SMC - Medicinal products clinical trials

1. General

1.1 The issue at hand

Research on humans is subject to strict conditions in order to protect the dignity and health of the persons concerned. Anyone intending to import or export medicinal products for clinical trials requires an authorisation from Swissmedic.

1.2 Basis and information

- Therapeutic Products Act (TPA; SR *812.21*)
- Human Research Act (HRA; SR *810.30*)
- Medicinal Products Licensing Ordinance (MPLO; SR *812.212.1*)

1.3 Reference in Tares

Tariff items that are relevant under therapeutic products law contain the note «Permit obligation: SMC-ClinT».

1.4 Terminology

Clinical trial	Research project involving individuals that prospectively assigns them to undergo a health-related intervention in order to study its effects on health or on the structure and function of the human body

2. Information in the customs/goods declaration

Anyone importing or exporting medicinal products for clinical trials must provide an indication in the goods declaration regarding the restriction obligation and enter the clinical trials establishment authorisation number.

Identification Regulation	Passar: - Regulation 1 (yes) - Regulation code 511 «SMC – M Clinical trials»
	e-dec: - Permit obligation «yes» - Authorising authority «SMC-ClinT»
Additional information	- Establishment authorisation licence - Authorisation holder