

# Research Project “Boosting Medical Device Approval Times”

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## Description of the project

You find a description of the project in the file “One-Pager\_Datacollection.pdf”.

To determine how different factors impact the medical device approvals times we collect data about the product and the approval process i.e. the conformity assessment procedure. The following data dictionary describes the data, data types and gives examples.

Please do not hesitate to reach out to our regulatory scientists Dr. Manuel Baur ([manuel.baur@johner-institut.de](mailto:manuel.baur@johner-institut.de)) and Dr. Alexander Everhart ([Alexander.Everhart@hms.harvard.edu](mailto:Alexander.Everhart@hms.harvard.edu)) for further information, explanations and help.

## Data Dictionary: Description of data and data types

All values can be left empty respectively filled with “unknown”

#	Attribute	Description	Data type, possible values	Example
1	Trade Name	One or more trade names of medical devices. Can be replaced by a pseudonym.	String	OncoFix 2.1
2	Contains software	Does the device contain software or is it a Software as a Medical Device (SaMD, MDS 1009)?	yes, no, unknown	yes
3	Contains medical substance	Does the device contain medical substances (MDS 1001)?	yes, no, unknown	no
4	Is sterile	Is the device sold in sterile conditions (regardless of whether it can be sterilized, MDS 1005)?	yes, no, unknown	no
5	Is surgical reusable	Is the device a surgical reusable device (MDS 1006)?	yes, no, unknown	no
6	Animal origin	Does the device contain tissues or cells of animal origin, or their derivatives, which are non-viable or rendered non-viable (MDS 1003)?	yes, no, unknown	no
7	Human origin	Does the device contain tissues or cells of human origin, or their derivatives, which are non-viable or rendered non-viable (MDS 1002)?	yes, no, unknown	no
8	Is implantable	Is the device an implantable device (MDS 1013)?	yes, no, unknown	no

9	Is absorbable	Is the device composed of substances or combinations of substances that are absorbed by or locally dispersed in the human body (MDS 1008)?	yes, no, unknown	no
10	Contains nanomaterials	Does the device incorporate or consist of nanomaterials (MDS 1007)?	yes, no, unknown	no
11	EMDN	Please select the appropriate EMDN Code from the drop-down list or type in "unknown".  See <a href="https://webgate.ec.europa.eu/dyna2/emdn/">https://webgate.ec.europa.eu/dyna2/emdn/</a> to navigate in the building structure.	Coded value from list	A030101
12	GMDN	Please fill in the GMDN Code for your device or type in "unknown" if the appropriate code is not known.	String	unknown
13	MDA / MDN	MDA/MDN codes reflect design and intended purpose of the device. Select one code respectively. Otherwise, type in "unknown" or "n/a", if the information is not applicable.	Coded value or unknown"	MDA 0102
14	MDT	Please select the appropriate MDT Codes from the drop-down list. This is a multi-select drop-down. More than one code may be selected.  The warning, which appears if more than one code is selected, may be ignored. Please type in "unknown" if the information is not known.	Coded value or "n/a"	
15	Directive / Regulation	Please select the directive/regulation under which conformity was declared for the device.  If you declared conformity to MDD and(!) MDR, please fill out two lines!	MDR or MDD or AIMDD	MDR
16	Notified Body	Please select the notified body you used for the conformity assessment procedure if the assessment was according to MDD, AIMDD, or MDR.  Please select "n/a" if the information is not applicable e.g. as no notified body was involved and "unknown" if the notified body is not known.	Coded value or "n/a" or "unknown"	TÜV SÜD
17	Risk Classification	Please select the risk classification.  Please write "unknown" if the information is unknown.	Coded value or "unknown"	Ila
18	Inquiry by manufacturer	When was the first inquiry for a TD assessment sent to the Notified Body by the manufacturer?  Please write "unknown" if the date is not available.	Date in canonical format or "unknown"	2018-08-22

19	Contract Signed OR order confirmation sent	On what date was the contract between manufacturer and Notified Body signed OR the order confirmation sent by the Notified Body? (Whatever date is later) Please write "unknown" if the information is not available.	Date in canonical format or "unknown"	2019-02-13
20	TD assessment started	When was the TD assessment started by the Notified Body? Please write "unknown" if the information is not available.	Date in canonical format or "unknown"	2019-04-22
21	TD assessment finished	When was the TD assessment declared as successfully finished by the Notified Body? Please write "unknown" if the information is not available.	Date in canonical format or "unknown"	2019-04-22
22	Audit involved	Was an audit involved in the TD (technical documentation) assessment? Please select "unknown" if the information is not available and "n/a" if it is not applicable as there was no notified body involved.	Yes, no, unknown	Yes
23	Audit started	If an audit was involved in the TD assessment, when was it started by the Notified Body? Please write "n/a" if there was no audit involved and "unknown" if the information is not available.	Date in canonical format or "unknown" or "n/a"	2019-04-22
24	Audit finished	If an audit was involved in the TD assessment, when was it finished by the Notified Body? Please write "n/a" if there was no audit involved and "unknown" if the information is not available.	Date in canonical format or "unknown" or "n/a"	2019-04-22
25	Findings closed	When did the manufacturer submit the last information to close the findings identified during audit and/or review of the TD? If you submitted more than one updates, pick the last date. Please write "n/a" if there was no audit involved or no findings to be closed. Please write "unknown" if the information is not available.	Date in canonical format or "unknown" or "n/a"	2019-04-22
26	Certification issued	When did the manufacturer receive the Certificate from the Notified Body? Please write "n/a" if there was no or not yet a certificate issued. Please write "unknown" if the information is not available.	Date in canonical format or "unknown" or "n/a"	2019-04-22

27	Comment	Enter any comments that you find valuable to explain your data or to provide additional information.	String	“We had to change the Notified Bodies” when switching from MDD to MDR”
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