

**LIFECYCLE EVALUATION OF MEDICAL DEVICES – SUPPORTING OR JEOPARDIZING PATIENT OUTCOMES? A COMPARATIVE ANALYSIS OF EVALUATION MODELS**

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**Harkin\_Supplemental-9\_Study (reference texts) Characteristics**

Table 9.1: Characteristics of the reference texts chosen to represent each model.docx

<i>Model</i>	<b>Paper</b>	<b>Author/Proposer</b>	<b>Publication period</b>	<b>Geographical region</b>	<b>Publication Category</b>	<b>Funding/support or COI declared</b>
<i>Baldock-NPD</i>	How to introduce a new product	Baldock	1960-1969	Americas	Conference/Presentation	None declared
<i>DOI</i>	Diffusion of Innovations	Rogers	1960-1969	Americas	Book	None declared
<i>PLC</i>	Exploiting the Product Life Cycle	Levitt	1960-1969	Americas	Magazine	None declared
<i>Bass</i>	A new product growth for model consumer durables	Bass	1960-1969	Americas	Journal article	None declared
<i>IRP</i>	Life Histories of Innovations: How New Practices Become Routinized	Yin	1980-1989	Americas	Journal article	Funding/support declared
<i>7Sm-IC</i>	From "Promising Report" to "Standard Procedure": Seven Stages in the Career of a Medical Innovation	McKinlay	1980-1989	Americas	Journal article	Funding/support declared
<i>BAH-NPD</i>	New product management for the 1980's	Booz, Allen & Hamilton	1980-1989	Americas	Book	Uncertain
<i>BLC</i>	Stages of Growth	Galbraith	1980-1989	Americas	Journal article	Personal interests stated
<i>ILC</i>	Time Paths in the Diffusion of Product Innovations	Gort & Klepper	1980-1989	Americas	Journal article	Funding/support declared

<i>CK-NPD</i>	An Investigation into the New Product Process: Steps, Deficiencies, and Impact	Cooper & Kleinschmidt	1980-1989	Americas	Journal article	Funding/support declared
<i>Norton-Bass</i>	A diffusion theory model of adoption and substitution for successive generations of high-technology products	Norton & Bass	1980-1989	Americas	Journal article	None declared
<i>SG-CK-NPD</i>	Stage-gate systems: A new tool for managing new products	Cooper	1990-1999	Americas	Journal article	None declared
<i>G-Bass-M</i>	Why the Bass Model Fits without Decision Variables	Bass, Krishnan, & Jain	1990-1999	Americas	Journal article	None declared
<i>TRL</i>	Technology Readiness Levels. A White Paper	Mankins	1990-1999	Americas	Academic publication	None declared
<i>MDDP</i>	Design Control Guidance for Medical Device Manufacturers	FDA	1990-1999	Americas	Regulatory guidance	Funding/support declared
<i>4S-IEE</i>	The iterative use of economic evaluation as part of the process of health technology assessment	Sculpher, Buxton, & Drummond	1990-1999	Europe	Journal article	Funding/support declared
<i>VA-NPD</i>	The Department of Veterans Affairs Rehabilitation Research and Development Service's Technology Transfer Process	Sheredos & Cupo	1990-1999	Americas	Journal article	None declared
<i>TPLC</i>	Appendix D. Impact of the Regulatory Framework on Medical Device Development and Innovation. IN: Public Health Effectiveness of the FDA 510(k) Clearance Process	Feigal Jr. for the Institute of Medicine	2010-2019	Americas	Book	Funding/support declared
<i>RE-AIM</i>	Evaluating the Public Health Impact of Health Promotion Interventions: The RE-AIM Framework	Glasgow, Vogt, & Boles	1990-1999	Americas	Journal article	Funding/support declared
<i>TALC</i>	Crossing the Chasm	Moore	2000-2009	Americas	Book	Personal interests stated

<i>MDLS</i>	Medical Device Regulations. Global overview and guiding principles	Cheng	2000-2009	International	WHO Guidance	Funding/support declared
<i>HCTLC</i>	Medical Device Regulations. Global overview and guiding principles.	Cheng	2000-2009	International	WHO Guidance	Funding/support declared
<i>SUHCD</i>	Designing for Patient Safety: A Review of the Effectiveness of Design in the UK Health Service	Clarkson	2000-2009	Europe	Journal article	Funding/support declared
<i>DDDI</i>	Diffusion of Innovations in Service Organizations: Systematic Review and Recommendations	Greenhalgh et al	2000-2009	Americas	Journal article	Funding/support declared
<i>TALC-CAHF</i>	The technology adoption life cycle attractor: Understanding the dynamics of high-tech markets	Meade & Rabelo	2000-2009	Europe	Journal article	Funding/support declared
<i>SG-MDDP</i>	Stage-gate process for the development of medical devices	Pietzsch et al	2000-2009	International	Journal article	Funding/support declared
<i>IEF</i>	Developing a Framework for Mapping Industrial Emergence	Phaal et al	2000-2009	Americas	Conference/Presentation	Funding/support declared
<i>IRM-TRL</i>	Technology readiness and risk assessments: A new approach	Mankins	2000-2009	Americas	Journal article	None declared
<i>IDEAL</i>	No surgical innovation without evaluation: the IDEAL recommendations	McCulloch et al	2000-2009	Europe	Journal article	Funding/support declared
<i>EIM-2DA</i>	EAES recommendations on methodology of innovation management in endoscopic surgery	Neugebauer & Becker et al	2010-2019	International	Journal article	Declared no COI
<i>TLC</i>	Introducing new technology safely	Mytton et al	2010-2019	Europe	Journal article	Funding/support declared
<i>IC+</i>	Innovate the Future: A Radical New Approach to IT Innovation	Croslin	2010-2019	Americas	Book	None declared

<i>MDLC</i>	Development of medical device policies	Velazquez-Berumen	2010-2019	International	WHO Guidance	Funding/support declared
<i>Bhuiyan-NPD</i>	A framework for successful new product development	Bhuiyan	2010-2019	Americas	Journal article	None declared
<i>USVP</i>	Understanding academic entrepreneurship: Exploring the emergence of university spin-off ventures using process theories	Rasmussen	2010-2019	Europe	Journal article	Funding/support declared
<i>WW-IC</i>	The Innovation Cycle: A Framework for Taking Surgical Innovation into Clinical Practice	Wright & Weinstein	2010-2019	Americas	Journal article	Declared no COI
<i>IC</i>	The Innovation Cycle	CIRAS	2010-2019	Americas	Website	None declared
<i>HCanada-MDRegLC</i>	Health Product Vigilance Framework. Release Date: 2012-09-12	Health Canada	2010-2019	Americas	Regulatory guidance	None declared
<i>TGA-MDRegLC</i>	Presentation: Life cycle of medical devices	Reeves & Garcia	2010-2019	Australia	Conference/Presentation	Disclaimer
<i>RxLCF</i>	Beyond the dichotomy: a tool for distinguishing between experimental, innovative and established treatment	Provoost et al	2010-2019	Europe	Journal article	Funding/support declared
<i>PrLC</i>	NASA Systems Engineering Handbook Rev 2	NASA	2010-2019	Americas	Book	None declared
<i>ELC</i>	Managing the life cycle of medical equipment	Worm (THET)	2010-2019	International	Online resource	Funding/support declared
<i>IDEAL-D</i>	Adapting the IDEAL Framework and Recommendations for medical device evaluation: A modified Delphi survey	Pennell et al	2010-2019	International	Journal article	Funding/support declared
<i>PILC</i>	How the new Procurement Directive may contribute to spur innovative purchases in the health sector	Baeyens	2010-2019	Europe	Conference/Presentation	None declared

<i>nHTLCAI</i>	New Health Technologies: Managing Access, Value and Sustainability	Paris et al	2010-2019	International	Book	Writing support acknowledged
<i>OIM-DA</i>	How should new orthopaedic implants be introduced: an example and recommendations for best practice	Hannan et al	2010-2019	Australia	Journal article	None declared
<i>HTLC</i>	The Life Cycle of Health Technologies. Challenges and Ways Forward	Gutiérrez-Ibarluzea, Chiumente & Dauben	2010-2019	International	Journal article	Declared no COI
<i>NASSS</i>	Beyond Adoption: A New Framework for Theorizing and Evaluating Nonadoption, Abandonment, and Challenges to the Scale-Up, Spread, and Sustainability of Health and Care Technologies	Greenhalgh et al	2010-2019	Europe	Journal article	Funding/support declared
<i>IRM-SaMDDP</i>	The integration of the risk management process with the lifecycle of medical device software	Pecoraro & Luzi	2010-2019	Europe	Journal article	None declared
<i>EUnetHTA-MDLC</i>	Session 3: Taking a lifecycle approach to EUnetHTA's work: Current and future collaborations between early dialogue and Relative Effectiveness Assessments	Meyer, Brühl & Omstad	2010-2019	Europe	Conference/Presentation	Funding/support declared
<i>FDA-MDRegLC</i>	TPLC - Total Product Life Cycle	FDA	2010-2019	Americas	Online resource	None declared
<i>Swissmedic-MDRegLC</i>	The tasks of Swissmedic - Lifecycle of a medical device	Swissmedic	2010-2019	Europe	Website	None declared