

# Investigational Device Accountability log – Site

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 “Investigational Device Accountability log – Site” template

This page is not included as part of the “Investigational Device Accountability log - Site” template, but gives a short introduction to you, who will use this template. This page should be removed when using this form. This “Investigational Device Accountability log - Site” 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). The Investigational Device Accountability log is designed to comply with the MDR.

This form should be used at the clinical investigation site(s) to document the physical location of all investigational devices from reception to return or disposal of the investigational device. Identification of the investigational device has to be adjusted according to each study.

### Version: 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

## INVESTIGATIONAL DEVICE ACCOUNTABILITY LOG – SITE

**Device Storage location**:…………………………………………….

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Device receipt** | **Device Dispense to Subject** | **Device Return from Subject** | **Device Return to Sponsor/Destroyed** | **Monitored** |
| Date Received | Initials of Receiver | Batch #  | Serial # | Quantity | Unique code # | Expiry date (if applicable) | Date Dispensed | Initials of Dispenser | Subject ID (#) | Date Returned | Initials of Receiver | Date Returned | Initials of Sender | CommentsFor example state: Device used/unused, expired, malfunctioning, destroyed, device not to be returned by user | Date, initials |
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NOTE: Retain a copy of the packing slip for all shipments received and sent.

Signature Principal Investigator:……………………………………………………… Date:……………………………………………………………….