**Manufacturer’s Trend Report**

**(TrendR)**

**Reporting Template Version 1.1**

**Medical Devices Vigilance System**

**For initial application all the fields should be completed except 4.2 analysis update.**

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| Section 1: Administrative information |
| **1.1** | **Corresponding competent authority** |
| **a** | To which NCA(s) is this report being sent?        |
| **b** | Reference number assigned by NCA for this TrendR |
| **1.2** | **Date, type, and classification of Trend Report** |
| **a** | Date of submissionYYYY.MM.DD |
| **b** | Date the trend was identifiedYYYY.MM.DD |
| **c** | Time period of trend analysisYYYY.MM.DD to YYYY.MM.DD |
| **d** | Type of report[ ] Initial[ ] Follow up [ ] Combined Initial and final[ ]  Final  |
| **e** | In case of initial and follow-up reports, please indicate the expected date of the next reportYYYY.MM.DD |
| **f** | What is the trend based on? [ ] Increase in the frequency of not serious incidents[ ] Increase in the severity of not serious incidents[ ]  Increase in the frequency of expected undesirable side-effects[ ] Increase in the severity of expected undesirable side-effects[ ]  Increase of expected erroneous results[ ] Other, please specify:  |

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| **1.3** | **Submitter information**  |
| **1.3.1** | **Submitter of the report** |
| **a** | [ ] Manufacturer[ ] Authorised representative[ ] Other, please specify |
| **b** | Manufacturer's reference number for this Trend Report |
| **1.3.2** | **Manufacturer information**  |
| **a** | Manufacturer organisation name      |
| **b** | Swiss single registration number(CHRN)      | **c** | Single registration number (SRN)      |
| **d** | Contact’s first name      | **e** | Contact’s last name      |
| **f** | Email      | **g** | Phone      |
| **h** | Country      |
| **i** | Street      | **j** | Street number      |
| **k** | Address complement      | **l** | PO Box      |
| **m** | City name      | **n** | Postal code      |
| **1.3.3** | **European authorised representative information** |
| **a** | Authorised representative Organisation name      |
| **b** | Single registration number (SRN)      |
| **c** | Contact’s first name      | **d** | Contact’s last name      |
| **e** | Email      | **f** | Phone      |
| **g** | Country      |
| **h** | Street      | **i** | Street number      |
| **j** | Address complement      | **k** | PO Box      |
| **l** | City name      | **m** | Postal code      |

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| **1.3.4** | **Swiss authorised representative information** |
| **a** | Authorised representative Organisation name      |
| **b** | Swiss single registration number (CHRN)      |
| **c** | Contact’s first name      | **d** | Contact’s last name      |
| **e** | Email      | **f** | Phone      |
| **g** | Country      |
| **h** | Street      | **i** | Street number      |
| **j** | Address complement      | **k** | PO Box      |
| **l** | City name      | **m** | Postal code      |

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| Section 2: Medical device information  |
| **2.1** | **Unique Device Identification (UDI)**  |
| **a** | UDI-DI      | Issuing entity:      | **b** | UDI-PI      |
| **c** | Basic UDI-DI      | Issuing entity:      | **d** | Unit of use UDI-DI      | Issuing entity:      |
| **2.2** | **Categorisation of device** |
| **a** | Medical device terminology[ ]  EMDN [ ]  GMDN [ ]  UMDNS(ECRI) [ ]  GIVD/EDMS |
| **b** | Medical device nomenclature code       |
| **2.3** | **Description of device and commercial information** |
| **a** | Medical device name(s) (brand / trade / proprietary or common name)      |
| **b** | Nomenclature text(s)/Description of the device(s) and its/their intended use      |
| **c** | Model List all applicable | **d** | Catalogue/reference numberList all applicable |
| **e** | Serial numberList all applicable | **f** | Lot/batch numberList all applicable |
| **g** | Software versionList all applicable | **h** | Firmware versionList all applicable |
| **i** | Device manufacturing dateYYYY.MM.DD to YYYY.MM.DD | **j** | Device expiry date YYYY.MM.DD to YYYY.MM.DD |
| **k** | Notified body (NB) ID number(s) (if applicable)      |
| **l** | Notified body (NB) certificate number(s) of device (if applicable)      |
| **m** | Please indicate the date of one of the following:[ ]  First declaration of conformity[ ]  The device first CE marked[ ]  First placed on the market [ ]  First put into service [ ]  If software, date first made availableYYYY/MM |
| **2.4** | **Risk class of device when placed on market** |
| **a** | **MDD/AIMDD**[ ]  active implant[ ]  class III[ ]  class IIb[ ]  class IIa[ ]  class I[ ]  class Is[ ]  class Im[ ]  class Ism[ ]  custom-made | **IVDD**[ ]  IVD Annex II List A[ ]  IVD Annex II List B[ ]  IVD devices for self-testing[ ]  IVD general |
| **b** | **MDR**[ ]  class III[ ]  class IIb [ ]  class IIa[ ]  class I | Type (Multiple choice)[ ]  implantable[ ]  active device[ ]  intended to administer and/or remove a medicinal product[ ]  sterile conditions[ ]  measuring function[ ]  reusable surgical instruments[ ]  software[ ]  systems[ ]  procedure packs[ ]  custom-made[ ]  non-medical purpose  | **IVDR**[ ]  class D[ ]  class C[ ]  class B[ ]  class A | Type (Multiple choice)[ ]  self-testing[ ]  near-patient testing[ ]  professional testing[ ]  companion diagnostic[ ]  reagent[ ]  software[ ]  instrument[ ]  sterile conditions |
| **2.5** | **Market distribution (region / country) (according to the best knowledge of the manufacturer)** |
| **a** | [ ]  All EEA, Great Britain, Switzerland, and Turkey[ ]  AT [ ]  BE [ ]  BG [ ]  CH [ ]  CY [ ]  CZ [ ]  DE [ ]  DK [ ]  EE [ ]  ES [ ]  FI [ ]  FR [ ]  GB[ ]  GR [ ]  HR [ ]  HU [ ]  IE [ ]  IS [ ]  IT [ ]  LI [ ]  LT [ ]  LU [ ]  LV [ ]  MT [ ]  NL [ ]  NO[ ]  PL [ ]  PT [ ]  RO [ ]  SE [ ]  SI [ ]  SK [ ]  TR |
| **2.6** | **Use of accessories, associated devices or other devices** |
| **a** | Relevant accessories used with the device(s) under this trend (please list with corresponding Manufacturer if different from device being reported on)      |
| **b** | Relevant associated devices used with the device(s) under this trend (please list with corresponding Manufacturer if different from device being reported on)      |

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| Section 3: Description of Trend |
| **a** | Background information on the trend, including probability of problem arising and the predicted risk to patient of other users.       |
| **b** | Please describe established trigger level:      |
| **3.1** | **Coded information on trend** |
| **3.1.1** | Medical device problem information |
| **a** | IMDRF Medical device problem codes (Annex A)Coding with IMDRF terms is a mandatory requirement.

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|  | Choice 1(most relevant) | Choice 2 | Choice 3 | Choice 4 | Choice 5 | Choice 6 |
| IMDRF 'Medical device problem codes' | Code       | Code       | Code       | Code       | Code       | Code       |

If you think the incident is unique and a suitable IMDRF term is missing, briefly explain:       |
| **3.1.2** | Possible risks to the health or safety |
| **a** | IMDRF 'Health Effect' terms and codes (Annex E, F)Coding with IMDRF terms is a mandatory requirement.

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|  | Choice 1*(most relevant)* | Choice 2 | Choice 3 | Choice 4 | Choice 5 | Choice 6 |
| IMDRF 'Clinical signs, symptoms, and conditions codes' (Annex E) | Code       | Code       | Code       | Code       | Code       | Code       |
| IMDRF 'Health impact' codes (Annex F) | Code       | Code       | Code       | Code       | Code       | Code       |

If you think the trend is unique and a suitable IMDRF term is missing, briefly explain:       |
| **3.1.3** | If trend is based on a root cause:  |
| **a** | IMDRF ‘Cause Investigation' terms and codes (Annex B, C, D)

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| Coding with IMDRF terms is a mandatory requirement. | Choice 1*(most relevant)* | Choice 2 | Choice 3 | Choice 4 | Choice 5 | Choice 6 | Choice 7 | Choice 8 |
| IMDRF Cause investigation : Type of investigation (Annex B)  | Code       | Code       | Code       | Code       | Code       | Code       | Code       | Code       |
|  |  |  |  |  |  |  |  |  |
| IMDRF Cause investigation : Investigation findings(Annex C) | Code       | Code       | Code       | Code       | Code       | Code       |  |  |
|  |  |  |  |  |  |  |  |  |
| IMDRF Cause investigation : Investigation conclusion (Annex D) | Code       | Code       | Code       | Code       | Code       | Code       |  |  |

If you think the trend is unique and a suitable IMDRF term is missing, briefly explain:       |
| **b** | IMDRF Component codes (Annex G)Coding with IMDRF terms is a mandatory requirement.

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|  | Choice 1*(most relevant)* | Choice 2 | Choice 3 |  Choice 4 | Choice 5 |  Choice 6 |
| IMDRF 'Component' codes (Annex G) | Code       | Code       | Code       |  Code       | Code       | Code       |

If you think the trend is unique and a suitable IMDRF term is missing, briefly explain:       |
| **3.2** | **Use of IMDRF terms and codes for identifying the trend**  |
| **a** | Identification of trend using IMDRF Adverse Event Reporting terms and codes Tick-mark which code or combination of codes were used for identifying the trend.

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|  | Choice 1 |
| IMDRF code relating to most relevant 'Medical device problem' (Annex A) | [ ]  |
| IMDRF code relating to most relevant'Investigation finding' (Annex C, ‘Cause investigation’) | [ ]  |
| IMDRF code relating to most relevant 'Clinical signs, symptoms, and conditions codes' (Annex E) | [ ]  |
| IMDRF code relating to most relevant 'Health impact' codes (Annex F) | [ ]  |
| IMDRF code relating to most relevant 'Componet' codes (Annex G) | [ ]  |

[ ]  Other – enter description of what the trend is based on and the rationale why the above IMDRF codes were not used:       |
| **3.3** | **Use of in-house terms/codes for identifying the trend**  |
| **a** | If trend was not identified by IMDRF codes but by in-house codes, please provide the codes and terms below.

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|  | Choice 1 |
| Code/term for most relevant medical device problem | Code      Term       |
| Code/term for most relevant root cause evaluation | Code      Term       |

[ ]  Other – enter description of what trend is based on and the rationale why the above codes were not used:       |
| **3.4** | **Number of devices on the market** |
| **a** | Indicate on which basis the trend was identified regarding the device or device variant:[ ]  Model [ ]  Software [ ]  Lot/Batch [ ]  Product platform [ ]  Other variantDetails of the selection made above      |
| **b** | Indicate to what criteria the number of devices on the market (also known as denominator data) is based on.(Tick the most appropriate):[ ]  Devices placed on the market or put into service[ ]  Units distributed within each time period[ ]  Number of tests performed[ ]  Number of episodes of use (for reusable devices)[ ]  Active installed base[ ]  Units distributed from the date of declaration of conformity/CE mark approval to the end date of each time period[ ]  Number of devices implanted[ ]  Other please describe:       |
| **c** | Enter the number of similar events (that are non-reportable incidents (not serious incidents or expected undesirable side- effects or expected erroneous results) or reportable incidents and devices on the market for the indicated time periodsPlease use time periods that best highlight the trend and describe why:

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|  | Time period (N) | Time period (N-1) | Time period (N-2) | Time period (N-3) |
| Start date |  |  |  |  |
| End date |  |  |  |  |
|  | Number of similarIncidents | Number of devices on market | Number of similarincidents | Number of devices on market | Number of similar incidents | Number of devices on market | Number of similarincidents | Number of devices on market |
| Switzerland  |       |       |       |       |       |       |       |       |
| EEA + CH + TR |       |       |       |       |       |       |       |       |
| World (incl. EEA + CH + TR) |       |       |       |       |       |       |       |       |

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| **d** | Have any of the trended events been submitted individually as reportable events under vigilance?[ ]  Yes [ ]  NoIf yes, please list reference numbers and the country where the event occurred:      |

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| Section 4: Manufacturer analysis |
| **4.1** | **Manufacturer’s preliminary comments** |
| **a** | For **initial** and **follow-up** reports: preliminary results and conclusions of manufacturer’s investigation      |
| **b** | Initial actions (corrective and/or preventive) implemented by the manufacturer      |
| **c** | What further investigations do you intend in view of reaching final conclusions?       |
| **4.2** | **Results of manufacturer’s final investigation into trend**  |
| **a** | **For Final:** Description of the manufacturer’s evaluation concerning (possible) root causes/causative factors and conclusion      |
| **b** | Is root cause confirmed?[ ]  Yes [ ]  No |
| **c** | Has the risk assessment been reviewed?[ ]  Yes [ ]  No If 'No', rationale for no review required:      If the risk assessment has been reviewed, is it still adequate?[ ]  Yes [ ]  No Results of the assessment:       |
| **d** | Description of remedial action / corrective action / preventive action / field safety corrective action (FSCA)      |
| **e** | Time schedule for the implementation of the identified actions      |
| **f** | Final comments from the manufacturer on cause of investigation and conclusion      |
| **g** | Further investigation      |

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|  | **Section 5: General comments** |
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Submission of this report does not represent a conclusion by the manufacturer and / or authorised representative or the national competent authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.

Please send the completed report as Word or PDF file to materiovigilance@swissmedic.ch