## 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**

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

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

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

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

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

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

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

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

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

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

					Approaches					
					to integrating		Repeated			
					innovation		evaluation			
		Define			into the		at each	Acquisition		
		actions or		Development	healthcare		lifecycle	&		
nHTLC4I	2017	activities	Policymakers	(stages)		Regulation	stage	Utilisation	New	Diffusion
MIIILC41	2017	activities	Folicymakers	(stages)	system	Regulation	·	Utilisation	New	Diffusion
							Repeated			
							evaluation			
		Define			Methods for	Evaluation	at each	Acquisition		
		actions or		Development	outcomes	methods or	lifecycle	&		Outcomes
OIM-DA	2017	activities	Healthcare	(stages)	evaluation	activities	stage	Utilisation	New	Evaluation
							Repeated	Provision		
							evaluation	&		
		Define			Methods for	Evaluation	at each	Acquisition		
		actions or		Development	outcomes	methods or	lifecycle	&		Outcomes
HTLC	2017	activities	Policymakers	(stages)	evaluation	activities	stage	Utilisation	New	Evaluation
							Separate			
		Explore					evaluation			
		Influencing					of different			
		or				Evaluation	phases at a	Acquisition		
		impacted		Adoption	Predicting	methods or	single	&		
NASSS	2017	factors	Policymakers	(pattern)	sales/adoption	activities	timepoint	Utilisation	New	Diffusion
		Define			What to do to		Separate			
IRM-		actions or	Trade &	Development	develop a new		evaluation			
SaMDDP	2017	activities	Industry	(stages)	product	'How to'	of different	Provision	New	NPD

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