

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

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Harkin_Supplemental-10_Lifecycle Evaluation Model Findings

Lifecycle Evaluation Model Findings

<i>Model</i>	Publication Year*	Purpose	Audience	Characterisation	Main interest	Outputs (Detailing ...)	Evaluation Timing	Scope - Lifecycle	Scope - Device	Model Archetype
<i>Baldock-NPD</i>	1960	Define actions or activities	Trade & Industry	Development (stages)	What to do to develop a new product	'How to'	Repeated evaluation at each lifecycle stage	Provision	New	NPD
<i>DOI</i>	1962	Explore Influencing or impacted factors	Policymakers	Adoption (pattern)	Influencing factors	Influencing factors	Lifecycle evaluation at a single point in time	Acquisition & Utilisation	New	Diffusion
<i>PLC</i>	1965	Define actions or activities	Trade & Industry	Sales (pattern)	How to influence lifecycle	Influencing factors	Lifecycle evaluation at a single point in time	Provision	Established	Diffusion

<i>Bass</i>	1969	Describe the lifecycle	Trade & Industry	Sales (pattern)	Predicting sales/adoption	Influencing factors	Lifecycle evaluation at a single point in time	Provision	New	Diffusion
<i>IRP</i>	1981	Describe the lifecycle	Policy-makers	Adoption (pattern)	Influencing factors	Influencing factors	Separate evaluation of different phases at a single timepoint	Utilisation	New	Diffusion
<i>7Sm-IC</i>	1981	Describe the lifecycle	Policy-makers	Adoption (pattern)	Evidence levels	What happens	Separate evaluation of different phases at a single timepoint	Provision & Acquisition & Utilisation	New	Diffusion
<i>BAH-NPD</i>	1982	Define actions or activities	Trade & Industry	Development (stages)	What to do to develop a new product	'How to'	Repeated evaluation at each lifecycle stage	Provision	New	NPD
<i>BLC</i>	1982	Define actions or activities	Trade & Industry	Development (stages)	What to do to develop a new product	'How to'	Separate evaluation of different	Provision	New	NPD

							phases at a single timepoint			
<i>ILC</i>	1982	Describe the lifecycle	Trade & Industry	Development (pattern)	Influencing factors	Influencing factors	Lifecycle evaluation at a single point in time	Provision	New	Diffusion
<i>CK-NPD</i>	1986	Define actions or activities	Trade & Industry	Development (stages)	Performance evaluation	'How to'	Separate evaluation of different phases at a single timepoint	Provision	New	NPD
<i>Norton-Bass</i>	1987	Explore Influencing or impacted factors	Trade & Industry	Sales (pattern)	Influencing factors	Influencing factors	Lifecycle evaluation at a single point in time	Provision	New	Diffusion
<i>SG-CK-NPD</i>	1990	Determine readiness to progress	Trade & Industry	Development (stages)	Performance evaluation	'How to'	Repeated evaluation at each lifecycle stage	Provision	New	NPD

<i>G-Bass-M</i>	1994	Explore Influencing or impacted factors	Trade & Industry	Sales (pattern)	Influencing factors	Influencing factors	Lifecycle evaluation at a single point in time	Provision	All	Diffusion
<i>TRL</i>	1995	Determine readiness to progress	Trade & Industry	Development (stages)	Performance evaluation	Evaluation methods or activities	Repeated evaluation at each lifecycle stage	Provision & Acquisition	New	Hybrid
<i>MDDP</i>	1997	Define actions or activities	Trade & Industry	Development (stages)	Process controls	Regulation	Repeated evaluation at each lifecycle stage	Provision	All	NPD
<i>4S-IEE</i>	1997	Define actions or activities	Policymakers	Adoption (pattern)	Methods for outcomes evaluation	Evaluation methods or activities	Repeated evaluation at each lifecycle stage	Acquisition	New	Outcomes Evaluation
<i>VA-NPD</i>	1997	Determine readiness to progress	Policymakers	Development (stages)	What to do to develop a new product & Methods for	What happens	Repeated evaluation at each lifecycle stage	Provision & Acquisition & Utilisation	New	Hybrid*

					outcomes evaluation					
<i>TPLC</i>	2010	Define actions or activities	HC & General public	Development (stages)	Regulatory requirements & activities	Regulation	Repeated evaluation at each lifecycle stage	Provision & Utilisation	All	Hybrid
<i>RE-AIM</i>	1999	Define actions or activities	Policy makers	Adoption (pattern)	Methods for outcomes evaluation	Evaluation methods or activities	Repeated evaluation at each lifecycle stage	Provision & Acquisition & Utilisation	New	Outcomes Evaluation
<i>TALC</i>	2001	Define actions or activities	Trade & Industry	Sales (pattern)	How to influence lifecycle	Influencing factors	Lifecycle evaluation at a single point in time	Provision	New	Diffusion
<i>MDLS</i>	2003	Define actions or activities	Policy makers	Development (stages)	Regulatory requirements & activities	Regulation	Repeated evaluation at each lifecycle stage	Provision & Utilisation	All	Hybrid
<i>HCTLC</i>	2003	Define actions or activities	Policy makers	Development (stages)	What happens across the lifecycle	What happens	Lifecycle evaluation at a single	Provision & Acquisition	All	Hybrid

							point in time	& Utilisation		
<i>SUHCD</i>	2004	Define actions or activities	Healthcare	Development (stages)	What to do to develop a new product & Methods for outcomes evaluation	'How to'	Repeated evaluation at each lifecycle stage	Provision & Acquisition & Utilisation	New	Hybrid*
<i>DDDI</i>	2004	Explore Influencing or impacted factors	Policymakers	Adoption (pattern)	Influencing factors	Influencing factors	Lifecycle evaluation at a single point in time	Acquisition	New	Diffusion
<i>TALC-CAHF</i>	2004	Identify lifecycle stage	Trade & Industry	Sales (pattern)	Identifying where in the lifecycle a technology is	Evaluation methods or activities	Separate evaluation of different phases at a single timepoint	Provision	New	Diffusion
<i>SG-MDDP</i>	2009	Determine readiness to progress	Trade & Industry	Development (stages)	What to do to develop a new product	'How to'	Repeated evaluation at each lifecycle stage	Provision	New	NPD

<i>IEF</i>	2009	Describe the lifecycle	Trade & Industry	Development (pattern)	What happens across the lifecycle	Influencing factors	Separate evaluation of different phases at a single timepoint	Provision	New	Diffusion
<i>IRM-TRL</i>	2009	Determine readiness to progress	Trade & Industry	Development (stages)	Performance evaluation	Evaluation methods or activities	Repeated evaluation at each lifecycle stage	Provision & Acquisition	New	Hybrid
<i>IDEAL</i>	2009	Define actions or activities	Healthcare	Development (stages)	Methods for outcomes evaluation	Evaluation methods or activities	Repeated evaluation at each lifecycle stage	Provision & Acquisition & Utilisation	New	Outcomes Evaluation
<i>EIM-2DA</i>	2010	Identify lifecycle stage	Healthcare	Development (stages)	Methods for outcomes evaluation	Evaluation methods or activities	Repeated evaluation at each lifecycle stage	Provision & Acquisition & Utilisation	New	Outcomes Evaluation
<i>TLC</i>	2010	Describe the lifecycle	Healthcare	Adoption (pattern)	What happens across the lifecycle	What happens	Separate evaluation of different phases at a	Provision & Acquisition	All	Outcomes Evaluation

							single timepoint	& Utilisation		
<i>IC+</i>	2010	Explore Influencing or impacted factors	Trade & Industry	Sales (pattern)	What happens across the lifecycle	Evaluation methods or activities	Separate evaluation of different phases at a single timepoint	Provision	New	Diffusion
<i>MDLC</i>	2011	Define actions or activities	Policymakers	Development (stages)	Process controls	'How to'	Separate evaluation of different phases at a single timepoint	Provision & Acquisition & Utilisation & Regulation	All	Hybrid*
<i>Bhuiyan- NPD</i>	2011	Define actions or activities	Trade & Industry	Development (stages)	Performance evaluation	'How to'	Repeated evaluation at each lifecycle stage	Provision	New	NPD
<i>USVP</i>	2011	Describe the lifecycle	Trade & Industry	Development (stages)	Influencing factors	Influencing factors	Lifecycle evaluation at a single point in time	Provision	New	NPD

<i>WW-IC</i>	2013	Define actions or activities	Healthcare	Development (stages)	Methods for outcomes evaluation	Evaluation methods or activities	Repeated evaluation at each lifecycle stage	Provision & Acquisition & Utilisation	New	Outcomes Evaluation
<i>IC</i>	2013	Define actions or activities	Trade & Industry	Development (stages)	Performance evaluation	'How to'	Repeated evaluation at each lifecycle stage	Provision	New	NPD
<i>HCanada-MDRegLC</i>	2013	Define actions or activities	General public	Development (stages)	Regulatory requirements & activities	Regulation	Repeated evaluation at each lifecycle stage	Provision & Utilisation	All	Hybrid
<i>TGA-MDRegLC</i>	2014	Define actions or activities	Trade & Industry	Development (stages)	Regulatory requirements & activities	Regulation	Repeated evaluation at each lifecycle stage	Provision & Utilisation	All	Hybrid
<i>RxLCF</i>	2014	Identify lifecycle stage	Healthcare	Development (stages)	Identifying where in the lifecycle a technology is	Evaluation methods or activities	Repeated evaluation at each lifecycle stage	Acquisition	New	Outcomes Evaluation

<i>PrLC</i>	2017	Define actions or activities	Policymakers	Development (stages)	What to do to develop a new product & Methods for outcomes evaluation	'How to'	Repeated evaluation at each lifecycle stage	Provision & Acquisition & Utilisation	New	Hybrid*
<i>ELC</i>	2015	Define actions or activities	Healthcare	Health technology management activities	How to perform HTM (highlighting potentially false assumptions & mitigating actions)	Evaluation methods or activities	Repeated evaluation at each lifecycle stage	Acquisition & Utilisation	Established	Diffusion
<i>IDEAL-D</i>	2016	Define actions or activities	Regulators	Development (stages)	Methods for outcomes evaluation	Evaluation methods or activities	Repeated evaluation at each lifecycle stage	Provision & Acquisition & Utilisation	New	Outcomes Evaluation
<i>PILC</i>	2016	Define actions or activities	T&I and HC	Development (stages)	Approaches to integrating innovation into the healthcare system	Regulation	Repeated evaluation at each lifecycle stage	Provision & Acquisition	New	Diffusion

<i>nHTLCAI</i>	2017	Define actions or activities	Policymakers	Development (stages)	Approaches to integrating innovation into the healthcare system	Regulation	Repeated evaluation at each lifecycle stage	Acquisition & Utilisation	New	Diffusion
<i>OIM-DA</i>	2017	Define actions or activities	Healthcare	Development (stages)	Methods for outcomes evaluation	Evaluation methods or activities	Repeated evaluation at each lifecycle stage	Acquisition & Utilisation	New	Outcomes Evaluation
<i>HTLC</i>	2017	Define actions or activities	Policymakers	Development (stages)	Methods for outcomes evaluation	Evaluation methods or activities	Repeated evaluation at each lifecycle stage	Provision & Acquisition & Utilisation	New	Outcomes Evaluation
<i>NASSS</i>	2017	Explore Influencing or impacted factors	Policymakers	Adoption (pattern)	Predicting sales/adoption	Evaluation methods or activities	Separate evaluation of different phases at a single timepoint	Acquisition & Utilisation	New	Diffusion
<i>IRM-SaMDDP</i>	2017	Define actions or activities	Trade & Industry	Development (stages)	What to do to develop a new product	'How to'	Separate evaluation of different	Provision	New	NPD

							phases at a single timepoint			
<i>EUnetHTA-MDLC</i>	2018	Define actions or activities	T&I and HTA	Adoption (pattern)	Methods for outcomes evaluation	Evaluation methods or activities	Repeated evaluation at each lifecycle stage	Provision & Acquisition	New	Outcomes Evaluation
<i>FDA-MDRegLC</i>	2018	Define actions or activities	General public	Development (stages)	Regulatory requirements & activities	Regulation	Repeated evaluation at each lifecycle stage	Provision & Utilisation	All	Hybrid
<i>Swissmedic-MDRegLC</i>	2019	Define actions or activities	T&I and General public	Development (stages)	Regulatory requirements & activities	Regulation	Repeated evaluation at each lifecycle stage	Provision & Utilisation	All	Hybrid

Note: Hybrid* indicates that the model includes a focus on outcomes evaluation as well as either new product development (NPD) and/or diffusion.