Maximizing Patient Outcomes Through Quantified Benefit-Risk in the Medical Device Sector

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At a time when misinformation spreads quickly and public scrutiny is high; trust and transparency are critical.

Trust and transparency are foundational to advancing innovation, improving health outcomes and sustaining long-term impact.

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Life is full of choices.

Each day, we make thousands of decisions.

Each decision carries its own balance of risks and rewards.


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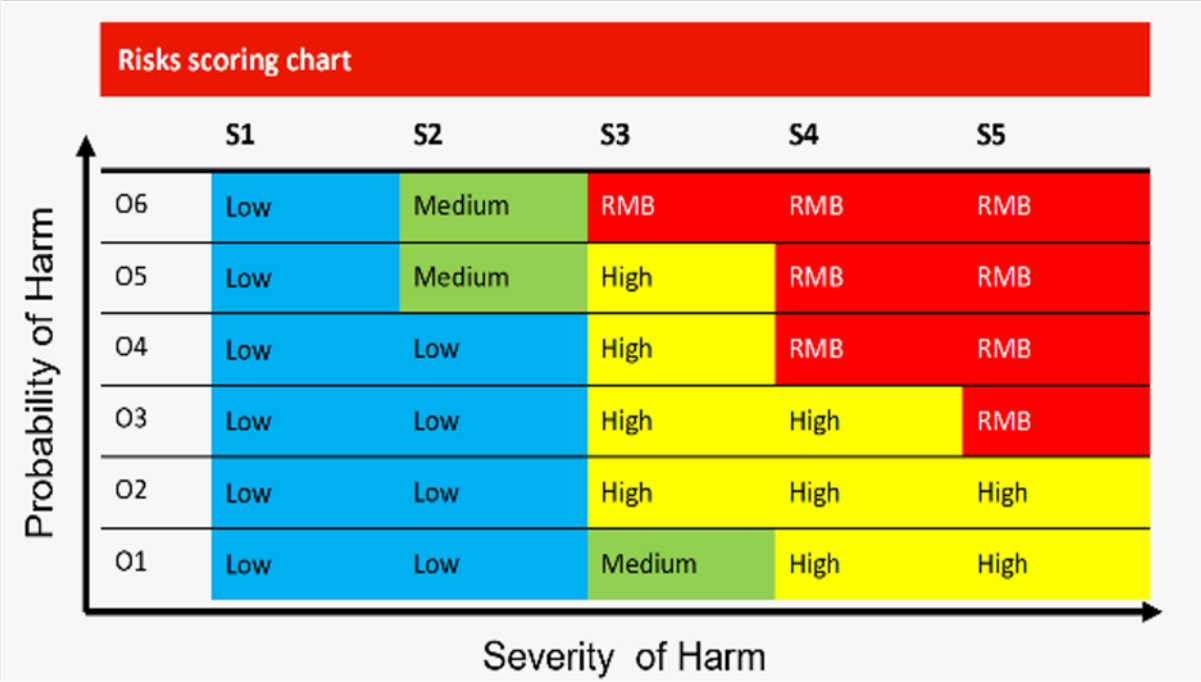
Benefit vs. Risks

Global regulatory landscape

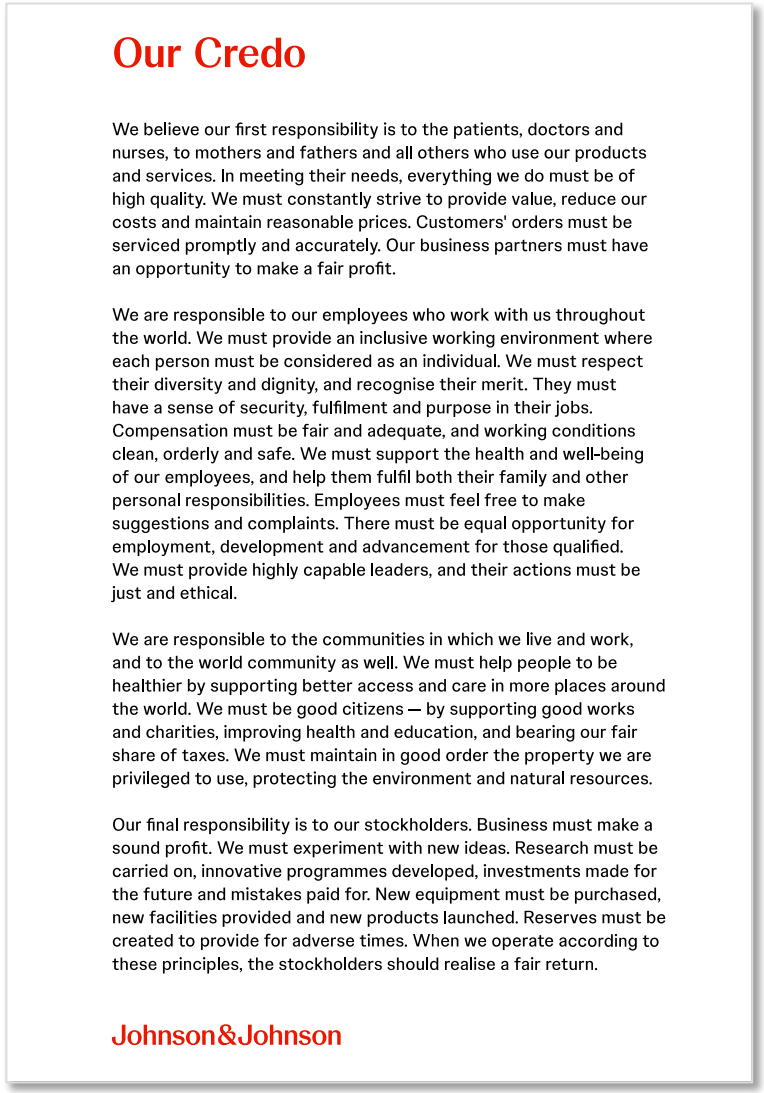
Globally, current regulations drive an industry focus on risk mitigation and clinical claims



The Office of the Chief Medical Officer: Driving healthcare innovation that patients, families and providers trust

Our Drivers

- ✓ Working in the tradition of Credo-based leadership
- ✓ An independent function led with care and science
- ✓ Safety and bioethics embedded in our culture



Our Credo

We believe our first responsibility is to the patients, doctors and nurses, to mothers and fathers and all others who use our products and services. In meeting their needs, everything we do must be of high quality. We must constantly strive to provide value, reduce our costs and maintain reasonable prices. Customers' orders must be serviced promptly and accurately. Our business partners must have an opportunity to make a fair profit.

We are responsible to our employees who work with us throughout the world. We must provide an inclusive working environment where each person must be considered as an individual. We must respect their diversity and dignity, and recognise their merit. They must have a sense of security, fulfilment and purpose in their jobs. Compensation must be fair and adequate, and working conditions clean, orderly and safe. We must support the health and well-being of our employees, and help them fulfil both their family and other personal responsibilities. Employees must feel free to make suggestions and complaints. There must be equal opportunity for employment, development and advancement for those qualified. We must provide highly capable leaders, and their actions must be just and ethical.

We are responsible to the communities in which we live and work, and to the world community as well. We must help people to be healthier by supporting better access and care in more places around the world. We must be good citizens — by supporting good works and charities, improving health and education, and bearing our fair share of taxes. We must maintain in good order the property we are privileged to use, protecting the environment and natural resources.

Our final responsibility is to our stockholders. Business must make a sound profit. We must experiment with new ideas. Research must be carried on, innovative programmes developed, investments made for the future and mistakes paid for. New equipment must be purchased, new facilities provided and new products launched. Reserves must be created to provide for adverse times. When we operate according to these principles, the stockholders should realise a fair return.

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Quantified benefit-risk methodology

We have developed a methodology to apply the same systematic rigor to benefit identification that we currently apply to risks

Our innovative methodology enables quantification of both risks *AND* benefits

Risk—Per ISO 14971	**Benefit—New model**
Health Impact (Death, impairment, inconvenience)	**B**enefit Impact (Life saving, Life Altering, Convenience)
Duration of Health Impact (Permanent, Reversible, Transient)	**D**uration of Benefit (Permanent, Long Term, Short Term)
Probability of Hazard (Always, Rare, Never)	**P**robability of Benefit (Always, Rare, Never)

Where **H** D P = Risk

Severity

Where **B** D P = Benefit

Magnitude

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Patient perspective

DE = Germany
BR = Brazil
US = United States

	Osteoarthritis	Cataracts	Atrial Fibrillation	Lung Cancer
Risks	• **DE** patients had greater concerns around **allergic reaction to metal implant** • **US** groups stressed fear around **addiction to painkillers**	• **US** & **BR** groups were anxious about **recovery limitations** (e.g., reliance on a caregiver, and avoiding straining activities and movements**)**	• While most fear surgical complications, **DE** patients were specifically anxious about **"open"* access to the groin and experiencing damage via surgical instruments**	• **US** patients worried about **pain during lung ablation**, given the extreme changes in temperature • **BR** questioned psychological impact and **ability to maintain hope** in their journey, esp. when doctors are cautiously optimistic about the procedure
Benefits	• Similar perceived benefits across markets; however, **DE** patients focused on improved mental health, specifically **alleviating the negative** attention and sympathy they receive from others when struggling with their mobility in public	• Both **DE** and **US** groups highlighted the **safety benefits of being able to see more clearly** (less likely to trip on uneven surfaces, fall, or get into car accident)	• **BR** and **US** groups emphasized the **ability to have a "normal"* diet** (e.g., caffeine, fewer medication restrictions) • **US** patients believed the ablation could **relieve the emotional stress** of waiting for their heart to reach its limit and "give up"*	• **BR** patients focused on the **psychological benefits** (relief if "cured"*) • **US** groups viewed the benefits of ablation through the lens of treatment type • Most appreciated the procedure as a preferred alternative to chemo or radiation

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Patient verbatim

Benefits analysis

Impact level of benefit

Benefit impact level	
B4	Life-saving and/or life-sustaining
B3	• Significant restoration of patient health, quality of life, or function • Significant improvement to clinical management and/or usability
B2	• Partial improvement of patient health, quality of life, or function • May require future medical intervention (to include interim steps in staged procedures) • Moderate improvement to clinical management and/or usability
B1	• Limited benefit to the patient, enabling general patient care • Minor improvement to clinical management and/or usability
B0	No clinical benefit (should not be included in Clinical RBA)

Duration of benefit | Qualitative assessment of the expectation of the physician and patient

Duration		Length of time
D3	Permanent	Life of the patient / user
D2	Long-term	12 months or greater, but less than permanent
D1	Short-term	Less than 12 months

Magnitude of benefit matrix

	B1	B2	B3	B4
D3	M2	M3	M4	M5
D2	M1	M2	M3	M4
D1	M1	M1	M2	M3

Benefits analysis

Probability of benefit occurring

Probability		Description	Suggested probability ranges
P1	Extremely rare	The identified benefit rarely occurs	Less than 10%
P2	Infrequently	The device has been known to result in the identified benefit but only occasionally and/or under unusual circumstances	10-30%
P3	Sometimes	The device can reasonably be expected to produce the identified benefit under normal circumstances	30-70%
P4	Frequently	The device has a high likelihood of producing the identified benefit	70-90%
P5	Almost always	The device will produce the identified benefit nearly every time	Greater than 90%

Magnitude of benefit matrix

	B1	B2	B3	B4
D3	M2	M3	M4	M5
D2	M1	M2	M3	M4
D1	M1	M1	M2	M3

Benefit matrix

	M1	M2	M3	M4	M5
P5	Medium	Medium	High	High	High
P4	Medium	Medium	High	High	High
P3	Low	Medium	Medium	High	High
P2	Low	Low	Medium	Medium	High
P1	Low	Low	Low	Medium	Medium

Benefit-risk analysis

Benefits scoring chart

	M1	M2	M3	M4	M5
P5	Medium	Medium	High	High	High
P4	Medium	Medium	High	High	High
P3	Low	Medium	Medium	High	High
P2	Low	Low	Medium	Medium	High
P1	Low	Low	Low	Medium	Medium

Risks scoring chart

	S1	S2	S3	S4	S5
O6	Low	Medium	RMB	RMB	RMB
O5	Low	Medium	High	RMB	RMB
O4	Low	Low	High	RMB	RMB
O3	Low	Low	High	High	RMB
O2	Low	Low	High	High	High
O1	Low	Low	Medium	High	High

Benefits scoring chart

	M1	M2	M3	M4	M5
P5	4.0	16.0	36.0	64.0	100.0
P4	3.2	12.8	28.8	51.2	80.0
P3	2.4	9.6	21.6	38.4	60.0
P2	1.6	6.4	14.4	25.6	40.0
P1	0.8	3.2	7.2	12.8	20.0

Risks scoring chart

	S1	S2	S3	S4	S5
O6	4.0	16.0	36.0	64.0	100.0
O5	3.3	13.3	30.0	53.3	83.3
O4	2.7	10.7	24.0	42.7	66.7
O3	2.0	8.0	18.0	32.0	50.0
O2	1.3	5.3	12.0	21.3	33.3
O1	0.7	2.7	6.0	10.7	16.7

Total benefit score ÷ total risk score = **total device ratio**

*RMB: J&J MedTech Risk Management Board

Benefit-risk analysis

Greater than 1.0	• Consider the therapeutic area when evaluating the overall risk ratio	• Team needs to ensure that supporting evidence and qualitative documentation clearly demonstrate the benefits outweigh the risk
Less than 1.0	• Additional comparison to SOA, alternative treatment and no treatment is required to substantiate that benefits are enough to support product • Potential target for patient preference	• Study to further clarify need

Value of a quantified benefit-risk methodology

An industry-first innovation

Framework for *evaluating, documenting, and quantifying* known or foreseeable product medical/ clinical benefits and risks

Promotes value across the product lifecycle

- Shapes initial design selection
- Evaluates benefit-risk before trials
- Drives initial benefit-risk assessment for submissions
- Assesses design changes
- Aids Post Market Surveillance
- Strengthens Health Hazard Evaluations

Improves healthcare

- Integrates patient, clinician, and regulatory feedback
- Drives patient-centric recall decisions (compares baseline and recall scores)
- Offers power to evaluate heath equity issues
- Moves us closer to continuously evolving benefit-risk profiles across a product's lifecycle

The Journey to Enhanced, Patient-Centered Decision-Making

Sustainability

- Building a scalable solution requires more than methodology—it demands smart technology.
- An automated IT platform is in development to streamline benefit-risk scoring.
- This creates a dynamic, evolving view of product performance across its lifecycle.

Regulatory Engagement

- Ongoing collaboration with global regulators is shaping the future of benefit-risk assessment.
- Feedback from the FDA and EU notified bodies has directly informed methodology enhancements.
- Transparent dialogue ensures alignment with evolving regulatory expectations.

Patient Centricity

- Every innovation is rooted in a human story—of resilience, healing, and hope.
- Empowering patients means designing solutions that reflect their lived experiences.
- Compassionate, patient-informed decision-making builds trust and drives better outcomes.

Questions & Answers

Thank you

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