

How Sponsor organisations can prepare for CTIS: Academia perspective

EMA Clinical Trials Information System (CTIS) webinar

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Introduction

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- **Head of Project Management, Coordination Centre for Clinical Trials (KKS) at the University of Heidelberg, Germany**
- **KKS Heidelberg is a member of the german KKS-Network**
- **Sponsor Product Owner CTIS, representing Academia (ECRIN)**

Academic Sponsors

- **Limited resources**
 - **Staff**
 - **Finance**
- **various organisational structures**
- **various levels of experience**
- **various levels of professionalisation**

Preparing for CTIS – Academia Perspective

Where are we?

- Still at the beginning
- Organisations are deciding on trial-centric or organisation-centric approach
- Roll-out of the decision in the organisations
- Sponsor Admin Teams are appointed
- Clinical Trial Teams in institutions, departments etc. are appointed



A lot of academic sponsor have already decided in favor of the organisation-centric approach

What are the current challenges?

- **Registration Process**

- Some Sponsors are registered under different names (Duplicates)
- What are the costs of registration?
- Possibility to bypass registration?

- **Working at european level**

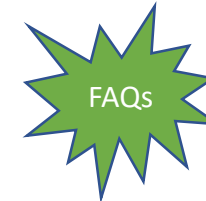
- OMS, IAM, xEVMPD → how to work with?
- Academia has to get used to a lot of new systems

What are the upcoming challenges?

- **All new workflows for management of a trial lifecycle**
- **Role management and access to CTIS**
- **Transition Period**
 - **Workload for transition**
- **Timelines**
 - **Working with industry partners and sites**
 - **Managing RFIs in short timelines**
- **Publication and Transparency**

Conclusion

- Academia is looking forward to the new regulation, but there are also many uncertainties and still a lot of questions
- CTIS enables a good oversight for academic sponsors
- Additional resources will be needed
- A lot of academic sponsors will be early adopters to avoid the additional burden of the transition
- EMA is providing very helpful training material



- A sandbox environment would help to prepare for the upcoming challenges

Thank you!