Codebook (project "MDRina T1")

Display options

Info: Here you can change the display options.

Edit display options:

- ☐ Show filters
- ☐ Show triggers
- ☐ Show plausibility checks
- ☐ Show hiding conditions
- ☐ Show direct links to edit the questionnaire
- ☐ Show fill-in instructions
- ☐ Show table of contents
- ☐ Show field positions in export template

Complete project

- ☐ Adjust column widths to effective size of data (excluding missing values)
- ☐ Show participant variables
- ☐ Show survey variables
- ☐ Display groups and group assignment of items and groups

Save settings

Select language

Edit variable names

Edit variable names

- ○ Edit variable names directly in this form
- ○ Create new variable names in accordance with selected algorithm (Select algorithm for creation of variable names)
- ○ Export variable names for external editing

UTF-8

- ○ Import externally edited variable names
- ○ Restore original variable names
- ○ Rename variables in dynamic answer blocks to make identification of original variable possible.

Save settings

Export

MDRina T1

Project ID	922521
Survey URL	https://ww3.unipark.de/uc/malyna_Bern_University_of_Applie/e40a/
Date	2022-08-04 11:46:00
Number of variables in survey table	121 (number might change due to compilation)

List: NoName

List type:	dynamic
List ID:	1
Used in questions:	-

Used in loops:	-

1 Page: System (PGID 6249038)

Scoring (- Type 933)

Variable name s_0001	External variable name s_0001	int	s_0001

User-defined variable (- Type 931)

Variable name c_0001	External variable name c_0001	varchar	User-defined variable

3 Page: Welcome! (PGID 6249057)

4 Page: T1Q1 (PGID 6271433)

4.1 Page: T1Q1 (PGID 6272908)

T1 Question 1: Please choose the right option: (q_11655601 - Type 111)

Variable name v_21	External variable name v_21	int	T1Q1
		1	Legacy Devices are defined as Medical Devices, Active Implantable Medical Devices and In Vivo Diagnostic Medical Devices
		2	Legacy Devices are defined as Active Implantable Medical Devices and In Vitro Diagnostic Medical Devices that are covered by a valid certificate issued in accordance with Directive 93/42/EEC
		3	Legacy Devices are defined as Medical Devices, Active Implantable Medical Devices and In Vitro Diagnostic Medical Devices that are covered by a valid certificate issued in accordance with Directive 93/42/EEC, Directive 90/385/EEC or Directive 98/79/EC and that continue to be placed on the market after May 26th 2021

4.2 Page: T1Q2 (PGID 6272909)

T1 Question 2: Manufacturers will have the possibility to register any of their Legacy Devices in EUDAMED. When will registration asap be mandatory? (q_11655602 - Type 111)

Variable name v_22	External variable name v_22	int	T1Q2
		1	Registration is asap mandatory for all legacy and “old” devices
		2	Registration is asap mandatory for all legacy and “old” devices in case a serious incident occurs or there is a field safety corrective action to apply
		3	Registration is never mandatory if the equivalent device is made compliant and registered as a MDR or IVDR device

4.3 Page: T1Q3 (PGID 6272910)

T1 Question 3: Legacy Devices with the risk class I that are not sterile and/or with a measuring function under the Directives cannot be considered as Legacy Devices because they do not require a certificate issued by a Notified Body. Within which time

because they do not require a certificate issued by a Notified Body. Within which time period must these devices be registered as Regulation Devices in EUDAMED? (q_11655603 - Type 111)

Variable name	External variable name	int	T1Q3
v_23	v_23		
		1	Within 24 months after the date of application
		2	Within 18 months after the date of application
		3	Within 18 months after the date of publication of the notice referred to in Article 34(3) if EUDAMED is not fully functional before the date of application of the MDR

4.4 Page: T1Q4 (PGID 6272911)

T1 Question 4: Basic UDI-DI will never be applicable and never be assigned to a Legacy Device, only EUDAMED DI. Please choose the correct way to generate identification details for a Legacy Device in EUDAMED when a UDI-DI equals M991CVS12130NES7. (q_11655604 - Type 111)

Variable name	External variable name	int	T1Q4
v_24	v_24		
		1	Generated EUDAMED DI: B-M991CVS12130NES7777
		2	Generated EUDAMED DI: B-M991CVS12130NES7
		3	Generated EUDAMED DI: D-M991CVS12130NES7

4.5 Page: T1Q5 (PGID 6272912)

T1 Question 5: Please choose the right option: (q_11655605 - Type 111)

Variable name	External variable name	int	T1Q5
v_25	v_25		
		1	When the equivalent of a Legacy Device becomes a compliant Regulation Device (having fulfilled all MDD and IVDR requirements to be covered by the required MDD and IVDR certificate(s)), a new Regulation Device shall be registered in EUDAMED in accordance with the MDD/IVDR requirements.
		2	When the equivalent of a Legacy Device becomes a compliant Regulation Device (having fulfilled all MDR or IVDR requirements to be covered by the required MDR or IVDR certificate(s)), a new Regulation Device shall be registered in EUDAMED in accordance with the MDR/IVDR requirements.
		3	When the equivalent of a Legacy Device becomes a compliant Regulation Device (having fulfilled all MDR or IVDR requirements to be covered by the required MDR or IVDR certificate(s)), no new Regulation Device is required to be registered in EUDAMED in accordance with the MDR/IVDR requirements.

4.6 Page: T1Q6 (PGID 6272913)

T1 Question 6: EUDAMED will allow linking of the Regulation Device with the Legacy Device and perform this linking automatically where the same DI has been assigned to both the Legacy Device and the Regulation Device. Please indicate the right type of DI.

both the Legacy Device and the Regulation Device. Please indicate the right type of DI. (q_11655730 - Type 111)

Variable name	External variable name	int	T1Q6
v_56	v_56		
		1	Basic UDI-DI
		2	UDI-DI
		3	EUDAMED-DI

4.7 Page: T1Q7 (PGID 6272915)

T1 Question 7: Please indicate in which case the link in EUDAMED between the Regulation Device and the Legacy Device will be made automatically. (q_11655608 - Type 111)

Variable name	External variable name	int	T1Q7
v_31	v_31		
		1	EUDAMED will allow linking of the Regulation Device with the Legacy Device and perform this linking automatically where the same UDI-DI has been assigned to both the Legacy Device and the Regulation Device. The link will be made at the level of the EUDAMED-DI.
		2	EUDAMED will allow linking of the Regulation Device with the Legacy Device and perform this linking automatically where the same EUDAMED-DI has been assigned to both the Legacy Device and the Regulation Device. The link will be made at the level of the UDI-DI.
		3	If the Regulation Device is the same as the Legacy Device (except that it is MDR or IVDR compliant), and the Regulation Device has the same UDI-DI as the Legacy Device.

4.8 Page: T1Q8 (PGID 6272918)

T1 Question 8: Please have a look on the following example and choose the correct explanation from the options below: Manufacturer Code provided for the product: CR023335 EUDAMED DI: B-BEMF000000106CR023335WE EUDAMED ID: D-BEMF000000106CR023335WE (q_11655609 - Type 111)

Variable name	External variable name	int	T1Q8
v_32	v_32		
		1	Because the format for generating EUDAMED DI codes does not necessarily include the unique identification number of the manufacturer provided by EUDAMED (i.e. the manufacturer’s SRN), there is a risk that the same code is assigned by two different manufacturers for different devices. Providing the SRN is optional, but is recommended.
		2	Because the format for generating EUDAMED DI codes does not necessarily include the unique identification number of the manufacturer provided by EUDAMED (i.e. the manufacturer’s SRN), there is a risk that the same code is assigned by two different manufacturers for different devices. Providing the SRN is a must.

5.1 Page: T2 (PGID 6272888)

5.1.1 Page: T2Q1 (PGID 6272935)

T2 Question 1: Please choose the right option: (q_11658533 - Type 111)

Variable name	External variable name	int	T2Q1
v_59	v_59		
		1	Legacy Devices are defined as Medical Devices, Active Implantable Medical Devices and In Vivo Diagnostic Medical Devices
		2	Legacy Devices are defined as Active Implantable Medical Devices and In Vitro Diagnostic Medical Devices that are covered by a valid certificate issued in accordance with Directive 93/42/EEC
		3	Legacy Devices are defined as Medical Devices, Active Implantable Medical Devices and In Vitro Diagnostic Medical Devices that are covered by a valid certificate issued in accordance with Directive 93/42/EEC, Directive 90/385/EEC or Directive 98/79/EC and that continue to be placed on the market after May 26th 2021

5.1.2 Page: T2Q2 (PGID 6272964)

T2 Question 2: Manufacturers will have the possibility to register any of their Legacy Devices in EUDAMED. When will registration asap be mandatory? (q_11658682 - Type 111)

Variable name	External variable name	int	T2Q2
v_61	v_61		
		1	Registration is asap mandatory for all legacy and “old” devices
		2	Registration is asap mandatory for all legacy and “old” devices in case a serious incident occurs or there is a field safety corrective action to apply
		3	Registration is never mandatory if the equivalent device is made compliant and registered as a MDR or IVDR device

5.1.3 Page: T2Q3 (PGID 6272966)

T2 Question 3: Legacy Devices with the risk class I that are not sterile and/or with a measuring function under the Directives cannot be considered as Legacy Devices because they do not require a certificate issued by a Notified Body. Within which time period must these devices be registered as Regulation Devices in EUDAMED? (q_11658686 - Type 111)

Variable name	External variable name	int	T2Q3
v_63	v_63		
		1	Within 24 months after the date of application
		2	Within 18 months after the date of application
		3	Within 18 months after the date of publication of the notice referred to in Article 34(3) if EUDAMED is not fully functional before the date of application of the MDR

5.1.4 Page: T2Q4 (PGID 6272968)

T2 Question 4: Basic UDI-DI will never be applicable and never be assigned to a Legacy Device, only EUDAMED DI. Please choose the correct way to generate identification details for a Legacy Device in EUDAMED when a UDI-DI equals M991CVS12130NES7. (q_11658691 - Type 111)

Variable name	External variable name	int	T2Q4

v_65	v_65		
		1	Generated EUDAMED DI: B-M991CVS12130NES7777
		2	Generated EUDAMED DI: B-M991CVS12130NES7
		3	Generated EUDAMED DI: D-M991CVS12130NES7

5.1.5 Page: T2Q5 (PGID 6272970)

T2 Question 5: Please choose the right option: (q_11658695 - Type 111)

Variable name	External variable name	int	T2Q5
v_67	v_67		
		1	When the equivalent of a Legacy Device becomes a compliant Regulation Device (having fulfilled all MDD and IVDR requirements to be covered by the required MDD and IVDR certificate(s)), a new Regulation Device shall be registered in EUDAMED in accordance with the MDD/IVDR requirements.
		2	When the equivalent of a Legacy Device becomes a compliant Regulation Device (having fulfilled all MDR or IVDR requirements to be covered by the required MDR or IVDR certificate(s)), a new Regulation Device shall be registered in EUDAMED in accordance with the MDR/IVDR requirements.
		3	When the equivalent of a Legacy Device becomes a compliant Regulation Device (having fulfilled all MDR or IVDR requirements to be covered by the required MDR or IVDR certificate(s)), no new Regulation Device is required to be registered in EUDAMED in accordance with the MDR/IVDR requirements.

5.1.6 Page: T2Q6 (PGID 6272972)

T2 Question 6: EUDAMED will allow linking of the Regulation Device with the Legacy Device and perform this linking automatically where the same DI has been assigned to both the Legacy Device and the Regulation Device. Please indicate the right type of DI. (q_11658699 - Type 111)

Variable name	External variable name	int	T2Q6
v_69	v_69		
		1	Basic UDI-DI
		2	UDI-DI
		3	EUDAMED-DI

5.1.7 Page: T2Q7 (PGID 6272974)

T2 Question 7: Please indicate in which case the link in EUDAMED between the Regulation Device and the Legacy Device will be made automatically. (q_11658703 - Type 111)

Variable name	External variable name	int	T2Q7
v_71	v_71		
		1	EUDAMED will allow linking of the Regulation Device with the Legacy Device and perform this linking automatically where the same UDI-DI has been assigned to both the Legacy Device and the

			been assigned to both the Legacy Device and the Regulation Device. The link will be made at the level of the EUDAMED-DI.
		2	EUDAMED will allow linking of the Regulation Device with the Legacy Device and perform this linking automatically where the same EUDAMED-DI has been assigned to both the Legacy Device and the Regulation Device. The link will be made at the level of the UDI-DI.
		3	If the Regulation Device is the same as the Legacy Device (except that it is MDR or IVDR compliant), and the Regulation Device has the same UDI-DI as the Legacy Device.

5.1.8 Page: T2Q8 (PGID 6272976)

T2 Question 8: Please have a look on the following example and choose the correct explanation from the options below: Manufacturer Code provided for the product: CR023335 EUDAMED DI: B-BEMF000000106CR023335WE EUDAMED ID: D-BEMF000000106CR023335WE (q_11658707 - Type 111)

Variable name	External variable name	int	T2Q8
v_73	v_73		
		1	Because the format for generating EUDAMED DI codes does not necessarily include the unique identification number of the manufacturer provided by EUDAMED (i.e. the manufacturer's SRN), there is a risk that the same code is assigned by two different manufacturers for different devices. Providing the SRN is optional, but is recommended.
		2	Because the format for generating EUDAMED DI codes does not necessarily include the unique identification number of the manufacturer provided by EUDAMED (i.e. the manufacturer's SRN), there is a risk that the same code is assigned by two different manufacturers for different devices. Providing the SRN is a must.

5.2 Page: T3 (PGID 6272889)

5.2.1 Page: T3Q1 (PGID 6272936)

T3 Question 1: Please choose the right option: (q_11658534 - Type 111)

Variable name	External variable name	int	T3Q1
v_60	v_60		
		1	Legacy Devices are defined as Medical Devices, Active Implantable Medical Devices and In Vivo Diagnostic Medical Devices
		2	Legacy Devices are defined as Active Implantable Medical Devices and In Vitro Diagnostic Medical Devices that are covered by a valid certificate issued in accordance with Directive 93/42/EEC
		3	Legacy Devices are defined as Medical Devices, Active Implantable Medical Devices and In Vitro Diagnostic Medical Devices that are covered by a valid certificate issued in accordance with Directive 93/42/EEC, Directive 90/385/EEC or Directive 98/79/EC and that continue to be placed on the market after May 26th 2021

5.2.2 Page: T3Q2 (PGID 6272965)

T3 Question 2: Manufacturers will have the possibility to register any of their Legacy Devices in EUDAMED. When will registration asap be mandatory? (q_11658684 - Type 111)

Variable name	External variable name	int	T3Q2
v_62	v_62		
		1	Registration is asap mandatory for all legacy and “old” devices
		2	Registration is asap mandatory for all legacy and “old” devices in case a serious incident occurs or there is a field safety corrective action to apply
		3	Registration is never mandatory if the equivalent device is made compliant and registered as a MDR or IVDR device

5.2.3 Page: T3Q3 (PGID 6272967)

Question 3: Legacy Devices with the risk class I that are not sterile and/or with a measuring function under the Directives cannot be considered as Legacy Devices because they do not require a certificate issued by a Notified Body. Within which time period must these devices be registered as Regulation Devices in EUDAMED? (q_11658688 - Type 111)

Variable name	External variable name	int	T3Q3
v_64	v_64		
		1	Within 24 months after the date of application
		2	Within 18 months after the date of application
		3	Within 18 months after the date of publication of the notice referred to in Article 34(3) if EUDAMED is not fully functional before the date of application of the MDR

5.2.4 Page: T3Q4 (PGID 6272969)

T3 Question 4: Basic UDI-DI will never be applicable and never be assigned to a Legacy Device, only EUDAMED DI. Please choose the correct way to generate identification details for a Legacy Device in EUDAMED when a UDI-DI equals M991CVS12130NES7. (q_11658693 - Type 111)

Variable name	External variable name	int	T3Q4
v_66	v_66		
		1	Generated EUDAMED DI: B-M991CVS12130NES7777
		2	Generated EUDAMED DI: B-M991CVS12130NES7
		3	Generated EUDAMED DI: D-M991CVS12130NES7

5.2.5 Page: T3Q5 (PGID 6272971)

T3 Question 5: Please choose the right option: (q_11658697 - Type 111)

Variable name	External variable name	int	T3Q5
v_68	v_68		
		1	When the equivalent of a Legacy Device becomes a compliant Regulation Device (having fulfilled all MDD and IVDR requirements to be covered by the required MDD and IVDR certificate(s)), a new Regulation Device shall be registered in EUDAMED in accordance with the MDD/IVDR

		requirements.
	2	When the equivalent of a Legacy Device becomes a compliant Regulation Device (having fulfilled all MDR or IVDR requirements to be covered by the required MDR or IVDR certificate(s)), a new Regulation Device shall be registered in EUDAMED in accordance with the MDR/IVDR requirements.
	3	When the equivalent of a Legacy Device becomes a compliant Regulation Device (having fulfilled all MDR or IVDR requirements to be covered by the required MDR or IVDR certificate(s)), no new Regulation Device is required to be registered in EUDAMED in accordance with the MDR/IVDR requirements.

5.2.6 Page: T3Q6 (PGID 6272973)

T3 Question 6: EUDAMED will allow linking of the Regulation Device with the Legacy Device and perform this linking automatically where the same DI has been assigned to both the Legacy Device and the Regulation Device. Please indicate the right type of DI. (q_11658701 - Type 111)

Variable name	External variable name	int	T3Q6
v_70	v_70		
		1	Basic UDI-DI
		2	UDI-DI
		3	EUDAMED-DI

5.2.7 Page: T3Q7 (PGID 6272975)

T3 Question 7: Please indicate in which case the link in EUDAMED between the Regulation Device and the Legacy Device will be made automatically. (q_11658705 - Type 111)

Variable name	External variable name	int	T3Q7
v_72	v_72		
		1	EUDAMED will allow linking of the Regulation Device with the Legacy Device and perform this linking automatically where the same UDI-DI has been assigned to both the Legacy Device and the Regulation Device. The link will be made at the level of the EUDAMED-DI.
		2	EUDAMED will allow linking of the Regulation Device with the Legacy Device and perform this linking automatically where the same EUDAMED-DI has been assigned to both the Legacy Device and the Regulation Device. The link will be made at the level of the UDI-DI.
		3	If the Regulation Device is the same as the Legacy Device (except that it is MDR or IVDR compliant), and the Regulation Device has the same UDI-DI as the Legacy Device.

5.2.8 Page: T3Q8 (PGID 6272977)

T3 Question 8: Please have a look on the following example and choose the correct explanation from the options below: Manufacturer Code provided for the product: CR023335 EUDAMED DI: B-BEMF000000106CR023335WE EUDAMED ID: D-BEMF000000106CR023335WE (q_11658709 - Type 111)

Variable name	External variable name	int	T3Q8

v_74	v_74		
		1	Because the format for generating EUDAMED DI codes does not necessarily include the unique identification number of the manufacturer provided by EUDAMED (i.e. the manufacturer's SRN), there is a risk that the same code is assigned by two different manufacturers for different devices. Providing the SRN is optional, but is recommended.
		2	Because the format for generating EUDAMED DI codes does not necessarily include the unique identification number of the manufacturer provided by EUDAMED (i.e. the manufacturer's SRN), there is a risk that the same code is assigned by two different manufacturers for different devices. Providing the SRN is a must.

6 Page: MLQ (PGID 6250756)

MDRina: please let me know you better. Are you... (q_11670378 - Type 111)

Variable name v_79	External variable name v_79	int	Female-Male
		1	FEMALE?
		2	MALE?
		3	ELSE or DO NOT WANT TO SHARE.

Please help me as your new algorithmic leader be a better leader answering the following questions below: (q_11670373 - Type 143)

Variable name v_76	External variable name v_76	varchar (with type check: Integer)	How old are you?
Variable name v_77	External variable name v_77	varchar (with type check: Integer)	Your management experience in years?
Variable name v_78	External variable name v_78	varchar (with type check: Integer)	How many times during the survey you (re-)read the suggested official MDR EUDAMED text on Management of Legacy Devices?

How do you feel about MDRina's Leadership Style? (q_11619788 - Type 311)

Variable name v_7	External variable name v_7	int	MDRina rewards in return for achievement
		1	Not at all
		2	Once in awhile
		3	Sometimes
		4	Fairly often
		5	Frequently, if not always
Variable name v_44	External variable name v_44	int	MDRina fails to interfere when necessary
		1	Not at all
		2	Once in awhile
		3	Sometimes

		4	Fairly often
		5	Frequently, if not always
Variable name v_8	External variable name v_8	int	MDRina talks about its most important values and beliefs
		1	Not at all
		2	Once in awhile
		3	Sometimes
		4	Fairly often
		5	Frequently, if not always
Variable name v_9	External variable name v_9	int	MDRina avoids involvement
		1	Not at all
		2	Once in awhile
		3	Sometimes
		4	Fairly often
		5	Frequently, if not always
Variable name v_11	External variable name v_11	int	MDRina instills pride in me for being part of its team
		1	Not at all
		2	Once in awhile
		3	Sometimes
		4	Fairly often
		5	Frequently, if not always
Variable name v_12	External variable name v_12	int	MDRina discusses in specific terms who is responsible for achieving performance targets
		1	Not at all
		2	Once in awhile
		3	Sometimes
		4	Fairly often
		5	Frequently, if not always
Variable name v_33	External variable name v_33	int	MDRina talks enthusiastically about what needs to be accomplished
		1	Not at all
		2	Once in awhile
		3	Sometimes
		4	Fairly often
		5	Frequently, if not always
Variable name v_35	External variable name v_35	int	MDRina makes clear what one can expect to receive when performance goals are achieved
		1	Not at all
		2	Once in awhile
		3	Sometimes
		4	Fairly often
		5	Frequently, if not always
Variable name	External variable name	int	MDRina treats me as an individual rather

v_36	v_36		than just a member of a group
		1	Not at all
		2	Once in awhile
		3	Sometimes
		4	Fairly often
		5	Frequently, if not always
Variable name	External variable name	int	MDRina concentrates attention on dealing with mistakes
v_37	v_37		
		1	Not at all
		2	Once in awhile
		3	Sometimes
		4	Fairly often
		5	Frequently, if not always
Variable name	External variable name	int	MDRina displays a sense of power and confidence
v_38	v_38		
		1	Not at all
		2	Once in awhile
		3	Sometimes
		4	Fairly often
		5	Frequently, if not always
Variable name	External variable name	int	MDRina expresses confidence that goals will be achieved
v_41	v_41		
		1	Not at all
		2	Once in awhile
		3	Sometimes
		4	Fairly often
		5	Frequently, if not always
Variable name	External variable name	int	MDRina uses methods of leadership that are satisfying
v_42	v_42		
		1	Not at all
		2	Once in awhile
		3	Sometimes
		4	Fairly often
		5	Frequently, if not always
Variable name	External variable name	int	MDRina gets me to do more than I expected to do
v_43	v_43		
		1	Not at all
		2	Once in awhile
		3	Sometimes
		4	Fairly often
		5	Frequently, if not always
Variable name	External variable name	int	MDRina leads a group to be effective
v_45	v_45		
		1	Not at all
		2	Once in awhile
		3	Sometimes

	4	Fairly often
	5	Frequently, if not always