

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

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List of Models

Table 1: Models included in the synthesis.

Model name given by Author	Also known as	(Abbreviated) Model Name	Author Year (Ref)
How to introduce a new product	-	<i>Baldock-NPD</i>	Baldock 1960 (1)
Life of an innovation	Diffusion of Innovations	<i>DOI</i>	Rogers 1963 (2)
A New Product Growth Model for Consumer Durables	Bass Model	<i>Bass</i>	Bass 1963, published 1969 (3)
Product Life Cycle	-	<i>PLC</i>	Levitt 1965 (4), but originally postulated by Kuznets in 1930 (5).
7 Stages in the Career of a Medical Innovation	-	<i>7Sm-IC</i>	McKinlay 1981 (6)
How innovations become routinized	-	<i>IRP</i>	Yin 1981 (7)
Stages of the New Product Development Process	BAH Model	<i>BAH-NPD</i>	Booz, Hamilton & Allen 1982 (8) (unavailable so we drew on Fortenberry’s summary (9))
The stages of growth: Organization development model	Business Life Cycle	<i>BLC</i>	Galbraith 1982 (10)
The five stages of new product industries	Industry Life Cycle	<i>ILC</i>	Gort & Klepper 1982 (11)
A <i>skeleton</i> of the new product process	New Product Development Process or New product process activities	<i>CK-NPD</i>	Cooper & Kleinschmidt 1986 (12)
A Diffusion Theory of Adoption and Substitution for Successive Generations of High-Technology Products	Norton-Bass Model	<i>Norton-Bass</i>	Norton & Bass 1987 (13)

A stage-gate system for managing new products	Stage-gate system	<i>SG-CK-NPD</i>	Cooper 1990 (14)
Technology Adoption Life Cycle	The High-Tech Marketing Model	<i>TALC</i>	Moore 1991 & 2005 (15)
Generalized Bass Model	GBM	<i>G-Bass-M</i>	Bass, Krishnan, & Jain 1994 (16)
Technology Readiness Levels	-	<i>TRL</i>	Mankins 1995 (17)
Design controls guidance for medical device manufacturers	-	<i>MDDP</i>	FDA 1997 (18)
Technology Transfer 'GATEWAY' chart	Veteran Affairs Research Development & Technology Transfer Process	<i>VA-NPD</i>	Sheredos & Cupo 1997 (19)
Four stages of economic evaluation	Iterative economic evaluation (across the health technology lifecycle)	<i>4S-IEE</i>	Sculpher, Drummond & Buxton 1997 (20)
Reach, Efficacy – Adoption, Implementation, Maintenance (RE-AIM)	RE-AIM	<i>RE-AIM</i>	Glasgow, Vogt & Boles 1999 (21)
Major phases in the life span of a medical device	-	<i>MDLS</i>	Cheng 2003 (22)
Healthcare Technology Life Cycle	-	<i>HCTLC</i>	Cheng 2003 (22)
A Systems-based User-centred Approach to Healthcare Design	-	<i>SUHCD</i>	Clarkson et al., 2004 (23)
Conceptual Model for Considering the Determinants of Diffusion, Dissemination, and Implementation of Innovations in Health Service Delivery and Organizations	-	<i>DDDI</i>	Greenhalgh et al., 2004 (24,25)
Total Product Life Cycle (Composed of the Marketing Development Life Cycle, the Device Scientific Life Cycle, and the Device Regulatory Life Cycle)	TPLC	<i>TPLC</i>	Feigal 2000 (FDA) (26)

Technology Adoption Life Cycle Conceptual Attractor H Framework	H-Framework	<i>TALC-CAHF</i>	Meade & Rabelo 2004 (27)
Equipment Life Cycle	Healthcare Technology Management Cycle	<i>ELC</i>	Worm 2015 (28) (Described by Temple-Bird et al in 2005 as the Healthcare Technology Management Cycle (29))
Technology Risk and Readiness Assessment Framework		<i>IRM-TRL</i>	Mankins 2009 (30)
IDEAL Framework	IDEAL	<i>IDEAL</i>	McCulloch et al., 2009 (31–33)
Industrial Emergence Framework	Technology Roadmapping	<i>IEF</i>	Phaal et al., 2009 (34)
Stage-gate process for the development of medical devices	Medical Device Development: High-level Representation of Development Phases and of Functional Activities	<i>SG-MDDP</i>	Pietzsch et al., 2009 (35)
The Innovation Cycle	-	<i>IC+</i>	Croslin 2010 (36)
Lifecycle of Technology	-	<i>TLC</i>	Mytton et al., 2010 (37)
EAES recommendations on methodology of innovation management in endoscopic surgery	-	<i>EIM-2DA</i>	Neugebauer & Becker et al., 2010 (38)
A framework for successful new product development	-	<i>Bhuiyan-NPD</i>	Bhuiyan 2011 (39)
Conceptual Framework of the University Spin-off Venturing Process	-	<i>USVP</i>	Rasmussen 2011 (40)
The four phases of the medical device life-cycle	Medical device life-cycle	<i>MDLC</i>	Velasquez-Berumen 2011 (41)
Health Canada's Lifecycle Approach to Health Product Vigilance & Product Vigilance and Benefit-Risk Management Cycle	-	<i>HCanada-MDRegLC</i>	Health Canada 2013 (42)
The Innovation Cycle	-	<i>IC</i>	CIRAS 2013 (43)
The Innovation Cycle	-	<i>WW-IC</i>	Wright & Weinstein 2013 (44)

The integration of risk management process with the lifecycle of medical device software	-	<i>IRM-SaMDDP</i>	Pecoraro & Luzi 2014 (45)
A tool for distinguishing between experimental, innovative and established treatment	Treatment 'lifecycle' framework	<i>RxLCF</i>	Provoost et al., 2014 (46)
Product Innovation Life Cycle	-	<i>PrLC</i>	EU Procurement Directive approach to procuring innovative products, presented by An Baeyens 2016 (47)
IDEAL-D	-	<i>IDEAL-D</i>	Sedrakyan et al., 2016 (48)
Framework for Theorizing and Evaluating Non-adoption, Abandonment, and Challenges to the Scale-up, Spread and Sustainability of Health and Care Technologies	NASSS Framework	<i>NASSS</i>	Greenhalgh et al., 2017 (49)
Health Technology Life Cycle	-	<i>HTLC</i>	Gutiérrez-Ibarluzea, Chiumente & Dauben 2017 (50)
Optimal methodology for the introduction of new orthopaedic implants	-	<i>OIM-DA</i>	Hannan et al., 2017 (51)
NASA Program/Project Life Cycle Process (NASA)	-	<i>PrLC</i>	NASA 2017 (52)
New Health Technologies – Lifecycle for integration into healthcare systems	-	<i>nHTLC4I</i>	Paris et al., 2017 (53)
Life cycle of medical devices - Lifecycle approach to regulation	-	<i>TGA-MDRegLC</i>	Reeves & Garcia 2014 (TGA) 2017 (54)
EUnetHTA's lifecycle approach	-	<i>EUnetHTA-MDLC</i>	Meyer, Brühl & Ormstad 2018 (55)
The Device Development Process	Total Product Life Cycle	<i>FDA-MDRegLC</i>	FDA (56)
Lifecycle of a medical device	-	<i>Swissmedic-MDRegLC</i>	Swissmedic 2018 (57)

Categorizing perspectives

The following table shows how individual study/model perspectives were grouped into four broad categories.

Trade & Industry (19)	Policymaking (16)
Academia & Marketing Business Business & Academia Business & Marketing Business Management Business Strategy Economics Industry Manufacturing Industry Marketing Medical device design engineers Procurement Software Engineering	Academia, Research, Economics, Sociology & Agriculture Academic Access, Value & Sustainability EU DG GROW Health systems policymaking Healthcare & Health economics Healthcare & research HTA HTA & Economists Public Health Sociology and agricultural policymaking Space & Aeronautics Systems Engineering
Healthcare (9)	Regulation (8)
Biomedical Engineering & Healthcare Management Clinical Engineering & Safety Healthcare Access Surgical	Healthcare/ Regulatory Regulatory

Model categorization

Trade & Industry (n=19)	 Policymaking (n=16)
<i>PLC</i> (4)	<i>DOI</i> (2)
<i>Baldock-NPD</i> (1)	<i>IRP</i> (7)
<i>Bass</i> (58,59)	<i>7Sm-IC</i> (6)
<i>BAH-NPD</i> (8,9)	<i>TRL</i> (17)
<i>BLC</i> (10)	<i>4S-IEE</i> (20,64)
<i>ILC</i> (11,60,61)	<i>RE-AIM</i> (21)
<i>CK-NPD</i> (12)	<i>DDDII</i> (24)
<i>Norton-Bass</i> (13)	<i>IRM-TRL</i> (30)
<i>SG-CK-NPD</i> (14)	<i>TLC</i> (37)
<i>TALC</i> (15,62)	<i>MDLC</i> (41)
<i>G-Bass-M</i> (16)	<i>PrLC</i> (52)
<i>TALC-CAHF</i> (27)	<i>PILC</i> (47)
<i>USVP</i> (40)	<i>NASSS</i> (49)
<i>IEF</i> (34,63)	<i>HTLC</i> (50)
<i>SG-MDDP</i> (35)	<i>nHTLC4I</i> (65)
<i>IC+</i> (36)	<i>EUnetHTA-MDLC</i> (55)
<i>Bhuiyan-NPD</i> (39)	
<i>IC</i> (43)	
<i>IRM-SaMDDP</i> (45)	
Healthcare (n=9)	Regulation (n=8)
<i>VA-NPD</i> (19)	<i>MDDP</i> (18)
<i>SUHCD</i> (23)	<i>TPLC</i> (26,69–71)
<i>ELC</i> (28,29)	<i>HCTLC</i> (22)
<i>IDEAL</i> (31,32,66)	<i>MDLS</i> (22)
<i>EIM-2DA</i> (38)	<i>HCanada-MDRegLC</i> (42,72)
<i>WW-IC</i> (44)	<i>TGA-MDRegLC</i> (54)
<i>RxLCF</i> (46)	<i>Swissmedic-MDRegLC</i> (57)
<i>IDEAL-D</i> (48,67,68)	<i>FDA-MDRegLC</i> (56)
<i>OIM-DA</i> (51)	

Model categorization with Author name

Trade & Industry (n=19)	Policymaking (n=16)
<i>PLC</i> , Levitt, 1965(4)	<i>DOI</i> , Rogers, 1962(2)
<i>Baldock-NPD</i> , Baldock, 1960(1)	<i>IRP</i> , Yin, 1981(7)
<i>Bass</i> , Bass, 1969(58,59)	<i>7SMI career</i> , McKinlay, 1981(6)
<i>BAH-NPD</i> , Booz, Allen & Hamilton, 1982(8,9)	<i>TRL</i> , Mankins, 1995(17)
<i>BLC</i> , Galbraith, 1982(10)	<i>4S-IEE</i> , Sculpher, Buxton, & Drummond, 1997(20,64)
<i>ILC</i> , Gort & Klepper, 1982(11,60,61)	<i>RE-AIM</i> , Glasgow, Vogt, & Boles, 1999(21)
<i>CK-NPD</i> , Cooper & Kleinschmidt, 1986(12)	<i>DDDII</i> , Greenhalgh et al., 2004(24)
<i>Norton-Bass</i> , Norton & Bass, 1987(13)	<i>IRM-TRL</i> , Mankins, 2009(30)
<i>SG-CK-NPD</i> , Cooper, 1990(14)	<i>TLC</i> , Mytton et al., 2010(37)
<i>TALC</i> , Moore, 2001(15,62)	<i>MDLC</i> , Velazquez-Berumen, 2011(41)
<i>GBM</i> , Bass, Krishnan, & Jain, 1994(16)	<i>PrLC</i> , NASA, 2014(52)
<i>TALC-CAHF</i> , Meade & Rabelo, 2004(27)	<i>PILC</i> , Baeyens, 2016(47)
<i>USVP</i> , Rasmussen, 2011(40)	<i>NASSS</i> , Greenhalgh et al., 2017(49)
<i>IEF</i> , Phaal et al., 2009(34,63)	<i>HTLC</i> , Gutiérrez-Ibarluzea, Chiumente & Dauben, 2017(50)
<i>SG-MDDP</i> , Pietzsch et al., 2009(35)	<i>nHTLC4I</i> , Paris et al., 2017(65)
<i>IC+</i> , Croslin, 2010(36)	<i>EUnetHTA-MDLC</i> , Meyer, Brühl & Omstad, 2018(55)
<i>Bhuiyan-NPD</i> , Bhuiyan, 2011(39)	
<i>IC</i> , CIRAS, 2013(43)	
<i>IRM-SaMDDP</i> , Pecoraro & Luzi, 2017(45)	
Healthcare (n=9)	Regulation (n=8)
<i>VA-NPD</i> , Sheredos & Cupo, 1997(19)	<i>MDDP</i> , FDA, 1997(18)
<i>SUHCD</i> , Clarkson et al., 2004(23)	<i>TPLC</i> , Feigal Jr. for the Institute of Medicine, 2010(26,69–71)
<i>ELC</i> , Worm (THET), 2015(28,29)	<i>HCTLC</i> , Cheng, 2003(22)
<i>IDEAL</i> , McCulloch et al., 2009(31,32,66)	<i>MDLS</i> , Cheng, 2003(22)
<i>EIM-2DA</i> , Neugebauer & Becker et al., 2010(38)	<i>HCanada-MDRegLC</i> , Health Canada, 2013(42,72)
<i>WW-IC</i> , Wright & Weinstein, 2013(44)	<i>TGA-MDRegLC</i> , Reeves & Garcia, 2014(54)
<i>RxLCF</i> , Provoost et al., 2014(46)	<i>FDA-MDRegLC</i> , FDA, 2018(56)
<i>IDEAL-D</i> , Pennell et al., 2016(48,67,68)	<i>Swissmedic-MDRegLC</i> , Swissmedic, 2017(57)
<i>OIM-DA</i> , Hannan et al., 2017(51)	

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Note – these include additional references to those listed in Supplemental-6_List of key reference texts.

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