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Translational Pathways for Cardiovascular Devices -eBook-

Part I: Basic Concepts In Device Development

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- I.1 **Introduction** ([Preview article for free Online](#))
David R. Holmes, MD; Anthony DeMaria, MD; Nabil Dib, MD, MSc; Spencer King III, MD;
David G. Reuter, MD, PhD
- I.2 **Overview of Cardiovascular Translational Research** ([Preview article and lectures by Nabil Dib, MD and Robert Califf, MD for free online](#))
Nabil Dib, MD, MSc
- I.3 **A Needs-Based Approach to Health Technology Innovation: The Stanford Biodesign Process Concept Development for Unmet Clinical Needs** ([Lecture: Todd Brinton, MD](#))
Todd J. Brinton, MD; Uday N. Kumar, MD; Jonathan G. Schwartz, MD; Paul G. Yock, MD
- I.4 **Intellectual Property and Strategy Development**
Neil K. Nydegger, Esq
- I.5 **Regulatory Requirement for Marketing Approval** ([Preview lecture by Bram Zuckerman, MD for free online](#))
Felipe Aguel; Deborah G. Castillo, PhD; Joseph Chin, MD; Bram D. Zuckerman, MD
- I.6 **Regulatory Assessment of Medical Devices in the European Union**
Alan G. Fraser, MD; Robert A. Byrne, PhD; Tom Melvin, MD; Niall MacAleenan, MD;
Olga Tkachenko, PhD; Paul Piscoi, MD
- I.7 **Requirements for Reimbursement for Innovation** ([Lecture: Joseph Chin, MD](#))
Joseph Chin, MD; Seth Clancy
- I.8 **Requirement for New Technology to be Included in the Guidelines: “The Ultimate Goal”** ([Lecture: Alice Jacobs, MD](#))
Alice Jacobs, MD

- I.9 [Advanced Biostatistics for Translational Research](#) (Lectures: Chris Mullin & Roseann White, PhD)
Chris Mullin; Roseann White
- I.10 [Early Feasibility Studies](#) (Lectures: Andrew Farb, MD & David Reuter, MD)
Andrew Farb, MD; David G. Reuter, MD, PhD

Part II: Translational Pathway For Transcatheter Aortic Valves

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Stanton Rowe
- II.2 [Unmet Clinical Needs](#) (Lecture: Martin Leon, MD)
Martin B. Leon, MD
- II.3 [Preclinical Evaluation for TAVR](#)
Sarah Ahlberg, Carol E. Eberhardt, Russell Hodge, Timothy Kelley, Jeffrey Kepner, Hatem Tadros
- II.4 [Clinical Evaluations – Methods](#) (Lectures: Nicole Ibrahim, PhD, & Stanton Rowe)
Nicole Ibrahim, PhD
- II.5 [Clinical Evaluations – Endpoints](#) (Lecture: Ori Ben-Yehuda, MD)
Ori Ben-Yehuda, MD
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Seth Clancy
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Stanton Rowe

Part III: Translational Pathway For Transcatheter Mitral And Tricuspid Valve Development

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Blasé Carabello, MD

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Patrick Verta, MS, DVM, MD
- III.4 [Clinical Evaluations – Methods \(Lecture: Michael Mack, MD\)](#)
John Laschinger, MD
- III.5 [Clinical Evaluations – Endpoints \(Lecture: Blasé Carabello, MD\)](#)
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Part IV: Translational Pathway For Coronary Stent Development

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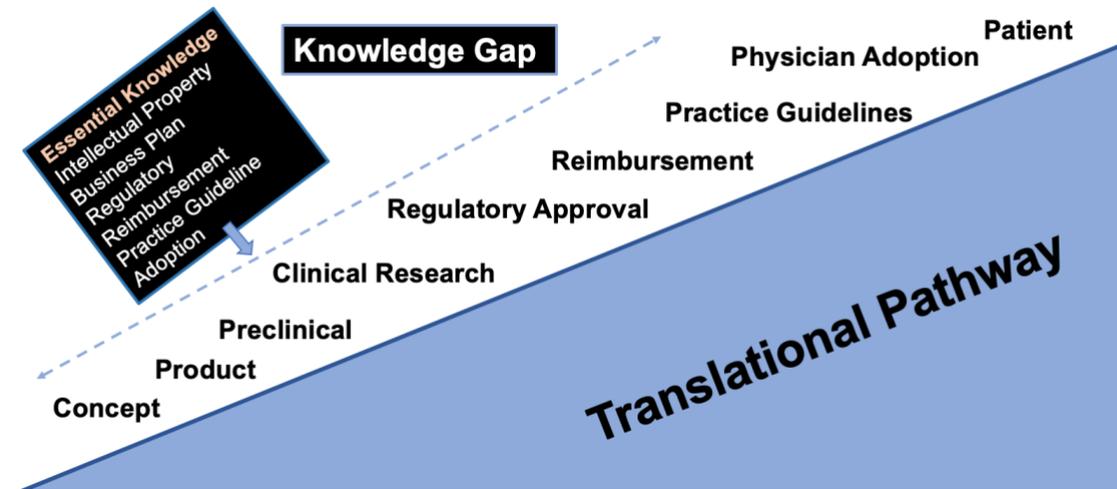
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