



Centrale Commissie Mensgebonden Onderzoek



**ccmo** Onderzoek met Mensen  
Portaal voor medisch-wetenschappelijk onderzoek in Nederland

**SAE's**

The screenshot displays the CCMO Research with human participants portal. At the top, the logo and text 'Research with human participants' and 'The Netherlands medical research portal' are visible. Below this, a 'Back' link is present. The study identifier 'NL-000784' is prominently displayed, along with two status tags: 'WMO / Embryo Act' and 'Not started yet'. The study title, 'The effect of green tea extract on LDL cholesterol in adults with elevated cardiovascular risk', is shown below. A navigation bar contains tabs for 'Submissions', 'Progress', 'SAE' (which is highlighted), and 'Other notifications', with a 'Help' icon to the right. A '+ SAE' button is located on the left, and a search bar with the placeholder 'Search by number of a participant' and a 'Search' button is on the right. Below these elements, the beginning of a table is visible, with columns labeled 'Submission', 'Type', 'Participant', 'ID', and 'Status'.

This guide explains how to create an SAE and follow-up for an SAE in the Research Portal. Ensure you are authorized to add SAEs to your study. The **'Authorizations'** guide provides step-by-step instructions on obtaining these rights. To create a new SAE, click the +SAE button in the portal.

← Back

# NL-000784

WMO / Embryo Act

Not started yet

The effect of green tea extract on LDL cholesterol in adults with elevated cardiovascular risk

Submissions

Progress

**SAE**

Other notifications

 Help

+ SAE

Search by number of a participant

Search

Submission	Type	Participant	ID	Status	
6-1-2025	SAE	Participant P01	SAE-01.01	Signed	⋮

The first SAE you create will automatically receive the ID SAE-01.01

ccmo Research with human participants  
The Netherlands medical research portal

← Back

**NL-000784** WMO / Embryo Act Not started yet

The effect of green tea extract on LDL cholesterol in adults with elevated cardiovascular risk

Submissions Progress **SAE** Other notifications Help

+ SAE Search by number of a participant Search

Submission	Type	Participant	ID	Status
6-1-2025	SAE	Deelnemer P01	SAE-01.01	Ondertekend

Preview  
Follow-up

You can only add a follow-up to an existing SAE once the original SAE has been signed.

To add a follow-up, click on the three dots next to the SAE you wish to update and select the 'follow-up' option.

CCMO Onderzoek met Mensen  
Portaal voor medisch-wetenschappelijk onderzoek in Nederland

Taal Nederlands MENU

SAE

- 0 Introductie
- 1 Melding
- 2 Voorval
- 3 Documenten
- 4 Controle
- 5 Verzenden

← Terug

Revisie Preview

## Melding

NL-000784 • SAE-01.02

**1.1**  
Is de contactpersoon voor SAE's dezelfde persoon zoals vermeld bij Indieningen 1.1 Indiener (contactpersoon voor toetsingscommissie)?\*

Ja  
 Nee

**1.2**  
Is dit een melding van een overzichtsjijst van meerdere SAE's of een MDCG-formulier?\*

Ja  
 Nee

**1.3**  
Wat is de reden van wijziging van het SAE-formulier?\*

**1.4**  
Datum waarop de melding voor het eerst ontvangen is\*

05-01-2025

Datum waarop de meest recente informatie ontvangen is\*

dd-mm-jjjj

### (Nog nieuwe engelse screenshot toevoegen)

When adding a follow-up, you will be asked two additional questions:

1.3 What is the reason for updating the SAE form?

1.4 What is the date the most recent information was received?

You can then upload additional documents and submit the follow-up.

← Back

# NL-000784

WMO / Embryo Act

Not started yet

The effect of green tea extract on LDL cholesterol in adults with elevated cardiovascular risk

Submissions

Progress

**SAE**

Other notifications

Help

+ SAE

Search by number of a participant

Search

Submission	Type	Participant	ID	Status	
6-1-2025	SAE	Deelnemer P01	SAE-01.02	Follow-UP	⋮

After submitting the follow-up, the SAE will now have the ID SAE-01.02 and the status Follow-up. If additional follow-ups are added, the ID will change incrementally (e.g., SAE-01.03, SAE-01.04, and so on)