

# 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)

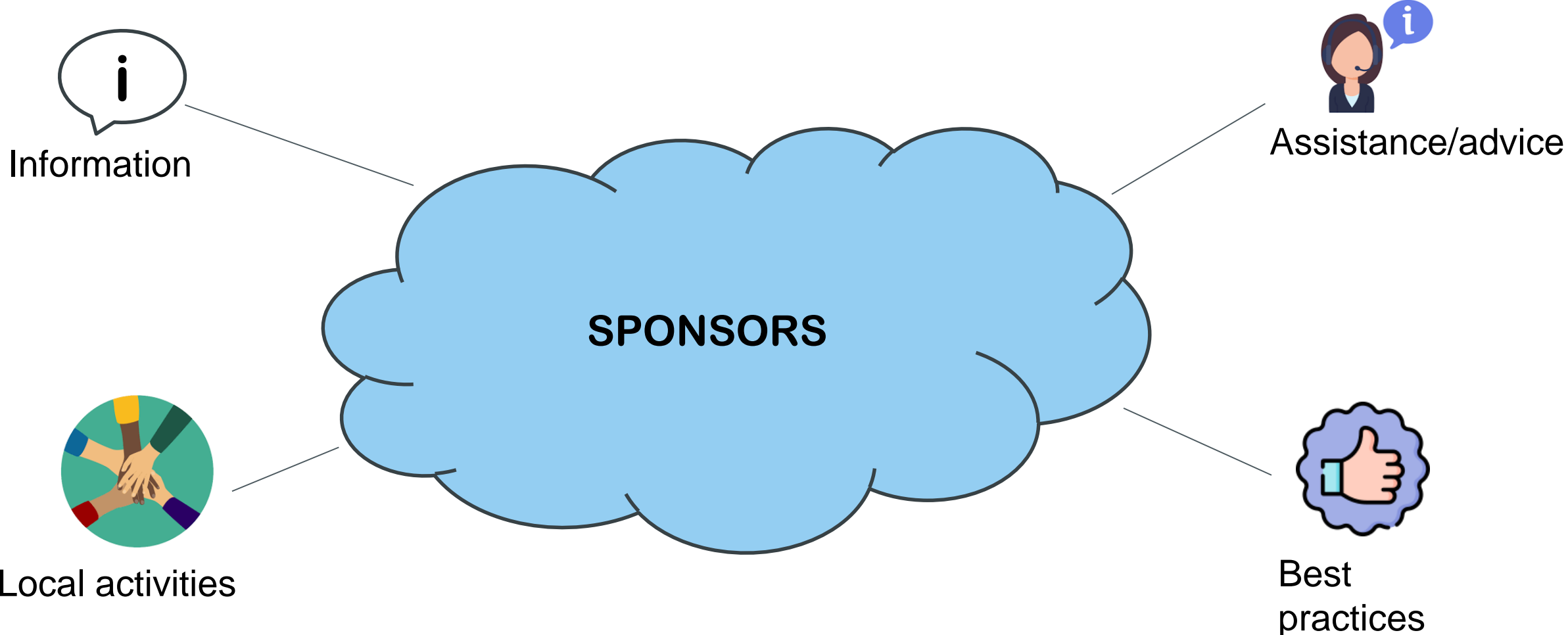
CTIS project since 2016

- Governance
- MS PO
- MS Master trainer

DKMA

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

# Member State support



## 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

# 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



# Thank you



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