Bundesamt für Sicherheit im Gesundheitswesen
BASG

EC-DG SANTE/HMA-CTFG/EMA joint training on the Clinical Trials Regulation (EU) 536/2014

Study vs. Trial

Stefan Strasser, MD

Department Clinical Trials, Austrian Medicines and Medical Devices Agency

Disclaimer

Bundesamt für Sicherheit im Gesundheitswesen
BASG

The content of this presentation reflects the personal knowledge, experience and view of the author.

It does not necessarily represent the view of the Federal Agency for Safety in Health Care (BASG), the Austrian Agency for Health & Food Safety (AGES), the European Medicines Agency (EMA) or the European Commission (EC).

Any omission or truncation of regulatory requirements found within this presentation does not relieve any entity or person of their legal obligations to fully comply with all applicable regulatory requirements.

Key definitions in Reg (EU) 536/2014

Bundesamt für Sicherheit im Gesundheitswesen
BASG

Clinical study

Any investigation in relation to humans [for effects, safety or PK] with the objective of ascertaining the safety or efficacy of medicinal products.

Clinical trial

ANY of the following applies:

- assignment to the therapeutic strategy is decided in advance and not within normal clinical practice in MSC
- decision to prescribe is simultaneous with decision to include subject in the trial
- diagnostic/monitoring procedures additional to normal clinical practice are applied

Non-interventional study (NIS)

A clinical study other than a clinical trial.

Why having a NIS at all?

Bundesamt für Sicherheit im Gesundheitswesen
BASG

- The purpose for excluding these studies from the scope of the Regulation (EU) 536/2014 is that these studies are **typically considered to have no or negligible risk.**

- It should be ensured that medical activities which are **normal clinical practice** and, as such, **part of the general medical surveillance of a patient,** are excluded from the scope of the Regulation (EU) No 536/2014.

In Austria we use the picture of „Looking over the doctor‘s shoulder and taking notes…“

Why is the definition important?

Bundesamt für Sicherheit im Gesundheitswesen
BASG

- According to Article 1 of the CTR, non-interventional studies are excluded from the scope of the CTR
  → **to be regulated in National law**

- The question if a submitted study falls under the CTR needs to be answered during validation (10 days)
  → **clear rules are required that do not require full assessment of the protocol**

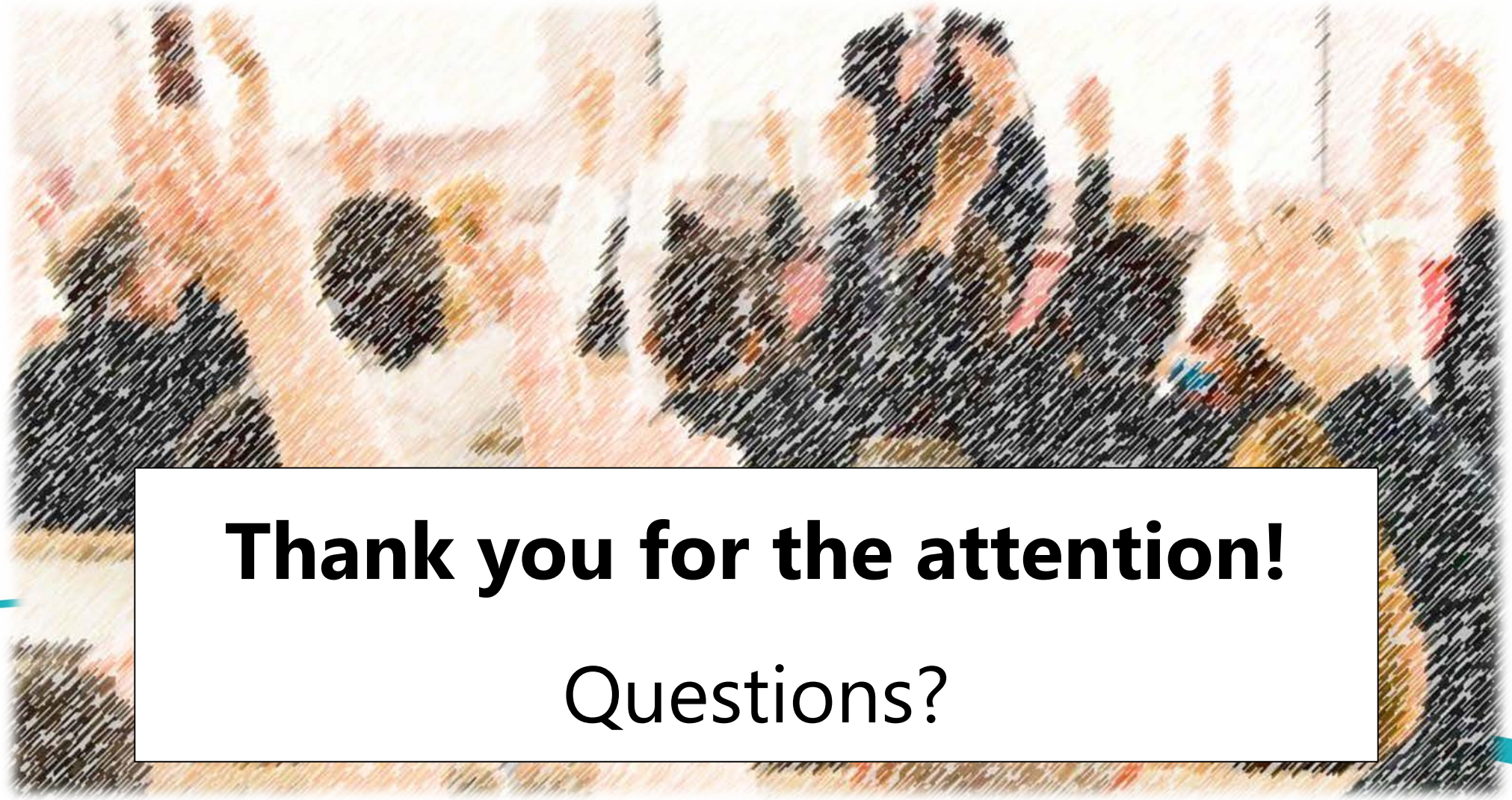
- „Clinical trial or not" is **one of the most frequent questions** in general queries to the Austrian NCA. With changed definitions this number will increase.

Decision criteria

Bundesamt für Sicherheit im Gesundheitswesen
BASG

Criteria for NIS	Examples?
The assignment of the subject to a particular therapeutic strategy is **NOT DECIDED IN ADVANCE**	- no randomisation - no artificial groups
The therapeutic strategy **DOES FALL WITHIN NORMAL CLINICAL PRACTICE** of the Member State concerned	- no products without marketing authorisation - no administration to healthy volunteers or without indication
The **DECISION TO PRESCRIBE** the investigational medicinal products is **NOT TAKEN TOGETHER WITH THE DECISION TO INCLUDE** the subject in the clinical study	- prescription should happen before inclusion - no randomisation - no blinding
NO DIAGNOSTIC OR MONITORING PROCEDURES IN ADDITION TO NORMAL CLINICAL PRACTICE are applied to the subjects	- no additional or more frequent sampling - *no research parameters that are not part of clinical practice (Austria)*

Bundesamt für Sicherheit im Gesundheitswesen
BASG



Thank you for the attention!

Questions?

Austrian
Federal Office for
Safety in Health Care

BASG

Stefan Strasser, MD

Head of Clinical Trials

BASG -
Austrian Federal Office for Safety in Health Care

Traisengasse 5
1200 Vienna

stefan.strasser@ages.at

www.basg.gv.at