

# Device Deficiency Form - Subject related

Clinical Investigations with Medical Devices

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## Introduction to the “Device Deficiency (DD) Form – Subject related” template

This page is not included as part of the “Device Deficiency Form – Subject related” template, but gives a short introduction to you, who will use this template. This page should be removed when using this form. This “Device Deficiency Form – Subject related” 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 Device Deficiency Form – Subject related is designed to comply with MDR and this guidance document.

This form should be used at the clinical investigation site(s) to document device deficiency for device assigned to participating subjects/patients. Please use the template “Device Deficiency Form – Non-subject related” for device deficiencies that occur before the device has been assigned to a subject/patient. Use the “Adverse Event Form” or “Adverse Event Form - Users or other persons” for registration of adverse events occurring for subjects or for users or other subjects.

If a device deficiency has been assigned as an event that could have led to a serious adverse event, use the “Safety Report Form template” for reporting to the sponsor within 3 calendar days from knowledge of the event. Please see the Clinical Investigation Plan for any additional requirements. 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

Clinical Studies Sweden (Kliniska Studier Sverige) is responsible for this template.The template will be reviewed regularly by Clinical Studies Sweden. Any suggestions for improvement of this template can be sent to any of the email addresses provided below.

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## DEVICE DEFICIENCY (DD) FORM – SUBJECT RELATED

|  |  |  |
| --- | --- | --- |
| Investigation arm (tick one box):  Investigational device  Comparator  Blinded |  | **No DD during the study**  (tick the box, add Investigator signature and date)  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** \_\_\_\_\_\_/\_\_\_\_/\_\_\_\_  Investigator Signature Date |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Description of the Device Deficiency**  Any inadequacy in the identity, quality, durability, reliability, safety or performance of an investigational device, including malfunction, use errors or inadequacy in information supplied by the manufacturer. | **Device details**  (model no, serial no, lot/batch no etc) | **Date of Deficiency**  **(YYYY/MM/DD)** | **Is this deficiency with respect to:**  1 = Identity  2 = Quality  3 = Durability  4 = Reliability  5 = Safety  6 = Performance | **Is the device deficiency due to:**  1 = Malfunction  2 = Error  3 = Inadequate labelling | **Action taken**  1 = No action  2 =Use of the device discontinued due to deficiency  3 = Other (please specify) | **Could the deficiency have led to a serious adverse device effect if:**   * either suitable action had not been taken * intervention had not been made, or * circumstances had been less fortunate   Yes or No  *If Yes, complete the Safety Report Form* | **Investigator Signature and Date** |
| **1.** |  | \_\_\_\_\_\_/\_\_\_\_/\_\_\_\_ |  |  |  |  | \_\_\_\_\_\_/\_\_\_\_/\_\_\_\_  Signature: \_\_\_\_\_\_\_ |
| **2.** |  | \_\_\_\_\_\_/\_\_\_\_/\_\_\_\_ |  |  |  |  | \_\_\_\_\_\_/\_\_\_\_/\_\_\_\_  Signature: \_\_\_\_\_\_\_ |
| **Description of the Device Deficiency**  Any inadequacy in the identity, quality, durability, reliability, safety or performance of an investigational device, including malfunction, use errors or inadequacy in information supplied by the manufacturer. | **Device details**  (model no, serial no, lot/batch no etc) | **Date of Deficiency**  **(YYYY/MM/DD)** | **Is this deficiency with respect to:**  1 = Identity  2 = Quality  3 = Durability  4 = Reliability  5 = Safety  6 = Performance | **Is the device deficiency due to:**  1 = Malfunction  2 = Error  3 = Inadequate labelling | **Action taken**  1 = No action  2 =Use of the device discontinued due to deficiency  3 = Other (please specify) | **Could the deficiency have led to a serious adverse device effect if:**   * either suitable action had not been taken * intervention had not been made, or * circumstances had been less fortunate   Yes or No  *If Yes, complete the Safety Report Form* | **Investigator Signature and Date** |
| **3.** |  | \_\_\_\_\_\_/\_\_\_\_/\_\_\_\_ |  |  |  |  | \_\_\_\_\_\_/\_\_\_\_/\_\_\_\_  Signature: \_\_\_\_\_\_\_ |
| **4.** |  | \_\_\_\_\_\_/\_\_\_\_/\_\_\_\_ |  |  |  |  | \_\_\_\_\_\_/\_\_\_\_/\_\_\_\_  Signature: \_\_\_\_\_\_\_ |