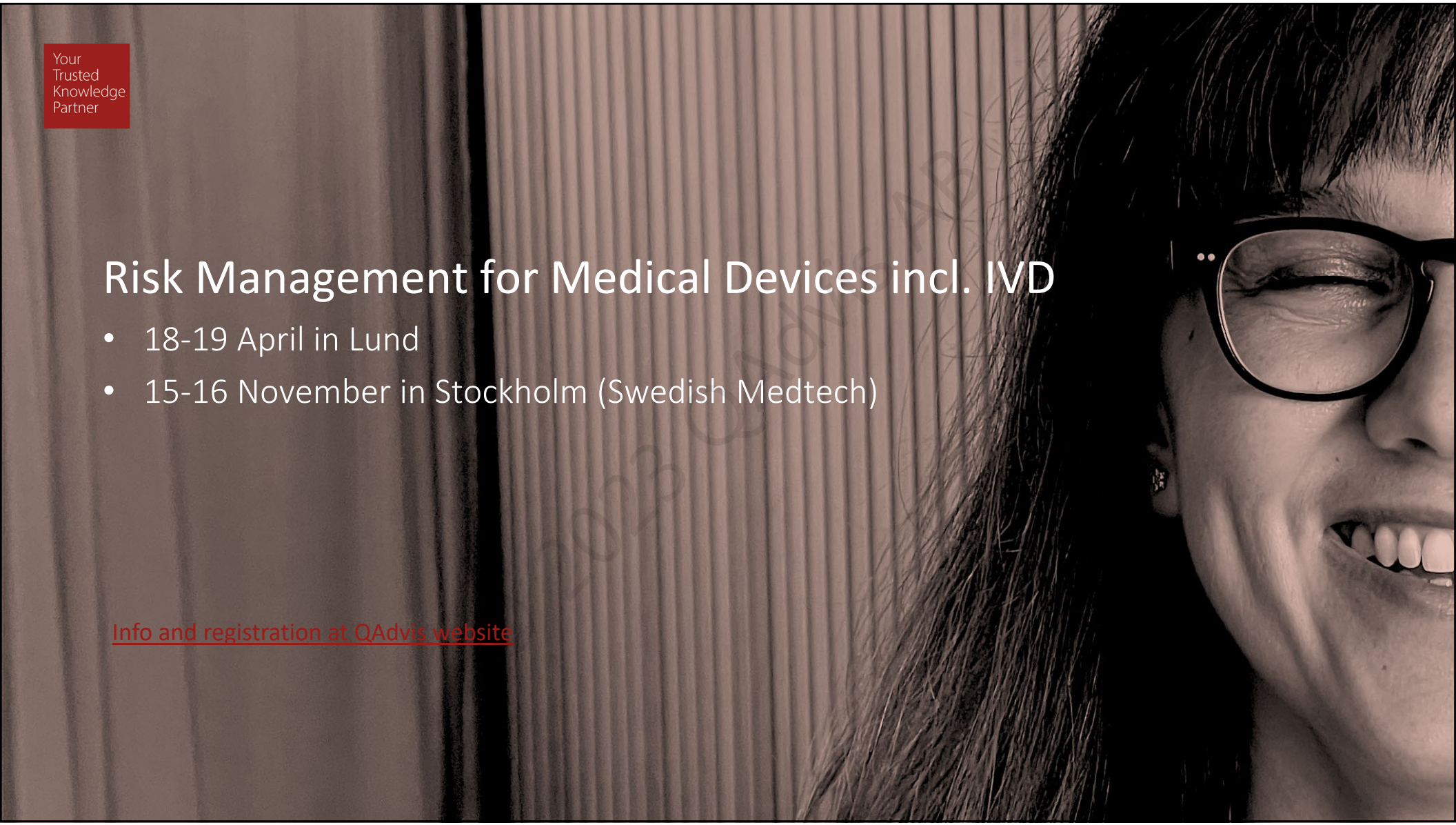
Your
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Risk Management for Medical Devices incl. IVD
• 18-19 April in Lund
• 15-16 November in Stockholm (Swedish Medtech)
Info and registration at QAdvis website

Regulatory Summit

30 mars 2023 - Delta i Stockholm eller online

6:e upplagan!

SWEDISH Medtech

PROGRAM TALARE AVGIFTER

Anna Lundgren
Utredare på Enheten för Medicinteknik,
Läkemedelsverket

Cecilia Emanuelsson
Chief Medical Officer,
QAdvis AB

Cilla Lundvall
Senior Quality & Regulatory Consultant, QAdvis AB

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Solution-oriented
knowledge

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Navigating the risk management maze: Benefit-risk analysis made easy

2023-03-21

Cristina Barkman

cristina.barkman@qadvis.com

+46 704 888819

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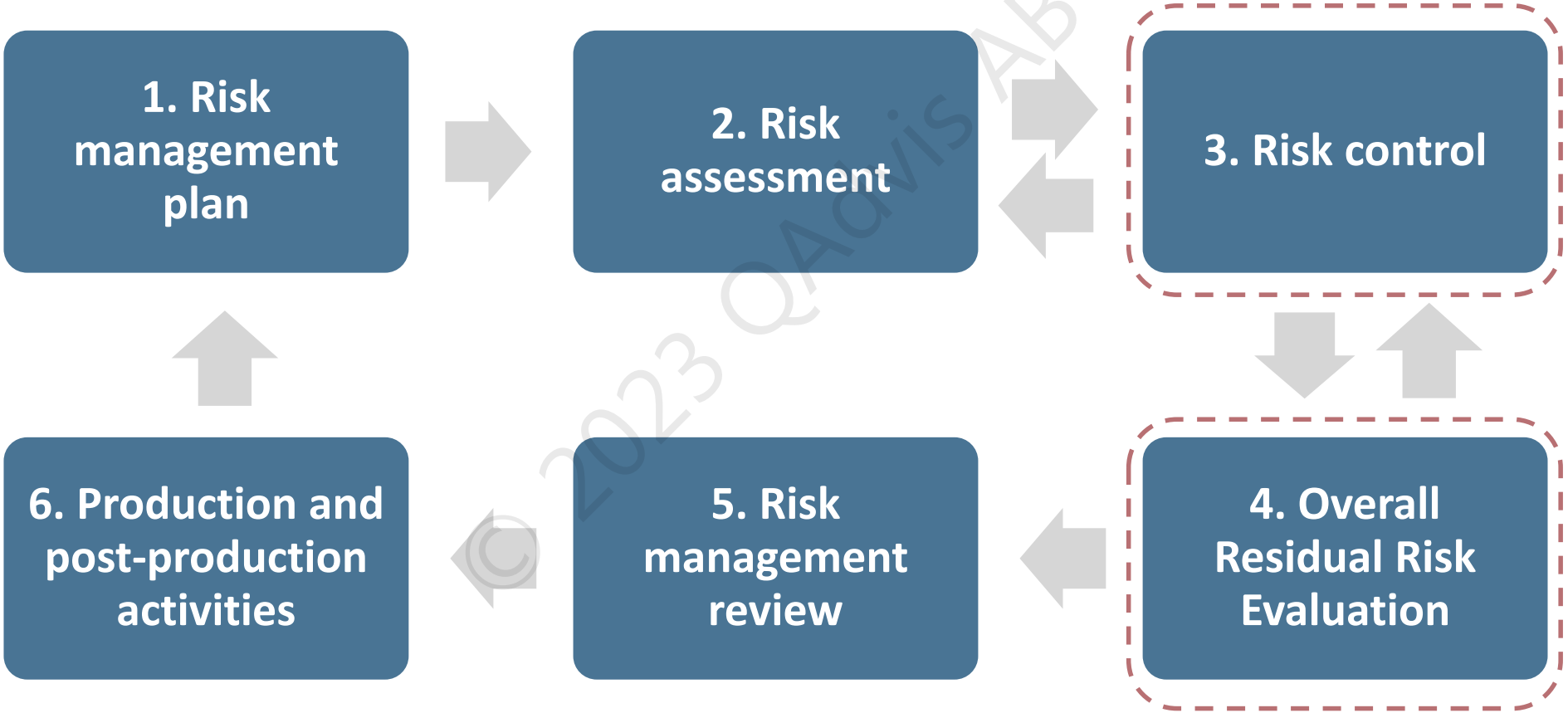
Presentation of the trainer
Cristina Barkman

- 25+ years in the medical device industry
- Extensive international experience from development and manufacture of complex medical devices
- Deep experience from risk management for medical devices
- Chairwoman of SIS TK 355
- Active member of international standardization committee TC 210/JWG1
- Co-author of ISO 14971 and ISO/TR 24971

Disclaimer

Please note that, any views given by us on the interpretation of the legislation represent our best judgement at the time, based on the information available. Such views are not meant to be a definitive statement of law, which may only be given by the Courts.

Risk management process by ISO 14971



When is benefit risk analysis needed?

Unacceptable residual risk:

” … the manufacturer may gather and review data and literature to determine if the benefits of the intended use outweighs this individual risk.”

(ISO 14971:2019, clause 7.4)

Overall residual risk:

” … the manufacturer shall evaluate the overall residual risk posed by the medical device taking into account the contributions of all residual risk in relation to the benefits of the intended use…”

(ISO 14971:2019, clause 8)

In focus:

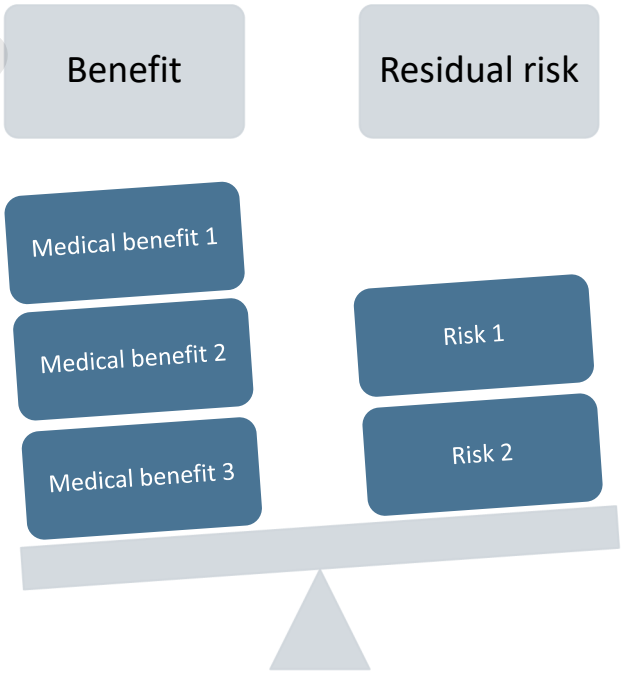
Benefit-risk analysis for overall residual risk

Overall Residual Risk Evaluation

Take into account the contributions of all residual risks in relation to the benefits of the intended use

Always do benefit-risk analysis for the overall residual risk!

Use method and criteria in the plan



Benefit-Risk Analysis

- Supported by objective evidence
- Based on judgment by experienced and knowledgeable individuals

NO STANDARDIZED APPROACH!

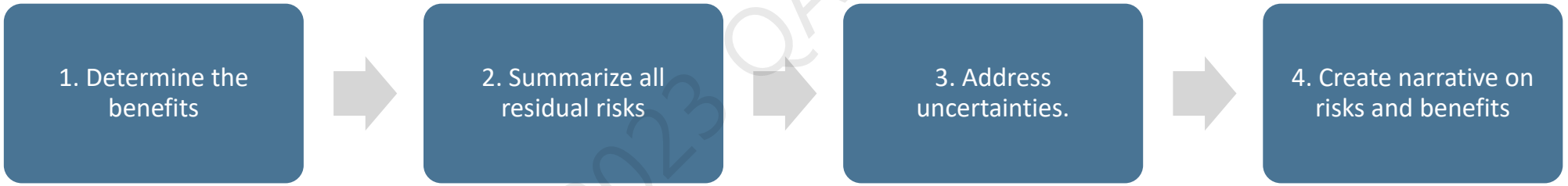
Guidance for Benefit-Risk Analysis

ISO/TR 24971:2020 Medical Devices – Guidance on the application of ISO 14971

FDA Guidance ”Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications”

FDA Guidance ”Consideration of Uncertainity in Making Benefit-Risk Determinations in Medical Device Premaket Approvals, De Novo Classifications and Humanitarian Device Exeptions”

Possible approach



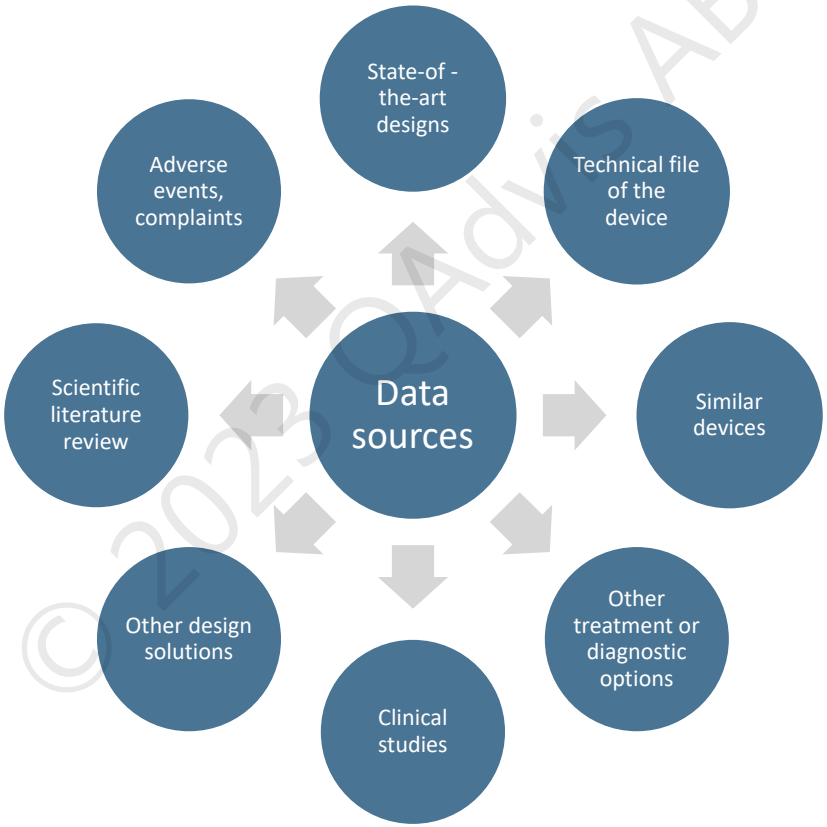
Benefit - Definition

"Positive impact or desirable outcome of the use of a medical device on the health of an individual, or a positive impact on patient management or public health."

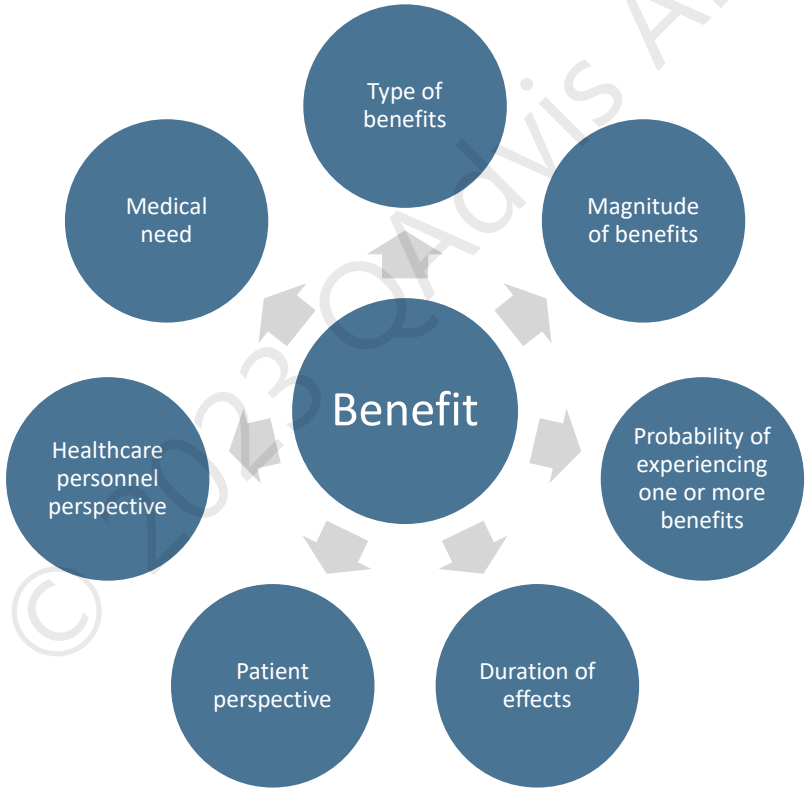
Benefits include

- Clinical outcomes
- Patient's quality of life
- Outcome related to diagnostics
- Impact from diagnostic devices on clinical outcomes
- Impact on public health

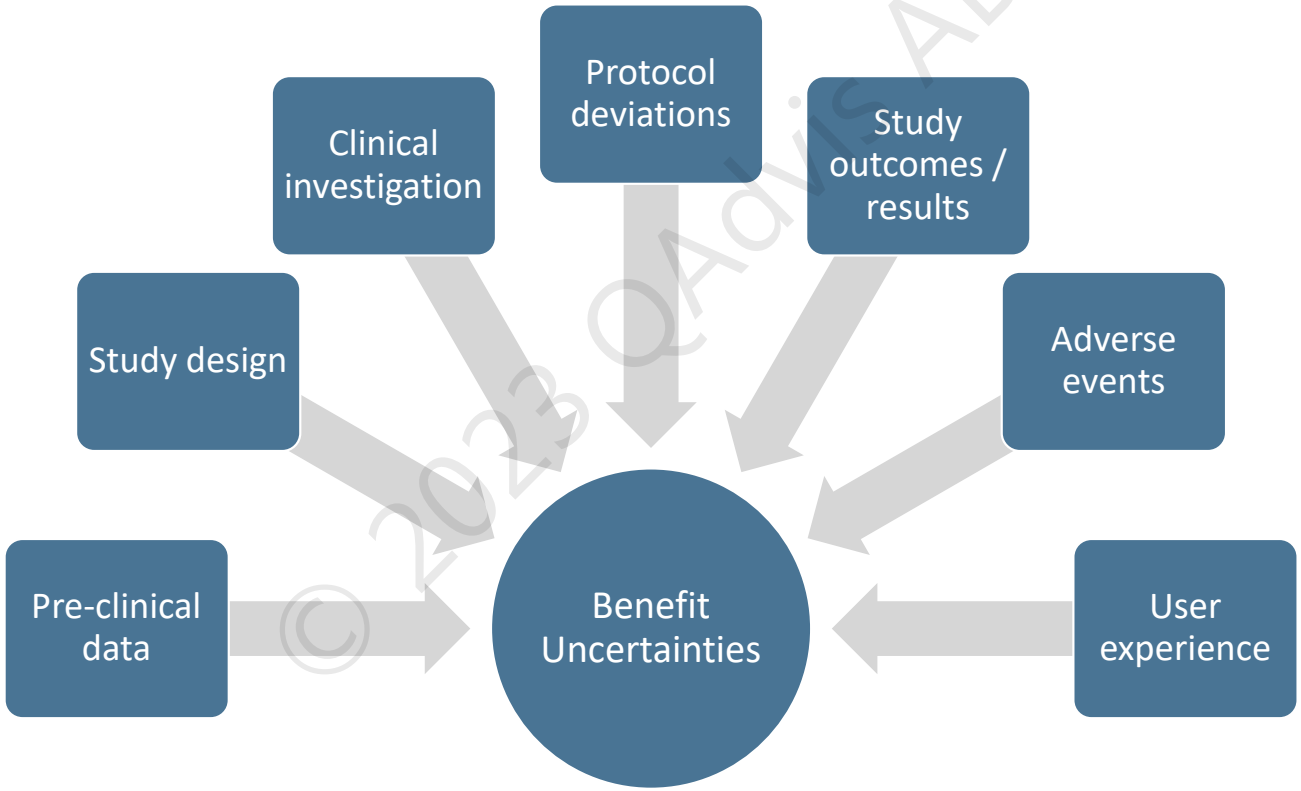
Data Sources



Consider benefits in terms of



Address Uncertainties for the Benefits



Summarize the findings

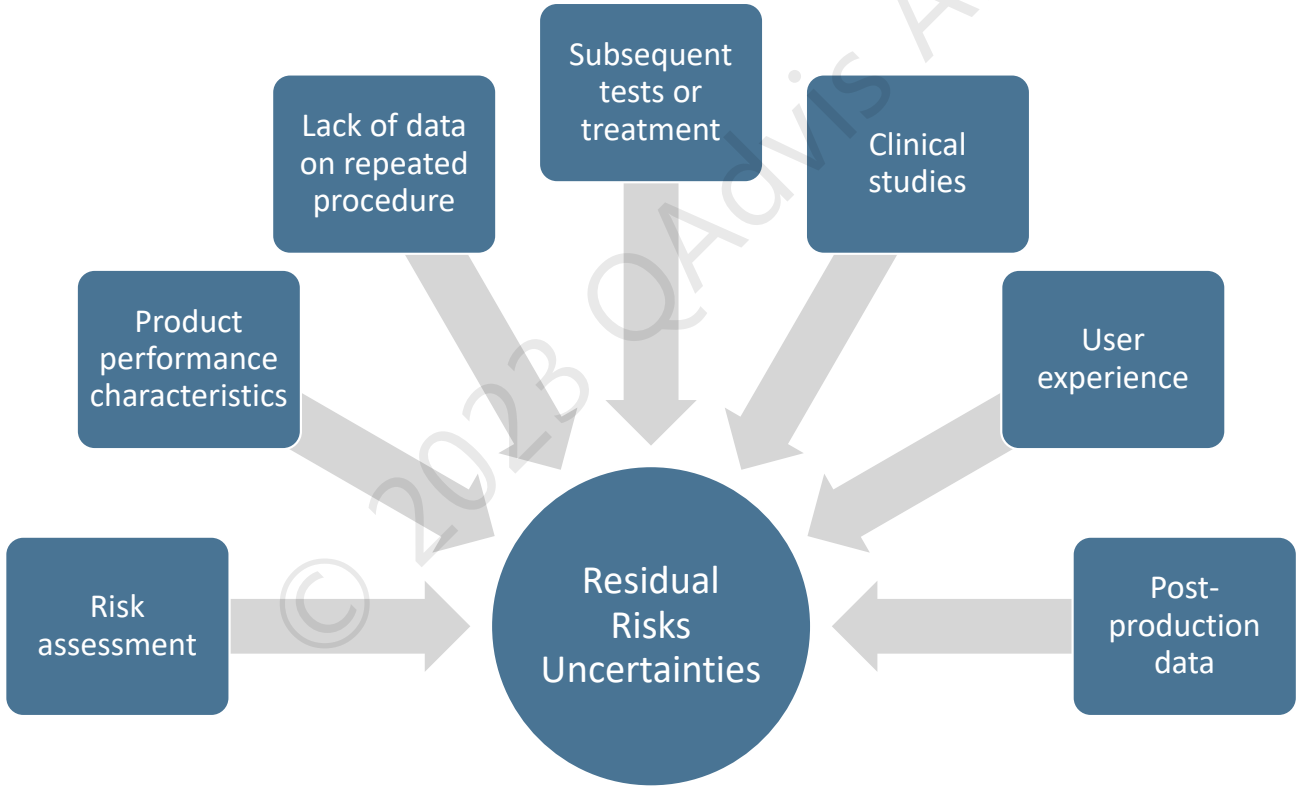
Possible way to summarize the findings of your analysis.

Create narrative for each benefit.

Benefits	Outcomes	Evidence in pre-clinical data	Evidence in Literature / Clinical Studies	Uncertainties

Consider residual risks in terms of

Address Uncertainties for the Risks



Summarize the findings

Possible way to summarize the findings of your analysis.

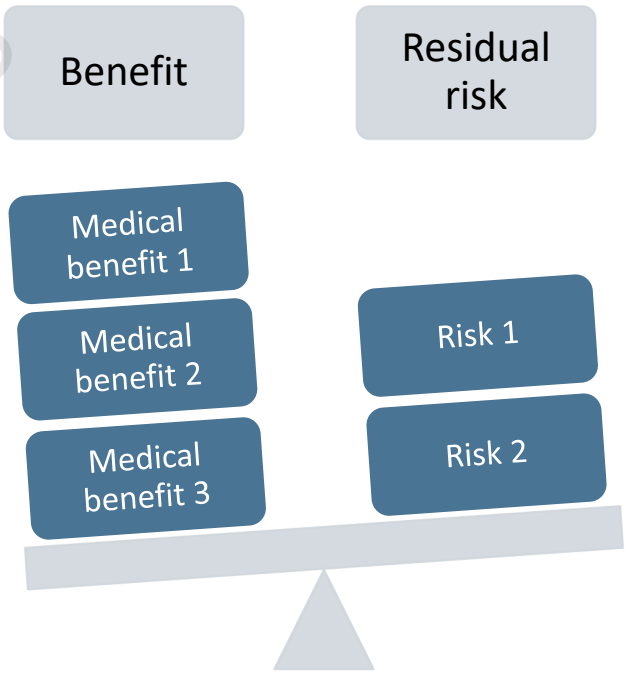
Create narrative for each harm / residual risk.

Harms / Risks	Outcome	Evidence in literature / clinical studies	Evidence in post-production data	Uncertainties

Overall Benefit-Risk Analysis

MDR & IVDR:

The benefit-risk analysis needs to be aligned with and confirmed by the clinical evaluation / performance evaluation.



Narrative - Example 1

“The post-processed images with the device are of comparable diagnostic quality and utility as the state-of-the-art conventional MRI and thus can be used to support diagnosis in the examination of soft tissues. The benefits to the patients are faster diagnosis support, and that could lead to a more precise diagnosis and disease follow-up. It can be concluded that the benefits of the device outweighs the residual risks.”

Narrative – Example 2

“Burns can occur where the return electrode of a high-frequency surgery device is improperly attached to the patient. Although conformance to the relevant product standard minimizes the probability of such burns, they still occur. Nevertheless, the benefit of using a high-frequency surgery device as compared to other surgical techniques outweighs the residual risk of burns.”

Common pitfalls

- Done only for unacceptable or ALARP residual risks
- Risk from manufacturing process not included
- Benefits from the intended use are not provided
- Not aligned with and confirmed by the clinical evaluation / performance evaluation
- Consists only of a statement
- Not based on objective evidence

Take-Aways

- Always for overall residual risks!
- Take into account all residual risk
- Summarize all residual risks
- Determine all benefits
- Create narratives on benefits and risks
- Confirmed by clinical / performance evaluation

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