Beyond Biocompatibility: Integrating Clinical Evidence into Biological Evaluation Across the Medical Device Lifecycle

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Objectives

- Explore how clinical data can strengthen biological evaluations throughout the entire medical device lifecycle, from development through post-market surveillance.
- Discuss the evolving role of clinical evidence in complementing traditional biocompatibility and toxicological assessments.
- Examine the relationship between preclinical biological testing and real-world clinical outcomes, including the limitations of predicting clinical performance solely through laboratory testing.
- Review how post-market surveillance (PMS) and clinical experience can provide valuable insights into biological safety and device performance over time.

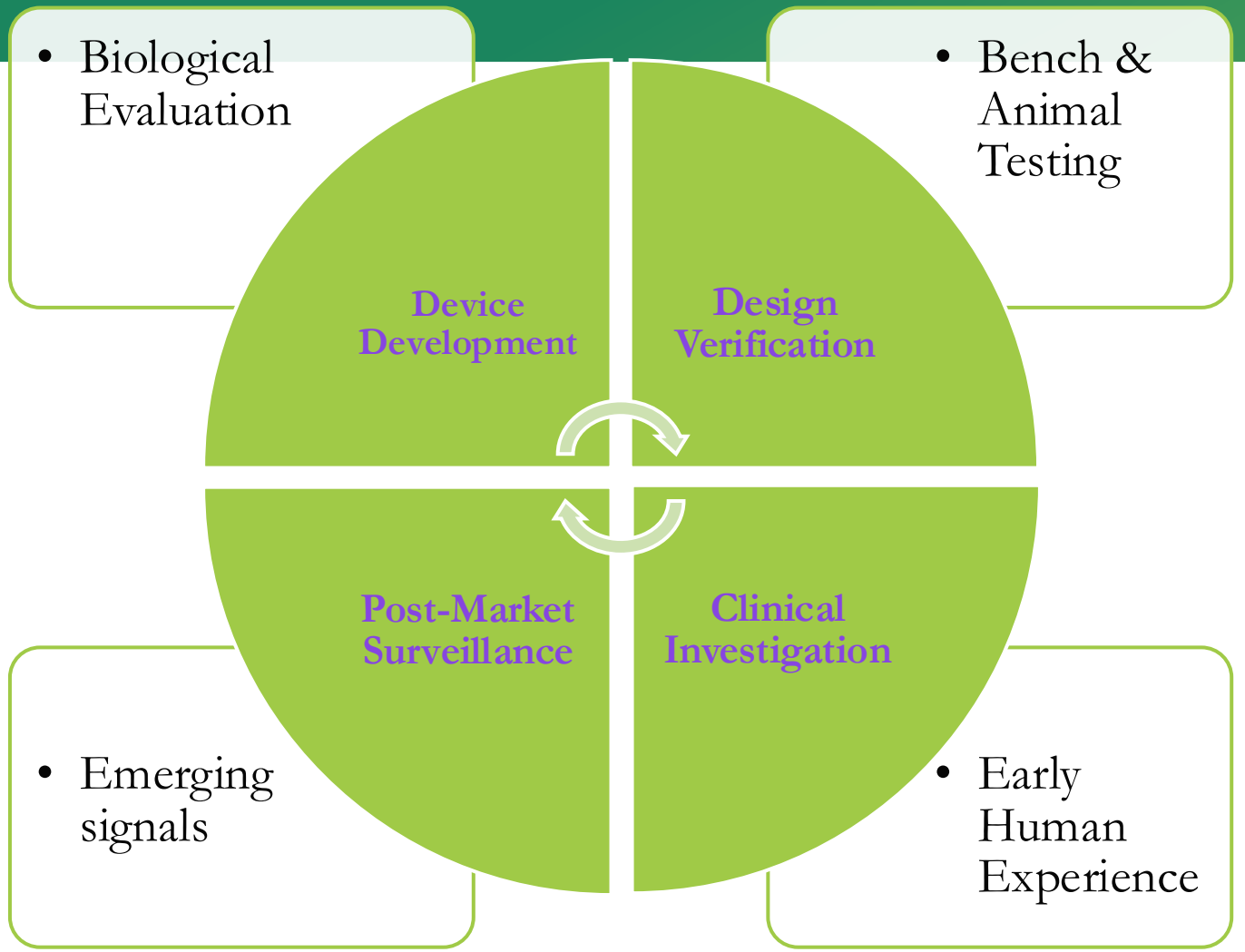
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Objectives

- Highlight the importance of clinical judgment in interpreting biological risks within the context of the device's intended use, patient population, and available treatment alternatives.
- Consider how benefit-risk assessment supports decision-making when biological risks must be balanced against significant clinical needs, particularly for life-threatening conditions.
- Discuss challenges in linking patient symptoms and adverse events directly to device-related biological effects and how clinical evidence can help bridge these gaps.
- Review emerging regulatory perspectives and lifecycle-focused approaches, including increased emphasis on integrating clinical and biological evidence throughout a device's market journey.

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Clinical Data as a Critical Component of Lifecycle Biological Evaluation



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Beyond Traditional Biocompatibility: The Evolving Role of Clinical Evidence

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Traditional Biological Evaluation

Predictive evidence

- Chemical and material characterization
- Toxicological risk assessment
- In vitro and in vivo testing
- Exposure-based risk estimation
- Identification of biological hazards

Clinical Evidence

Observed human outcomes

- Clinical investigation findings
- Patient-reported symptoms
- Adverse events and complications
- Real-world and registry data
- Long-term clinical experience

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Preclinical Biological Testing vs. Real-World Clinical Outcomes

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Preclinical observations Controlled experimental conditions	Clinical outcomes Complex human environments
• Cytotoxicity	• Inflammation or hypersensitivity
• Sensitization and irritation	• Pain and tissue reactions
• Systemic toxicity	• Device-related complications
• Local tissue response	• Functional outcomes
• Material degradation	• Long-term performance

⇆ **Imperfect correlation — clinical interpretation required**

Why predictions may differ from clinical reality

- Differences in species, exposure, and biological response
- Patient comorbidities and physiological variability
- Device interactions with tissues and concomitant therapies
- Limitations of test conditions and follow-up duration

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Post-Market Surveillance: Translating Clinical Experience into Biological Safety Knowledge

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- ✓ Predict biological hazards
- ✓ Identify potential toxicological risks
- ✓ Demonstrate compliance with ISO 10993
- ✓ Support initial regulatory approval

What Preclinical Testing Can Tell Us?

What Clinical Experience Adds?

- ✓ Validates biological safety in humans
- ✓ Detects rare or delayed adverse events
- ✓ Evaluates long-term tissue responses
- ✓ Assesses performance across diverse patient populations
- ✓ Identifies previously unrecognized biological risks
- ✓ Supports continuous improvement of the Biological Evaluation Report (BER)

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Importance of intended use, patient population, disease severity, expected clinical benefit, and available therapeutic alternatives

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BioComp Evidence Answers

- Is there a biological hazard?
- What is the magnitude of exposure?
- What toxicological effects are possible?
- How predictable are these findings?
- What uncertainties remain?

Clinical Judgment Answers

- Does this risk matter clinically?
- Which patients are exposed?
- How serious is the underlying disease?
- What benefit does the device provide?
- Are safer therapeutic alternatives available?
- Is the residual biological risk acceptable?

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Connecting Patient Symptoms to Device-Related Biological Effects

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Potential contributors to a reported adverse event

Device materials

Toxicity, sensitization, degradation

Device mechanics

Wear, friction, pressure, structural failure

Procedure

Tissue injury, infection, technique

Patient factors

Disease progression, comorbidities, medications

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Structured Causality Assessment

Timing • Biological plausibility • Exposure • Alternative causes • Supporting evidence

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How clinical evidence bridges the gap?

- Characterize patterns, timing, and frequency of adverse events
- Evaluate alternative explanations and competing risks
- Correlate clinical findings with laboratory, pathology, and explant data
- Use longitudinal evidence to reassess biological risks

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Case Examples

Clinical Context	Acceptability of Residual Biological Risk
Cosmetic skin device	Very low tolerance for uncertainty
Elective orthopedic implant	Low tolerance; high expectations for long-term safety
Life-saving ventricular assist device	Higher residual risk may be acceptable if substantial survival benefit exists
Emergency thrombectomy device	Greater uncertainty may be acceptable given immediate risk of death or disability
Novel therapy for patients with no effective alternatives	Benefit may justify accepting greater biological uncertainty with appropriate controls

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Key Take-Home Messages

✓ Biological testing identifies potential hazards

✓ Clinical judgment determines the clinical relevance of those hazards

✓ Benefit-risk assessment is patient-centered, not test-centered

✓ The same biological finding may lead to different regulatory decisions depending on the intended use and patient population

✓ Biological evaluation is a living process that continuously integrates new clinical evidence to ensure patient safety while preserving access to beneficial technologies

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Thank you

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