Member State support for sponsor preparedness and adoption

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15JUNE2021

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Introduction

Maria Elgaard, Special adviser in the CT unit at the Danish Medicines Agency (DKMA)

CTIS project since 2016

- Governance
- MS PO
- MS Master trainer

DKMA

- Former CT assessor
- CTR implementation
- IT solutions for CT

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Member State support

Information

Assistance/advice

SPONSORS

Local activities

Best practices

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Information

- EU- Commissions guidelines: Eudralex volume 10
  - Q&A document on the Clinical Trials Regulation
  - Risk proportionate approaches in clinical trials (April 2017)

Best practices

Clinical Trial Facilitation and Coordination Group (**CTFG**): Promoting harmonisation of clinical trial assessment decisions and administrative processes across the national competent authorities (NCAs)

- Transition of Clinical Trials to Regulation (EU) No. 536/2014
- Long list of best practices in progress, new and existing guidance to be adapted

Assistance/advice

- Streamlining questions from stakeholder groups on CTIS/CTR topics - support harmonisation
- Master Trainers with sponsor knowledge
- Support the sponsor training

Local activities

- Organisational structure/set up
  - Especially ethics
- Pilots
- National IT – integration with CTIS

Examples of local activities

Denmark

Organisational set up

– New organisation of the Medicinal Research Ethic Committees (MREC) in Denmark - centralizing

– Close collaboration between national authorities in defining local procedures for timely assessments

System integration to CTIS

– Oversight and timely streamlined procedures

Communication with local stakeholders

– Website update news and QnA

– Actively promoting training/info events arranged by EMA

– Info – event/webinar in Autumn

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Key message

Keep in touch and tuned in on the various websites!

- Commission Eudralex 10
- EMA CTIS training and newsletter
- CTFG
- Local authorities' websites: DKMA: prepare for new regulation

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Thank you

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