Federal Institute
for Drugs
and Medical Devices

Early Phase Trials under the EU Clinical Trial Regulation – What changes in the interaction between competent authorities and ethics committees?
- Situation in Germany -

Thomas Sudhop (BfArM)

Federal Ministry
of Health

Federal Institute
for Drugs
and Medical Devices

Paul-Ehrlich-Institut

ROBERT KOCH INSTITUT

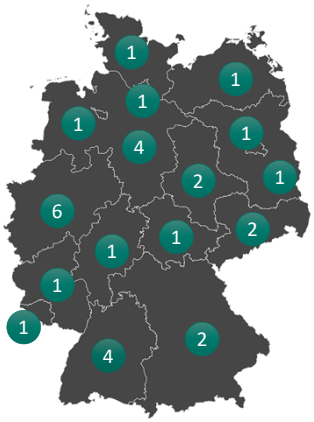
BZgA
Federal Centre
for
Health Education

As independent higher federal authority the BfArM is part of the portfolio of the Federal Ministry of Health.

Legal Situation in Germany since 31 January 2022

- CTR applicable
- Two NCAs for CTA authorisation (BfArM, PEI)
  - National Contact Point according Art. 83 (1): BfArM (ctr@bfarm.de)
- 30 local authorities in 16 federal states (”Länder”)
- 37 registered ethics committees (EC) at medical faculties and state medical associations

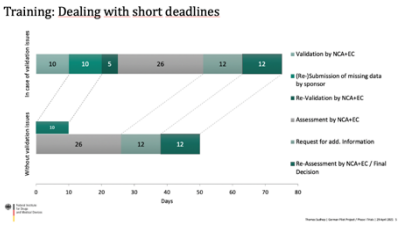
- German Medicines Act (AMG) amended on 27 January 2022
  - to comply with CTR
  - to regulate the aspects that the CTR has left to the Member States (MS), i.e. informed consent in incapable subjects, damage comp.
  - to establish collaboration between ethics committees (EC) and NCAs (additional Ordinance)
  - to regulate competence between NCAs and local authorities
  - to establish standards and processes for ECs registration at BfArM
  - ...



Number of local authorities per federal state

Federal Institute for Drugs and Medical Devices

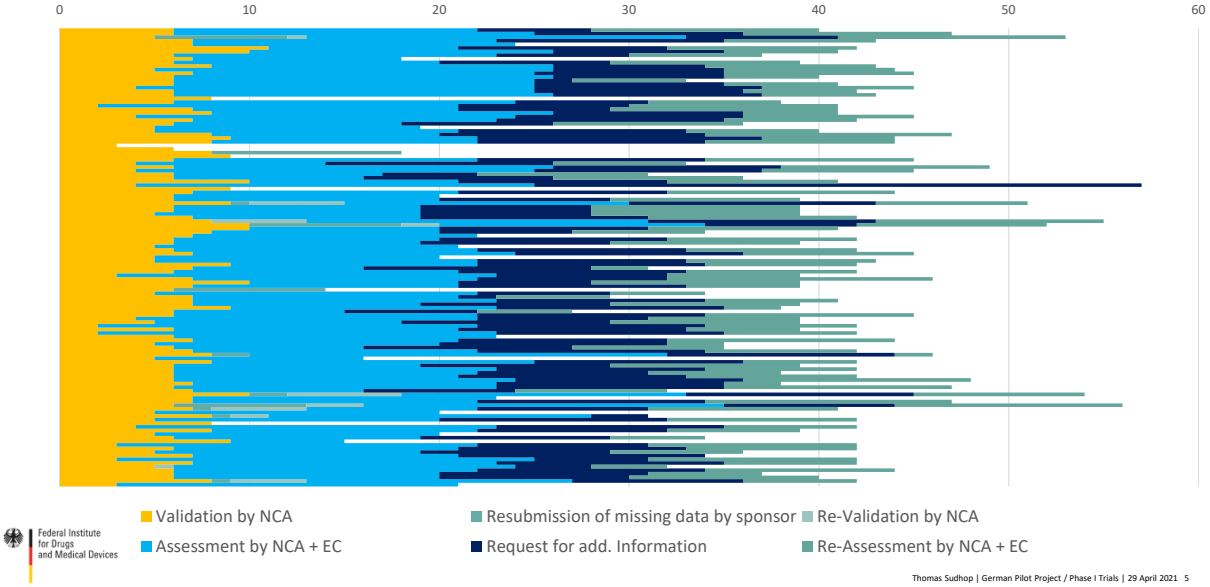
Pilot project: National training on cooperation betweeen NCA and EC



- Launched in 2015
- Only open for mono-national CTAs
- 36 of 50 Ethics Committees took part
- To take part in the Pilot Project the sponsor had to choose a principle investigator in the competence of one of the 36 participating ECs
- Only 5 ECs received more than 5 CTAs in over 150 CTAs
- Participating NCAs: BfArM (PEI)

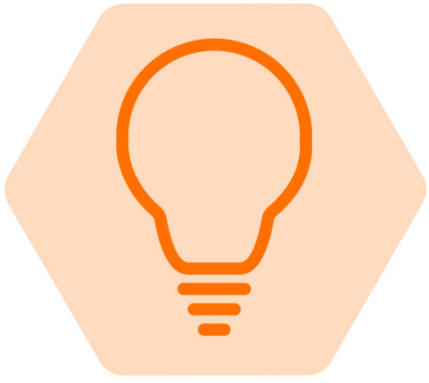
Federal Institute for Drugs and Medical Devices

Duration & Deadline Compliance



Federal Institute for Drugs and Medical Devices

Procedure for CTA EC assignment / Scientific advise



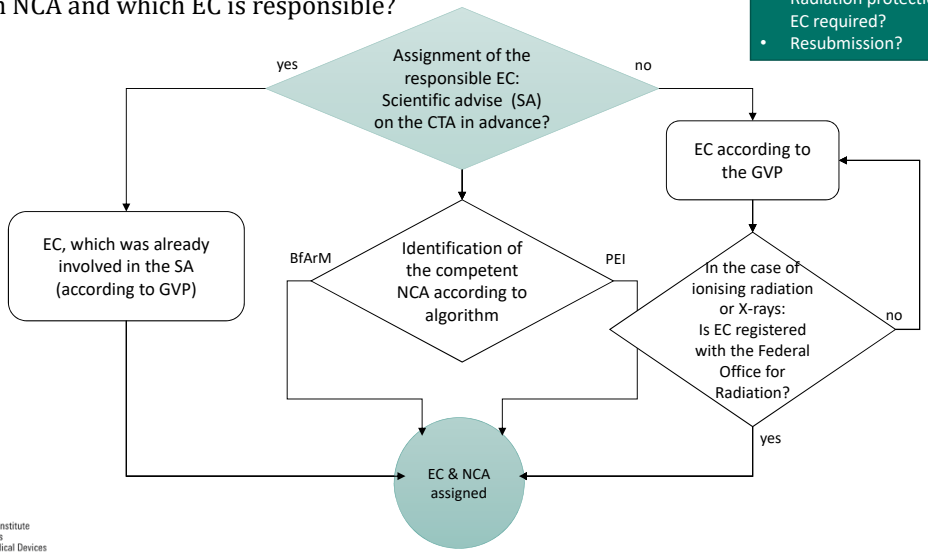
- Only one EC is responsible for a CTA (and its subsequent procedures)
  - Part II of the CTA is solely assessed by the EC
  - Part I is assessed jointly by NCA and EC
- The responsible EC is selected by the „schedule of responsibilities for registered ethics committees“ (schedule of business, GVP)
- The GVP is updated at least once a year and published on the internet
- In case of a scientific advise procedure in advance of a CTA submission which requires a joint advise by the competent NCA and the EC the next EC to take its turn is selected according to the GVP.
- This EC remains responsible for the subsequent assessment of the CTA, its substantial modifications, safety assessment and other CTA related procedures jointly with the competent NCA

Federal Institute for Drugs and Medical Devices

Hour „0“ of a CTA

Which NCA and which EC is responsible?

Must be stated in the cover letter:
- Previous joint scientific advise with NCA and EC
- Radiation protection assessment by EC required?
- Resubmission?



Federal Institute for Drugs and Medical Devices

Qualification and independence of CTA reviewers

Qualification requirements for EC members are laid down in Section 41a of the German Medicines Act and are part of the registration requirements for ECs

- Up-to-date scientific expertise of the members as well as that of external experts
- Interdisciplinary composition of the ethics committee (aiming for gender parity) with the participation of at least
  - **1 jurist**
  - **1 person** with scientific or professional experience in the field of **ethics in medicine**
  - **1 person** with experience in the field of **experimental design and statistics**
  - **3 physicians** with experience in **clinical medicine**, including **one specialist** in **clinical pharmacology** or in pharmacology and toxicology
  - **1 layperson**
- Written rules of procedure
- Managing office with the necessary qualified personnel to organise the tasks incumbent on the ethics committee
- Material resources, that make it possible to conduct voting procedures on **short notice** and **to draw up statements and assessment reports on time**
- For each application, the EC obtains DOIs from the participating members and external experts

Federal Institute for Drugs and Medical Devices