



# Essential Document Log – Version Tracker

Samverkansmonitorering med koordinerande monitor

**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

## Om dokumentet

Essential Document Log – Version Tracker publicerades första gången den 2022-05-19. Detta är version 1.

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| --- | --- |
| **Trial Protocol name/no:** | **Sponsor:** |
| **Contact person:** *e.g. coordinating monitor/node, PM* |  |

***Regulatory Approvals*** *(**Note: for clinical trials submitted and approved in CTIS, assessment from the Swedish Ethical Review Authority and approval from the Swedish Medical Products Agency are included in the decision received in CTIS)*

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| --- | --- | --- |
| **Ethic*s* Approval** *(date of approval)* | **Approval MPA** *(date of approval)* | ***Content of application*** |
| ***Ex. 2020-12-03*** | ***Ex. 2020-12-03*** | ***Ex. Protocol v. 1.0, ICF v.1.0*** |
| ***Ex. 2021-03-17*** | ***Ex. NA*** | ***Ex. Addition of site XXX*** |
|  |  |  |

***Other Approvals***

|  |  |  |
| --- | --- | --- |
| **Approval** | ***Content of approval/reason for update/comments*** | ***Date implemented on each site*** |
| ***Ex. Biobank*** |  | ***Ex. Umeå 2021-10-21*** |
| ***Ex. Radiology*** |  | ***Ex. Umeå 2021-12-12, Uppsala 2021-12-12*** |
|  |  |  |

***Trial protocol***

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| **Version/date** | **Substantial amendment** *(yes/no)  (If yes: date of approval)* | ***Reason for update/comments*** | ***Date implemented on each site*** |
| ***Ex. Version 1.0/ 2020-11-03*** | ***Ex. No*** |  | **Ex. *Umeå* 2021-10-21** |
| ***Ex. Version 2.0/ 2021-03-25*** | ***Ex. 2021-11-22*** |  | ***Ex. Umeå 2021-12-12, Uppsala 2021-12-12*** |
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***Subject information and Informed Consent Form (ICF)*** *(Note: for clinical trials submitted and approved in CTIS, assessment from the Swedish Ethical Review Authority and approval from the Swedish Medical Products Agency are included in the decision received in CTIS)*

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| **Version/date** | **Ethics Approval** *(date of approval)* | ***Reason for update/comments*** | ***Date implemented on each site*** |
| ***Ex. Version 1.0/ 2020-11-03*** | ***Ex. 2020-12-03*** |  | ***Ex. Umeå 2021-10-21*** |
| ***Ex. Version 2.0/ 2021-03-25*** | ***Ex. 2021-04-08*** |  | ***Ex. Umeå 2021-12-12, Uppsala 2021-12-12*** |
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***Case Report Form (CRF)***

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| **Version/date** | ***Reason for update/comments*** | ***Date implemented on each site*** |
| ***Ex. Version 1.0/ 2020-11-03*** |  | ***Ex. Umeå 2021-12-12, Uppsala 2021-12-12*** |
| ***Ex. Version 2.0/ 2022-03-25*** |  | ***Ex. Uppsala 2022-03-25*** |
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***Other Documents (Ex Lab manuals, instructions etc.)***

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| **Document** | **Version/date** | ***Reason for update/comments*** | ***Date implemented on site*** |
| ***Ex. Lab manual*** | ***Ex. Version 1.0/ 2020-11-03*** |  | ***Ex. Umeå 2021-12-12, Uppsala 2021-12-12*** |
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