

# Adverse Event Form - Users or other persons

Clinical Investigations with Medical Devices

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

Vi utvecklar och erbjuder stöd för kliniska studier i hälso- och sjukvården.
Stödet vi erbjuder ger goda förutsättningar för kliniska studier av hög kvalitet.

## Introduction to the “Adverse Event Form - Users or other persons” template

This page is not included as part of the “Adverse Event Form – users or other persons” template, but gives a short introduction to you, who will use this template. This page should be removed when using this form. This “Adverse Event Form – users or other persons” 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. The “Adverse Event Form – users or other persons” template is designed to comply with MDR and this guidance document.

This form should be used at the clinical investigation site(s) to document adverse events for users or other persons other than participating subjects/patients. Please use the “Adverse Event Form” for registration of adverse events occurring to subjects/patients, The Device Deficiency Forms for registration of device deficiencies, and the “Safety Report Form” for reporting of events from the investigator to the sponsor. 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, MDCG 2020-10/1 and the Clinical Investigation Plan 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).

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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

**ADVERSE EVENT FORM – users or other persons**

Note, only AEs related (at least possibly) to the Investigational device or comparator should be documented for users or other persons

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Adverse Event****(diagnosis or symptom)** | **Affected person’s relationship to the study (e.g. staff, relative, other)** | **Date of event onset****(YYYY/MM/DD)** | **Relationship to Investigational Device or Comparator**1 = Possible2 = Probable3 = Causal relationship | **Serious Adverse Event?**Yes or No*If Yes, complete the Safety Report Form* | **Date of event resolution****(YYYY/MM/DD)** | **Event status**1 = Resolved2 = Resolved with Sequelae3 = Ongoing4 = Death | **Investigator Signature and Date** |
|  |  | \_\_\_\_\_\_/\_\_\_\_/\_\_\_\_ |  |  | \_\_\_\_\_\_/\_\_\_\_/\_\_\_\_ Ongoing at study end [ ]  |  | \_\_\_\_\_\_/\_\_\_\_/\_\_\_\_Sign: \_\_\_\_\_\_\_ |
|  |  | \_\_\_\_\_\_/\_\_\_\_/\_\_\_\_ |  |  | \_\_\_\_\_\_/\_\_\_\_/\_\_\_\_ Ongoing at study end [ ]  |  | \_\_\_\_\_\_/\_\_\_\_/\_\_\_\_Sign: \_\_\_\_\_\_\_ |
|  |  | \_\_\_\_\_\_/\_\_\_\_/\_\_\_\_ |  |  | \_\_\_\_\_\_/\_\_\_\_/\_\_\_\_ Ongoing at study end [ ]  |  | \_\_\_\_\_\_/\_\_\_\_/\_\_\_\_Sign: \_\_\_\_\_\_\_ |
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