

# Safety Report Form

Clinical Investigations with Medical Devices

**Detta dokument är framtaget och kvalitetssäkrat av Kliniska Studier Sverige.**

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Vi utvecklar och erbjuder stöd för kliniska studier i hälso- och sjukvården.

Stödet vi erbjuder ger goda förutsättningar för kliniska studier av hög kvalitet.

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## About the document

This page is not included as part of the “Safety Report Form”, but gives a short introduction to you, who will use this template. This page should be removed when using this form. This “Safety Report Form” template aims to serve as a help document to facilitate your work. The template may need adjustments so that it fits your clinical investigation.

The planning and execution of a clinical investigation with a medical device initiated on or after May 26, 2021 shall comply with the EU Regulation 2017/745 on Medical Devices (MDR). Please note that transition rules apply to clinical investigations initiated before May 26, 2021. The guidance document “MDCG 2020-10/1 Safety reporting in clinical investigations of medical devices under the Regulation (EU) 2017/745” provides guidance on safety reporting during clinical investigations. This reporting form is designed to comply with MDR and the guidance document. See the Clinical Investigation Plan for requirements specific for your clinical investigation.

This form should be used for reporting of events (SAEs and DDs that could have led to a SAE) from the investigator to the sponsor. At the clinical investigation site(s), please use the “Adverse Event” form to document adverse events for participating subjects/patients, the “Adverse Event Form - Users or Other persons” for registration of adverse events occurring for users or other subjects, and the ”Device Deficiency Form – subject related” and the ”Device Deficiency Form – non-subject related” for registration of device deficiencies. For reporting from sponsor to the relevant authorities, the form “MDCG 2020-10/2 Clinical Investigation Summary Safety Report Form v1.0” shall be used. Please see MDR and MDCG 2020-10/1 for details regarding the requirements for registration and reporting of the different events.

For more information and useful links, please visit the websites of the Swedish Medical Products Agency (Läkemedelsverket) and the Swedish Ethical Review Authority (Etikprövningsmyndigheten).

### Version: 1.0, 18 August 2021

The national network for clinical investigations with medical devices within the node organization connected to Clinical Studies Sweden (Kliniska Studier Sverige) is responsible for the template.

The template will be reviewed regularly by the national network. Any suggestions for improvement of this template can be sent to any of the email addresses provided below and the designated contact at the respective regional node can then further lift the proposal.

Contact information for the regional nodes:

* Gothia Forum: gothiaforum@vgregion.se
* Forum Norr: forumnorr@regionvasterbotten.se
* Forum Mellansverige: Info-fou@ucr.uu.se
* Forum Sydost: forumo@regionostergotland.se
* Forum Stockholm-Gotland: feasibility.karolinska@sll.se
* Forum Söder: forumsoder@skane.se

## SAFETY REPORT FORM

**Please forward by fax or e-mail, within 3 calendar days of awareness**

**Sponsor: Fax:**

**Contact person: e-mail:**

**Initial report** [ ]  **Follow-up report** [ ]

**Investigation site:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**The report concerns the following (choose one option):**

[ ]  SAE for a study subject with the following Subject ID code: \_\_\_\_\_\_\_\_\_\_\_\_\_

[ ]  SAE for a user or another person (other than a study subject).

[ ]  DD that might have led to a SAE. If applicable add: Subject ID code: \_\_\_\_\_\_\_\_\_\_\_\_\_

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**Description of the event:**

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**Description of relevant medical history and medications:**

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**Description of action taken/treatment and patient outcome:**

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**Date of event onset (dd/mm/yyyy):** \_\_ \_\_ - \_\_ \_\_ - \_\_ \_\_ \_\_ \_\_

Time of event onset, if known (hh:mm): \_\_ \_\_ : \_\_ \_\_

**Date of event resolution, if resolved (dd/mm/yyyy):** \_\_ \_\_ - \_\_ \_\_ - \_\_ \_\_ \_\_ \_\_

**Event status:**

Recovered [ ] Resolved with Sequelae [ ]  Ongoing [ ]  Death [ ]

**Which SAE criteria(s) are fulfilled (i.e. Classification of event)?**

Death [ ]

Life-threatening illness or injury [ ]

Permanent impairment/Chronic disease [ ]

Hospitalization [ ]

Medical or surgical intervention [ ]

Foetal distress, foetal death or
congenital physical or mental or
birth defect [ ]

Not applicable [ ]

**………………………………………………………………………………………………………**

**Patient gender:**

Female [ ]  Male [ ]  Other [ ]  Unknown [ ]

**Age of patient on date of event onset:** \_\_\_\_\_\_\_\_\_\_\_\_

**Investigation arm:**

Test group [ ]  Comparison group [ ]  Blinded [ ]  Not applicable [ ]

Randomization code broken:

Yes [ ]  No [ ]  NA [ ]

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**Name and lot no of the device, if applicable: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date of procedure/ first use of the device, if applicable (dd/mm/yyyy):**

\_\_ \_\_ - \_\_ \_\_ - \_\_ \_\_ \_\_ \_\_

**Current location of the device, if applicable:**

Investigational/study site [ ]  Sponsor [ ]  Subject [ ]  Manufacturer [ ]

Remains implanted [ ]  Discarded [ ]  Unknown [ ]  Other [ ]

If “other”, please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**Relationship to procedure**

Not related [ ]  Possible [ ]  Probable [ ]  Causal [ ]

**Relationship to device**

Not related [ ]  Possible [ ]  Probable [ ]  Causal [ ]

**Unanticipated SADE**

Yes [ ]  No [ ]

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**Investigator signature**