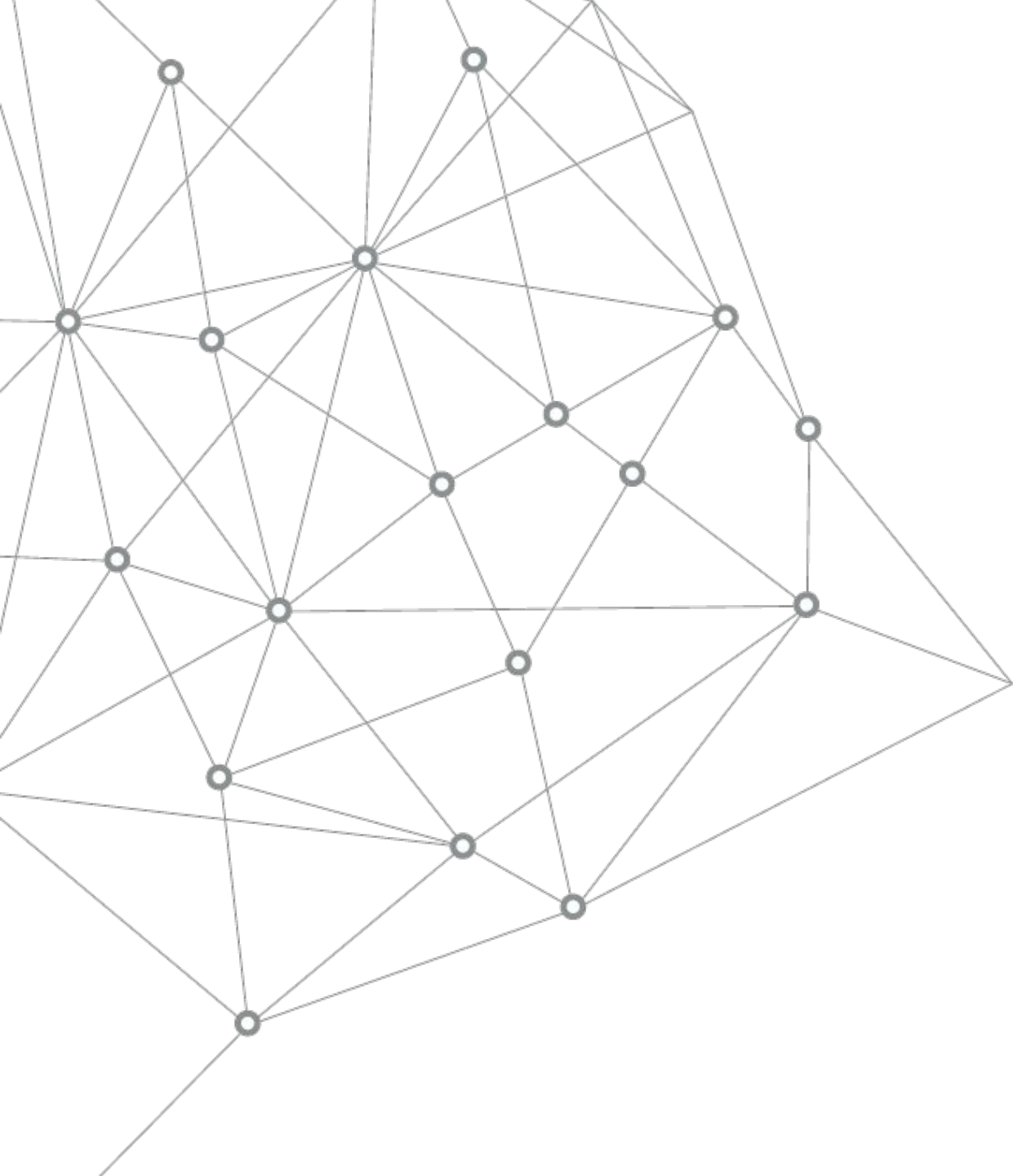




Optimizing Medical Device Design and Lifecycle Management: From Innovation to Surveillance

**ENHANCING SAFETY THROUGH
COMPREHENSIVE DEVICE
DEVELOPMENT STRATEGIES**



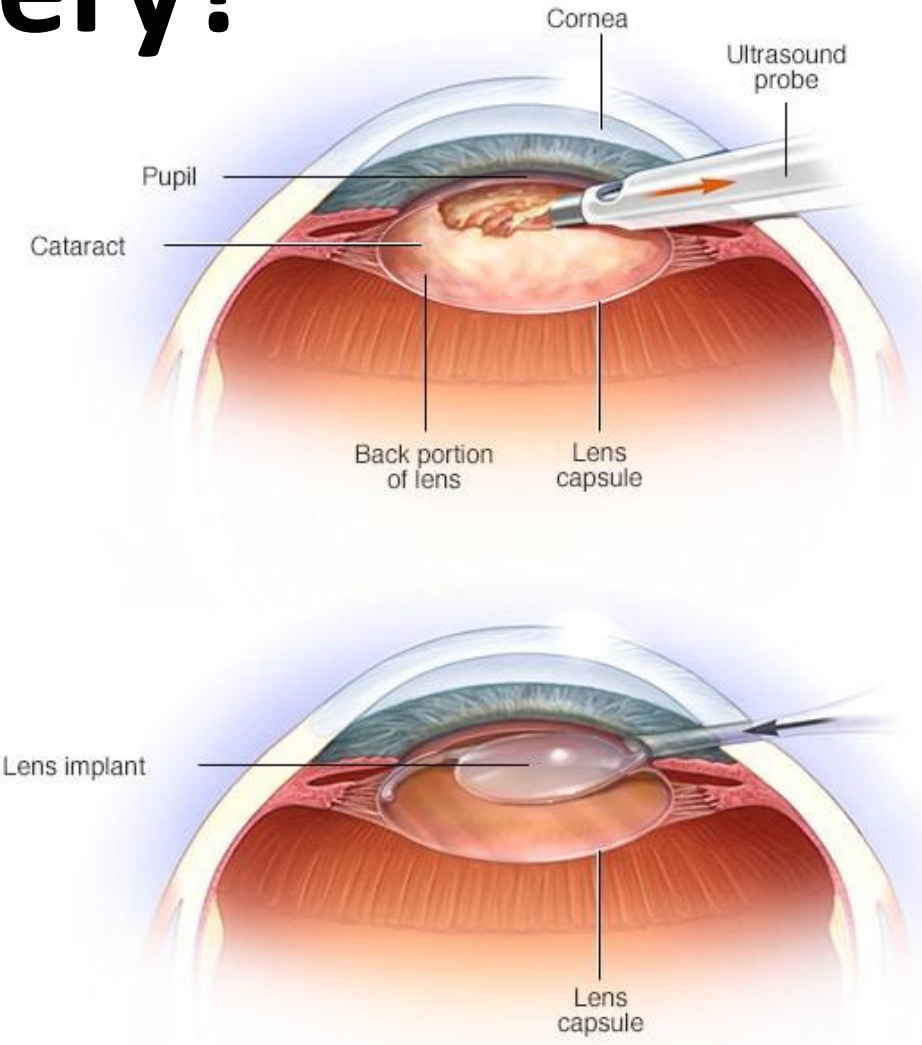
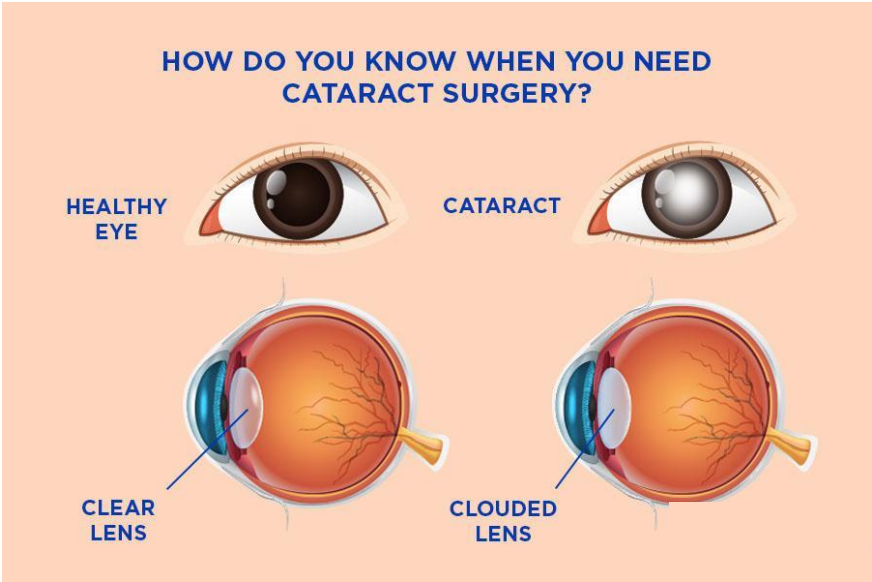
HOYA

SURGICAL OPTICS

Madhu Ayyagari

Chief Technology Officer

What is Cataract Surgery?



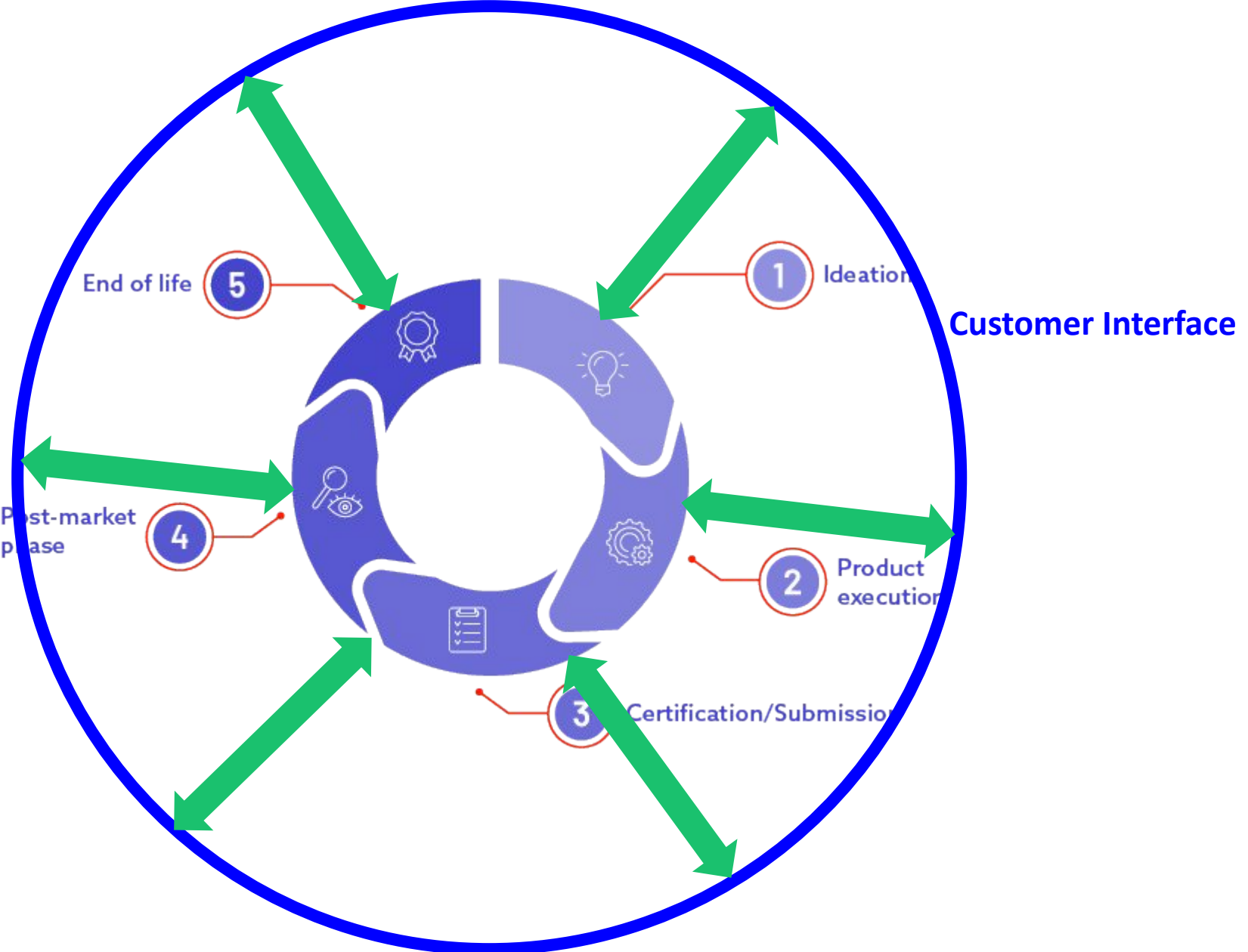


Agenda Overview

customer/consumer

- Driving innovation with patient feedback to refine device safety and efficacy
- Integrating real-world data into post-market surveillance for proactive risk management
- Leveraging advanced analytics to enhance medical device design and functionality
- Ensuring compliance through lifecycle management and continuous performance monitoring

Product Lifecycle & Customer/Consumer Interaction



**Driving innovation with
patient feedback to
refine device safety and
efficacy**

Identifying Unmet Clinical Needs and Challenges



Recognizing Unmet Needs

Identifying gaps in current medical care is essential to drive meaningful innovation in healthcare devices.

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Collaborative Approach

Collaboration with clinicians, patients, and stakeholders ensures comprehensive understanding of real-world healthcare challenges.

Identifying Unmet Clinical Needs and Challenges



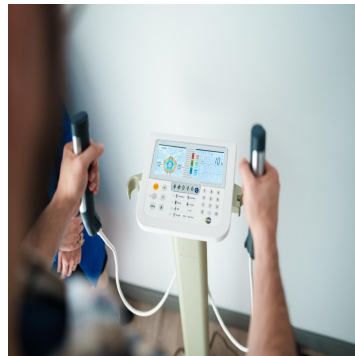
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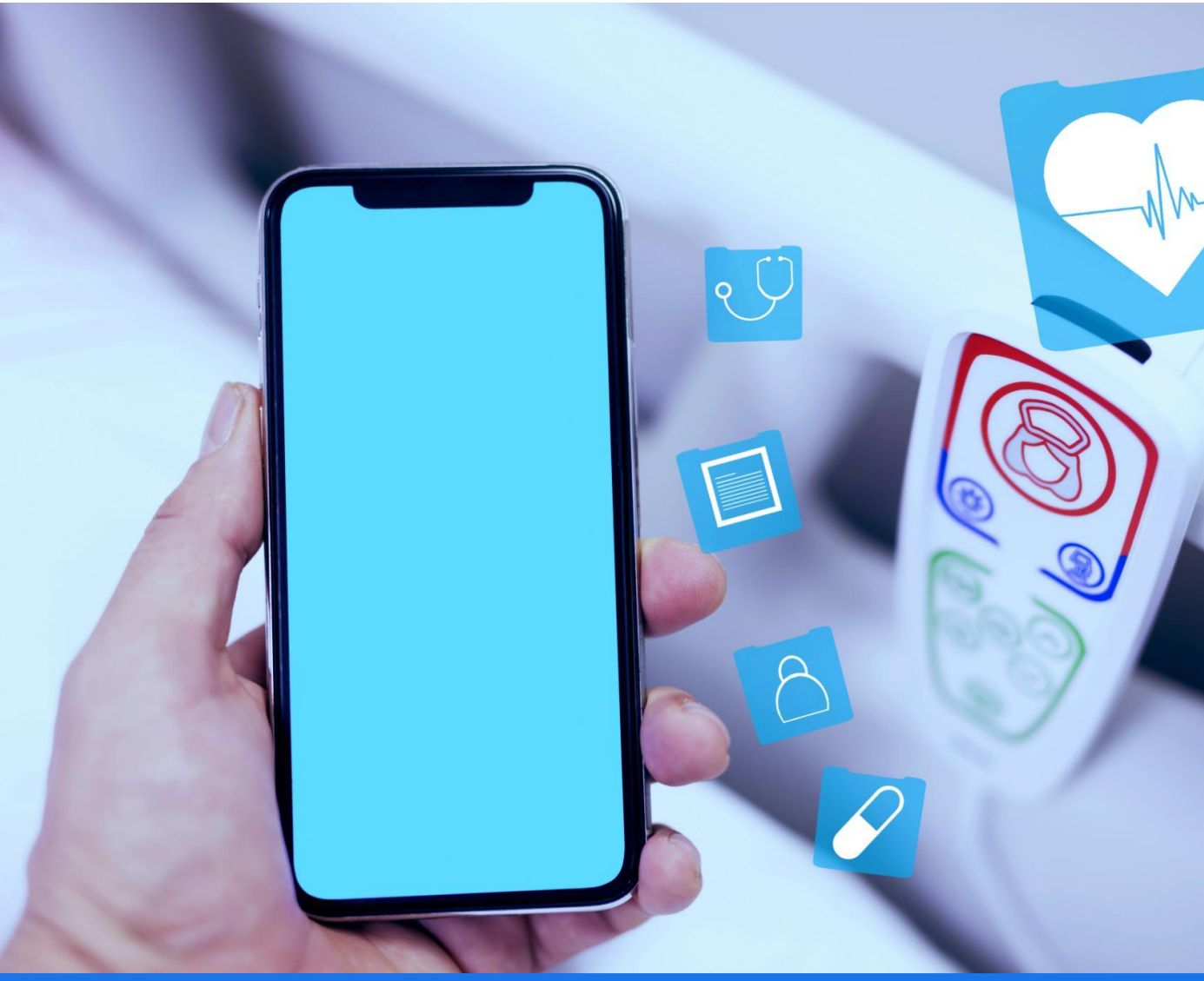
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Addressing Real-World Problems

Innovations must effectively address practical problems faced in medical care to improve patient outcomes.



Incorporating User-Centered Design Principles

Focus on User Needs

User-centered design ensures that the needs and limitations of end-users guide the development process.

Early Stakeholder Engagement

Involving healthcare professionals and patients early improves device usability, safety, and acceptance.

Navigating Regulatory Requirements in Early Development



Importance of Early Compliance

Understanding regulatory standards early helps prevent costly development delays and ensures smoother project progression.

Classification and Documentation

Proper classification and thorough documentation are critical steps to meet regulatory requirements effectively.

Adherence to Guidelines

Aligning development with global regulatory guidelines ensures acceptance and reduces risk of non-compliance.

Risk Management and Design Validation

Systematic Risk Assessment

Risk assessment identifies potential hazards early and implements mitigation strategies during design.

Design Validation

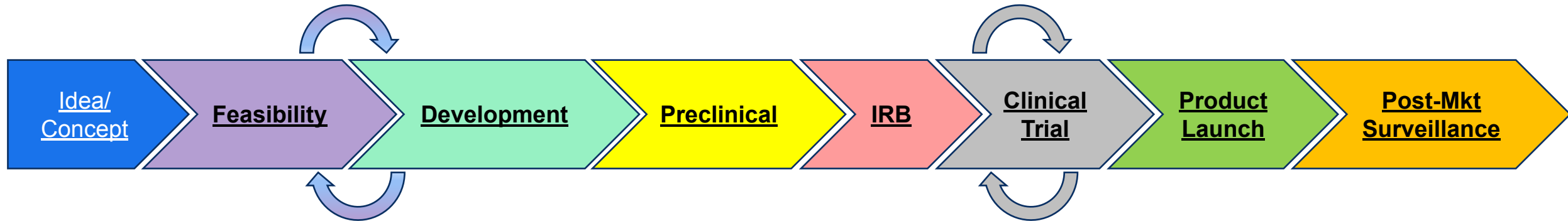
Validation ensures devices meet intended use and comply with regulatory safety standards.



**Integrating real-world data
into post-market
surveillance for proactive
risk management**



Pre- and Post-Market Surveillance



- Clinical studies validate that the product design meets patient needs. Very important to prove to regulatory bodies that the product meets their expectations.
- Clinical studies are conducted in a systematic and tightly controlled manner under a strict protocol. Surgeon selection, geography, training, patient selection, indications & contra-indications, etc.
- Real-world clinical outcomes may be different due to several variables at play. Companies may choose to employ different strategies to maximize product performance depending on the complexity of the product. For examples, wet-labs, soft-launch, HCP in-servicing, close monitoring, etc.



Collecting and Analyzing Real-World Evidence

Real-World Data Sources

Real-world data come from clinical practice and registries, offering insights beyond controlled clinical trials.

Support for Evidence-Based Decisions

Analyzing real-world evidence supports informed decisions for device improvements and regulatory submissions.



Implementing Feedback-Driven Design Enhancements

User Feedback Integration

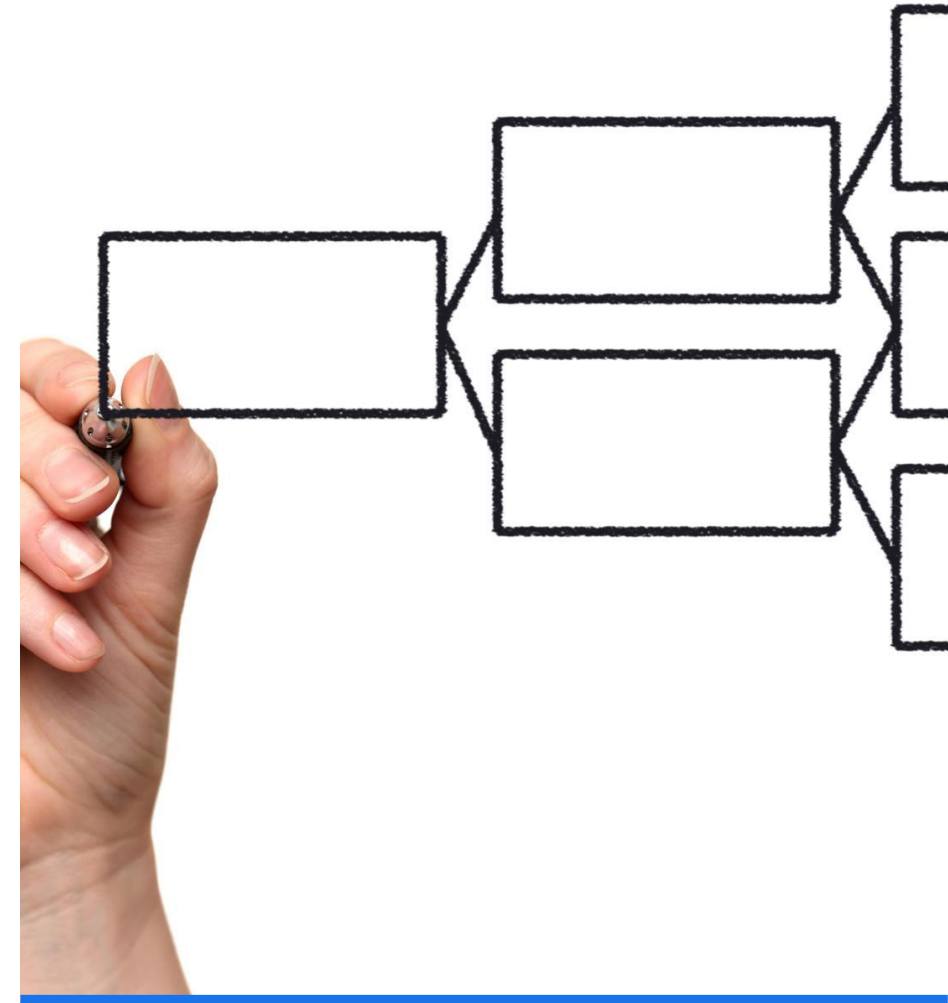
Incorporating continuous user feedback helps refine designs to better meet user needs and expectations.

Surveillance Data Utilization

Analyzing surveillance data enables identification of design issues and opportunities for enhancement.

Iterative Design Process

Iterative modifications foster innovation while ensuring safety and effectiveness in device design.





Monitoring Device Safety and Performance

Data Collection on Adverse Events

Surveillance systems gather detailed data on adverse events to identify potential device risks early.

Device Efficacy Monitoring

Continuous monitoring of device performance ensures effectiveness and safety for patients.

Proactive Risk Mitigation

Early issue detection allows proactive measures to reduce risks and maintain patient trust.

Risk Management and Design Validation

Systematic & Pro-Active Risk Assessment

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**Leveraging advanced
analytics to enhance medical
device design and
functionality**



Leveraging Advanced Engineering Tools and Simulation

Computer-Aided Design

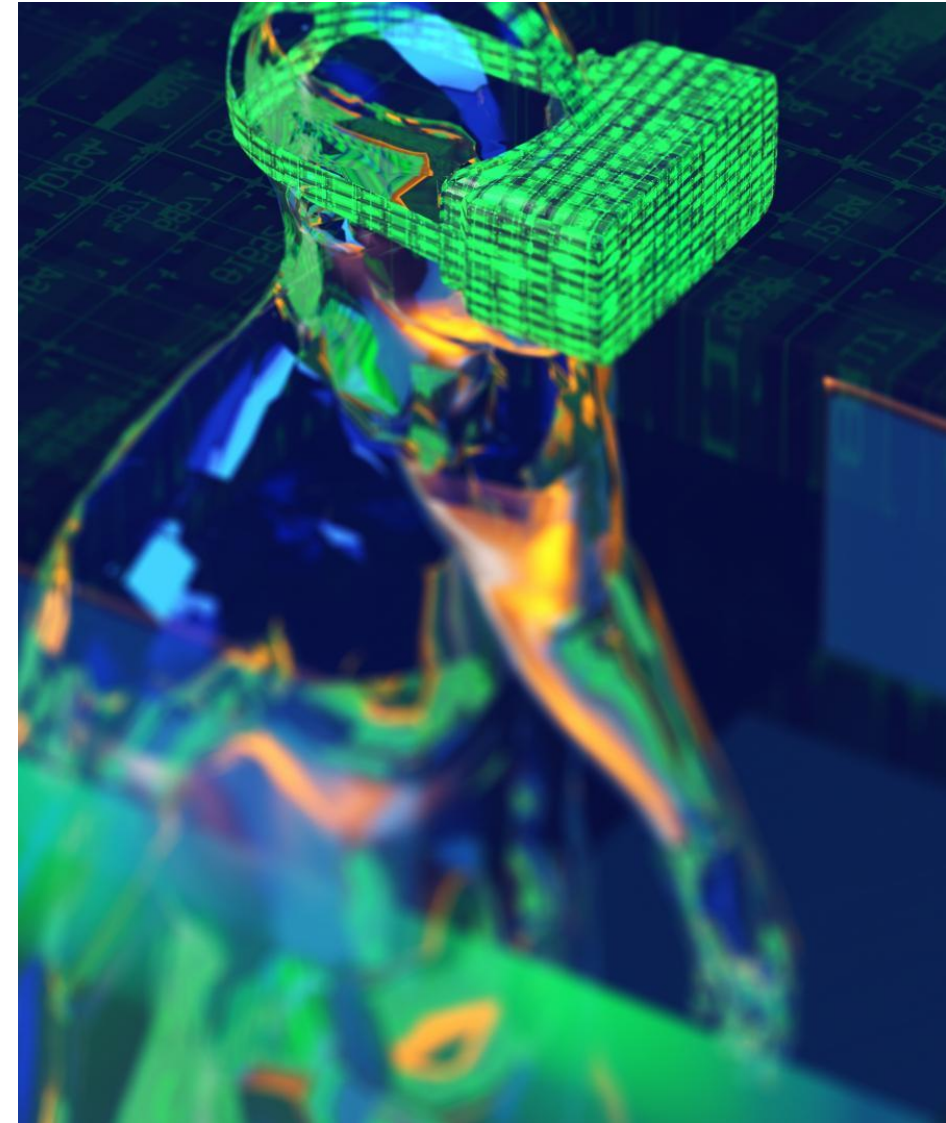
CAD enables precise digital modeling of devices, facilitating detailed designs and modifications before production.

Finite Element Analysis

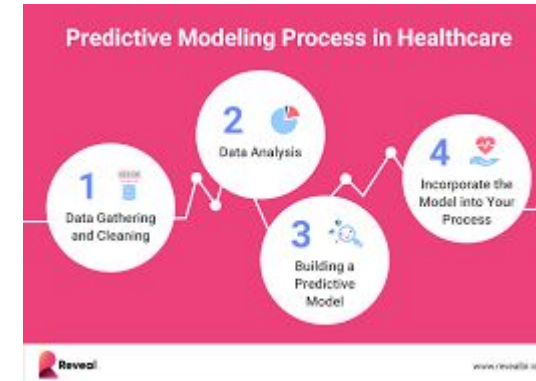
FEA predicts structural behavior and potential failures by simulating stress and strain on components.

Virtual Simulations

Virtual simulations optimize device parameters and reduce development time by testing scenarios digitally.



- **Predictive Modeling**
- **FEA, MFA**
- **Monte Carlo Simulations**
- **Material Informatics**
- **SPC**
- **Clinical study database analytics**
- **Manufacturing data analytics**
- **Pre- and post-op data correlation**





Iterative Prototyping and Usability Testing

Multiple Prototype Iterations

Creating several prototype versions allows for practical testing and gathering valuable user feedback at each stage.

Usability Testing Benefits

Conducting usability tests helps identify design flaws early and enhances device ergonomics for better safety and effectiveness.

Lifecycle Management Strategies

Manufacturing Scalability and Quality Assurance



Scalability Challenges

Scaling production from prototype to mass manufacturing demands efficient process adaptation and resource management.

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Quality Systems

Implementing robust quality systems ensures consistent device quality and safety throughout production batches.

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Regulatory Compliance

Maintaining regulatory compliance is essential to meet safety standards and legal requirements in large-scale manufacturing.



Post-Market Modifications and Upgrades

Need for Post-Market Updates

Devices often need updates after launch to improve functionality and address issues discovered in real use.

Risk Evaluation

Evaluating potential risks from modifications is essential to maintain device safety and effectiveness.

Regulatory Compliance

Documenting changes ensures compliance with regulations and supports transparency during audits.

Sustainability and End-of-Life Considerations

Eco-Friendly Materials

Using sustainable and biodegradable materials reduces the environmental footprint of medical devices.

Proper Disposal and Recycling

Planning for disposal or recycling ensures minimal environmental harm at the end of device life.

Lifecycle Management

Integrating sustainability into lifecycle management supports long-term environmental responsibility.



Post-Market Surveillance and Continuous Improvement



Post-Market Challenges



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Continuous Improvement



Mfg Processes for capacity, COGS, RA demands

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Conclusion

Holistic Development Approach

Integrating customer-centric innovation and design optimization ensures development of effective medical devices.

Lifecycle Management

Managing the lifecycle of devices promotes sustainability and long-term effectiveness.

Post-Market Surveillance

Vigilant monitoring after market release ensures safety and regulatory compliance.