**SMART-TRIAL Study Validation Report for STUDY\_NAME**

< Organisation LOGO/NAME >

**TABLE OF CONTENTS**

[**1**](#_heading=h.tyjcwt) **Introduction 3**

[1.1](#_heading=h.3dy6vkm) Purpose 3

[1.2](#_heading=h.1t3h5sf) Scope and Plan 3

[**2**](#_heading=h.4d34og8) **Validation Test Specification Plan 3**

[**3**](#_heading=h.2s8eyo1) **Validation Test execution and results 3**

[3.1](#_heading=h.17dp8vu) General study setup 3

[3.2](#_heading=h.3rdcrjn) Summary of Form test results 4

[3.3](#_heading=h.26in1rg) Processes and Data event test results 4

[**4**](#_heading=h.lnxbz9) **Collaborators 5**

[**5**](#_heading=h.35nkun2) **Conclusion 5**

# Introduction

This report summarizes the results from a validation test done on the SMART-TRIAL study setup of STUDY NAME.

The export of the executed validation data is attached to this report in a .CSV file if required (include .csv file export for the subjects’ data used for this validation test).

## Purpose

The purpose of the validation testing is to ensure that the STUDY NAME setup in SMART-TRIAL meets the requirements in the study protocol and/or statistical analysis plan. Please note that SMART-TRIAL is a validated system and that this validation therefore covers the setup performed in SMART-TRIAL, including the Forms, Process, Sites, and any Rules (Process Rules, Show Rules, and/or Validation Rules) applied.

## Scope and Plan

The complete Study setup is covered by this test report. The test was performed by NAME, during the PERIOD/DATE.

# Validation Test Specification Plan

The validation test of the Study setup was completed as follows:

1. Individual Forms are reviewed inside of SMART-TRIAL, under the “Forms” section, and specifications are compared with the eCRF template/specification document. Question types, Validation Rules, Show Rules, and Export Labels are validated and tested.
2. Process is reviewed inside of SMART-TRIAL, under the “Process” section, and specifications are validated according to protocol. Data Event specifications, Process Rules, and Export Labels are validated according to study protocol.
3. Study is placed into test mode, and at least one subject is enrolled according to the study protocol. Data entry is completed for all Data Events, including unscheduled events and adverse events (if needed). All Process Rules are tested according to specifications in the Process Rule section of the Study in SMART-TRIAL.
4. Data is exported and examined for any input errors or missing data and validated against the data input found in SMART-TRIAL.

# Validation Test execution and results

## General study setup

This covers test results from the study overall set up, such as correct subject attributes, number of data events, Form validation etc.

**Have the correct modules been enables in the study, e.g. the Adverse Event Module, the Medication Module, eConsent, Randomization, etc.?** YES/NO

**Are correct demographic attributes required when enrolling a subject profile, as specified in the study protocol, such as subject ID, gender, date of birth, etc.?** YES/NO

**Have correct sites been created and assigned to the right process(es)?** YES/NO

**Clarification of failed validation, if any:** Describe what is not being fulfilled for the process OR N/A

## Summary of Form test results

Attached to this report, is an eCRF template for each Form, where specifications are listed. The below table covers validation test of the Forms.

| **Form Name** | **Form Version** | **Are Export Labels added to all Forms and questions?** | **Is form type and are data fields correct?** | **Are data field texts/translations and possibilities (if applicable) correct?** | **Are settings correct, such as validation rules, show rules?** | **If validation failed, clarify** |
| --- | --- | --- | --- | --- | --- | --- |
| Form name | Form version | YES/NO | YES/NO | YES/NO | YES/NO | clarify what is not being fulfilled if relevant |
| Demographics | 0.25 | YES | YES | YES | YES | NA |
| Vital Signs | 0.57 | YES | YES | YES | YES | NA |
| … |  |  |  |  |  |  |

## Processes and Data event test results

This table presents the validation test results of the Study Process(es) and Data Events.

### PROCESS 1 NAME

**Is the process structure of Data Events correct (such as type, when they are activated, etc.)?** YES/NO

**Is the process name and settings correct (such as unscheduled events etc.)?** YES/NO

**Have Export Labels been added to all Data Events?** YES/NO

**Clarification of failed validation, if any:** Describe what is not being fulfilled for the process OR N/A

| **Data event Name** | **Is data event type correct?** | **Is the data event activation timing correct?** | **Is data event text for e.g. e-mail/SMS correct according to study protocol?** | **Is data event settings correct (reminders, process rules etc.)** | **Is user/subject able to submit Forms for the event?** | **If validation failed, clarify** |
| --- | --- | --- | --- | --- | --- | --- |
| Data event name | YES/NO | YES/NO | YES/NO/NA | YES/NO/NA | YES/NO | clarify what is not being fulfilled if relevant |
| Screening | YES | YES | NA | YES | YES | NA |
| Baseline | YES | YES | NA | YES | YES | NA |
| … |  |  |  |  |  |  |

# Collaborators

**Have the correct collaborators been added to the study?** YES/NO

**Have the collaborators been assigned the correct Study and/or Site permissions?** YES/NO

# Conclusion

Validation tests have been completed as specified in section 2. It’s concluded that the SMART-TRIAL Study setup adheres to the Study protocol, and is accepted to be used for active clinical data collection.

| For and on behalf of | For and on behalf of |
| --- | --- |
| **COMPANY** | **COMPANY** |
| Name: | INSERT NAME | Name:  | INSERT NAME |
| Position:  | INSERT POSITION | Position:  | INSERT POSITION |
| Date:  | INSERT DATE | Date:  | INSERT DATE |
| Signature: | Signature:  |  |