HEIDELBERG UNIVERSITY HOSPITAL

HEIDELBERG FACULTY OF MEDICINE

Preparation for the Implementation of Clinical Trials Regulation No. 536/2014 and working with CTIS

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UK HD

A lot to think about…….

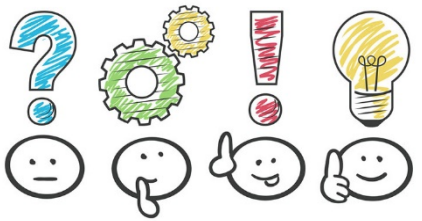
User Management

Transition Period

New processes

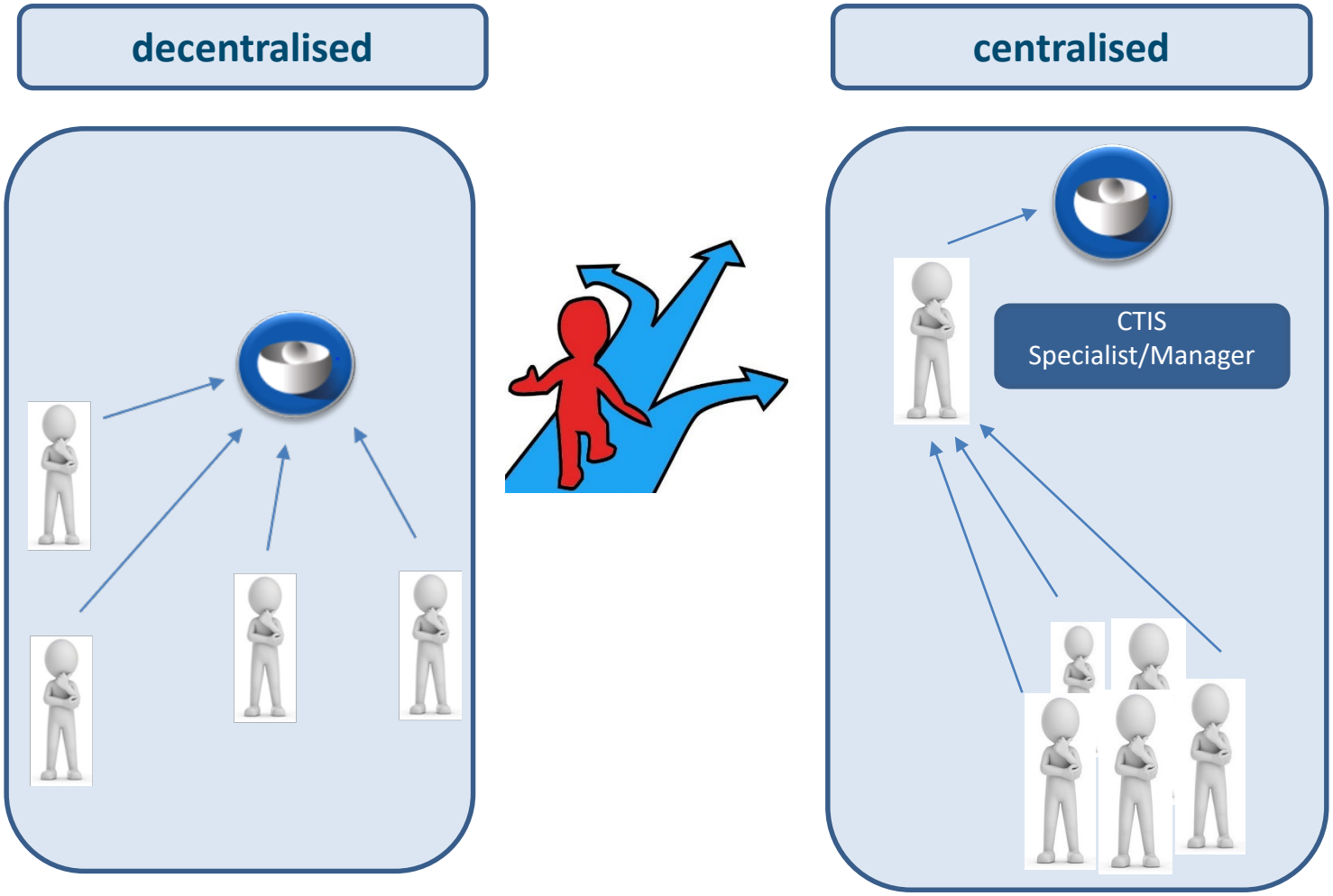
Timelines and Documents

User management



- Number of roles and role assignment need to be assessed by each organisation
- If using different roles be aware of the different role profiles (who can see and do what?)
- RFI process (can be the same one that prepares the initial CTA or a different person)
- Trial lifecycle (Submission, notifications, reporting, safety/ASR)
- Working with external partners
- Working with industry partners (use of Q-IMPD roles/cross-reference letters)
- Checking CTIS on a daily base

Who needs access to CTIS?

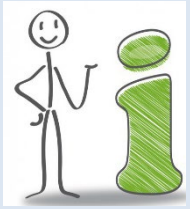


Transition Period

- Which trials will be finished until 2025?
- Which trials have to be moved to the new EU-CTR?
- Which trials can directly be submitted under the new CTR and which might be better submitted under the old Directive?
- When will we be prepared to start ?
- What is the cost impact of a transition- additional work, additional fees?
- Time Management- fixed funding periods
- Sponsor/Investigator information and discussion

  about strategy

Timelines and Documents



- Time for trial preparation will extend
- Timelines will be short

  - **all** signatures
  - complete and correct documents

- Some processes need to start earlier (e.g.DSMB charter)
- New documents (recruitment arrangements)
- Deferrals and publication of documents need to be discussed and clarified in advance

New processes

Example Serious Breach

Possible serious breach

Reporting Process

Impact Assessment

Reporting

- **Who is reporting?**
- **How to report?**
- **Who is responsible?**

- **Who is involved?**
- **Decision document-ation**

Summary

- Which roles will we use and who is responsible for user management?
- Who should get access to CTIS? Has the team the ability to handle if we centralize (manpower) ?
- Write all the new SOPs
- Change the sequences for preparation processes (e.g.DSMB)
- Define new processes like Serious Breaches
- Which documents need to be changed? Which need to be created?
- Update templates (protocol template etc.)
- Train, advise and discuss with our partners and investigators
- Try to get as much information and training as possible to be prepared

Thank you!