E-SUBMISSION GUIDE FOR NEW ADVERSE EVENT NOTIFICATION FOR DEVICE STUDY

NO	MEDCAST NOTIFICATION FORM	EXPLANATION
	Adverse Event	**Untoward medical Occurrence, unintended disease or injury or untoward clinical sign (including abnormal laboratory findings) in subjects, users or other persons, whether or not related to the investigational medical deviceand whether anticipated or unanticipated.**
1.*	**CIP Number/ Study Number**	The unique identification code or short name assigned to the specific clinical investigation plan by the Sponsor (numeric, alphanumeric or acronym) should be indicated.
2.*	**CIP Title / Study Title**	The identifying title of the Clinical Investigation. The title indicated here should be consistent with other title entries (such as in clinical investigation application form, clinical investigation plan cover page etc).
3.*	**Date Sponsor Received Report of AE**	Indicate the date when the sponsor was first notified by the investigation site about the event. This date is checked for compliance with reporting timelines
4.	**Country Code :**	Indicate the country code for the country in which the subject associated with the event has been enrolled.
5.*	**Study Site**	Name identifying institution or site where the clinical investigation is carried out.
6.*	**Patient ID Code**	The study specific subject ID code, i.e. the link between study data and the actual subject identity.
7.	**AE ID Code**	The investigator, sponsor or manufacturer should assign a unique ID to each AE that has occurred, This number shall remain unchanged throughout all other alterations of the particular AE-reporting due to ongoing assessment.
8.*	**Date of Procedure / First Use**	Indicate the date of the relevant procedure or the date when the subject was exposed to the device for first use. Format DD/MM/YYYY.
9.*	**Date of Event Onset**	The date when the first signs of an event were noticed may be different (earlier) than the date when the event fulfilled the seriousness criteria. The date when the event became an SAE should be reported as Date of event onset. In case of Device Deficiencies which did not lead to an AE, the date the Device Deficiency was discovered should be indicated.

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10.*	**Serious AE or Non Serious AE**	Serious adverse event – led to death, serious deterioration in the health of the subject, users or other persons as defined by one or more of the following: 1. A life-threatening illness or injury 2. A permanent impairment of a body structure or a body function including chronic diseases, 3. In-patient or prolonged hospitalization 4. Medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function. Foetal distress, foetal death, a congenital abnormality, or birth defect including physical or mental impairment.
11.*	**Description of Event**	Provide a description of the event in free text. Below is a non-exhaustive list of items that could be relevant to cover: • Nature of the observed symptoms • Duration and severity of the symptoms • Date of onset of first signs of the event (before it became a SAE) • Medical background of the patient • Medical care of the patient • Comments on the event in relation to already known safety data Use of standardised terminology corresponding to relevant IMDRF codes is encouraged.
12.*	**Action / Treatment / Patient Outcome**	Provide information in free text on actions taken, treatment(s) administered and the outcome.
13.*	**Relationship to Procedure**	Choose one option from the following list of causality levels : • Not related • Possible • Probable • Causal Please report the assessments by sponsor and investigator in the respective columns.

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14.*	**Relationship to Investigational Device**	Choose one option from the following list of causality levels : • Not related • Possible • Probable • Causal Please report the assessments by sponsor and investigator in the respective columns.
15.*	**Unanticipated Serious Adverse Device Effect (USADE)**	Serious adverse device effect which by its nature, incidence, severity or outcome has not been identified in the current risk assessment.
16.*	**Treatment Arm**	Choose one option from the following list: • Test group • Comparison group • Blinded • Not applicable Note: For some study designs it might be more relevant to add name of device; i.e. in a clinical investigation with several test groups it might be useful to differentiate which investigational device that the subject has been exposed to.
17.*	**Event Status**	Choose one option from the following list (do not add other options): • Resolved • Resolved with Sequelae • Ongoing • Death
18.	**Date of Event Resolution**	Add date in format DD/MM/YYYY. If event status is “Ongoing” enter Not Applicable.