

Controllership of centralised data platforms, esp. clinical trials

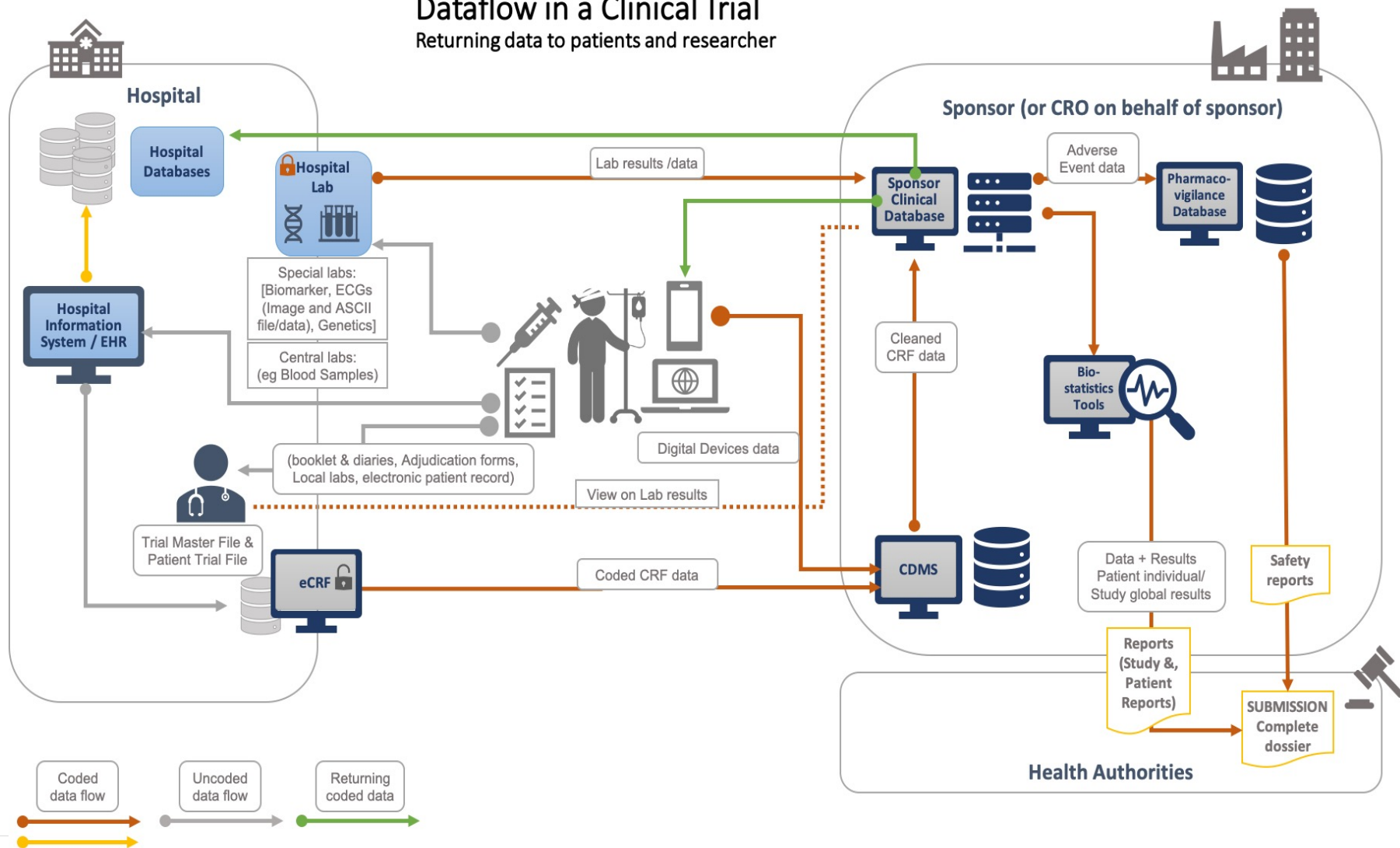
Webinar on „Joint controllers in large research consortia: what are the limits?“

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Dataflow in a Clinical Trial

Returning data to patients and researcher



The choices regarding controllership



Controller/Processor	Joint Controller	Independent Controller (Data transfer)
Art. 28 GDPR	Art. 26	Usual case
Dependent on controller's instructions Own decisions only under Art. 32 GDPR	Joint decision on equal level (mutual acceptance. i.e. veto of each partner) Each partner has own interest in processing	Independent decisions, whereas contractual obligation for data transfer remain possible, e.g. limited use of transferred data.
Purpose and means of the processing are determined by controller	Purpose and means are jointly determined	Each controller determines his own purposes and means

EDPB Guidelines 07/2020 on the concepts of controller and processor in the GDPR, Vers.01

Example: Clinical Trials

- Research data are not health care data: distinct controllership

“The collection of personal data from the medical record of the patient for the purpose of research is to be distinguished from the storage and use of the same data for the purpose of patient care, for which the health care provider remains the controller.”

- Investigator not co-drafting protocol is processor on behalf of sponsor

“In the event that the investigator does not participate to the drafting of the protocol (he just accepts the protocol already elaborated by the sponsor), and the protocol is only designed by the sponsor, the investigator should be considered as a processor and the sponsor as the controller for this clinical trial.”

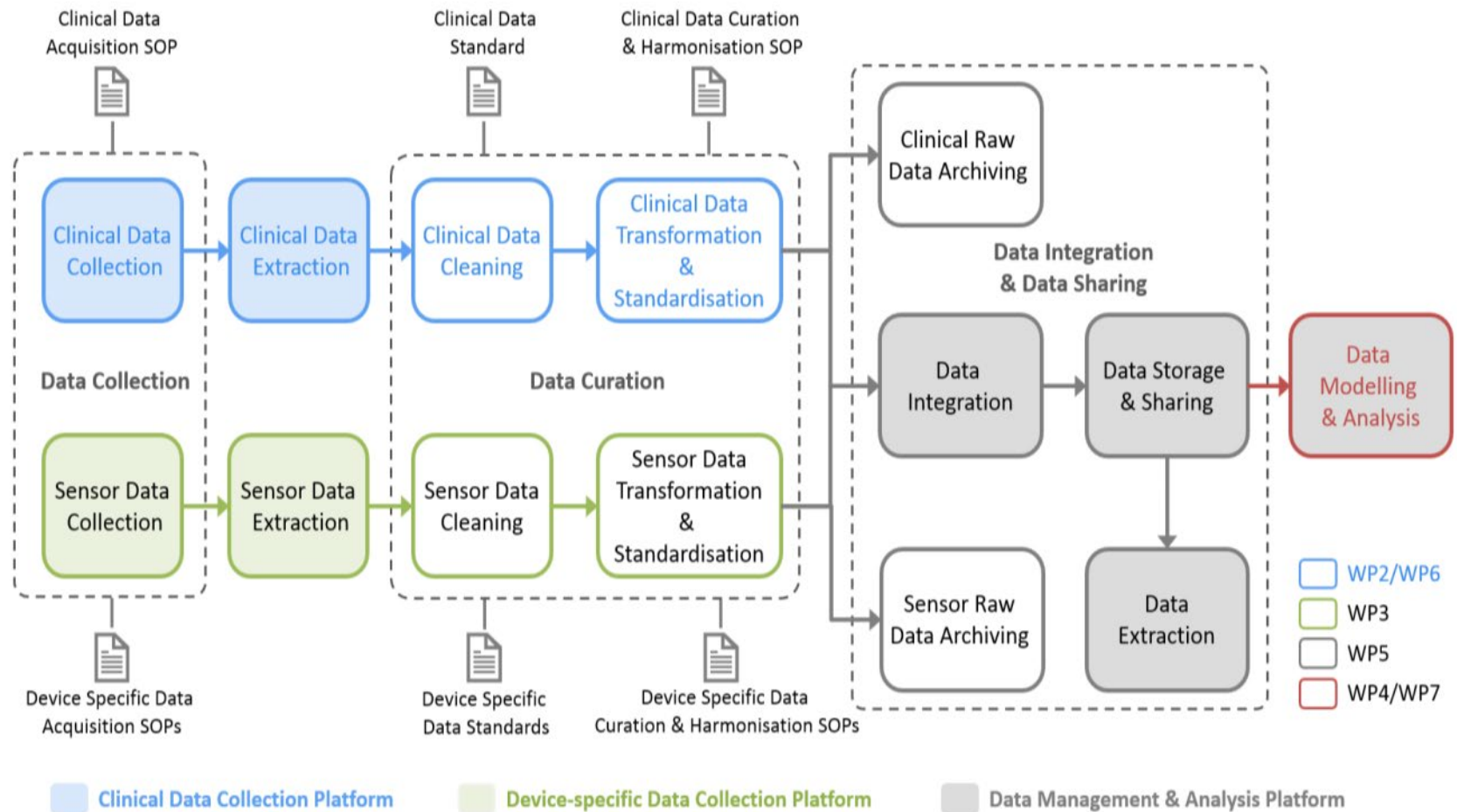
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- Drafting protocol together: joint controller

“A health care provider (the investigator) and a university (the sponsor) decide to launch together a clinical trial with the same purpose. They collaborate together to the drafting of the study protocol (i.e. purpose, methodology/design of the study, data to be collected, subject exclusion/inclusion criteria, database reuse (where relevant) etc.). They may be considered as joint controllers, for this clinical trial as they jointly determine and agree on the same purpose and the essential means of the processing.”

- What if many investigators collaborate with many university as it is usual in large research consortia?
- What about those partners who are neither investigators nor sponsors?

Data flow in IDEA-FAST



Different roles in platform building consortia

- Data Provider
 - e.g. health care provider, medical device vendor
- Data (platform) manager
- Platform hosters (cloud)
- Techies: platform builders, tool/code providers
- Consultants (legal/ethical/interoperability etc.)
- Platform users (if not third parties)

Contractual implementation

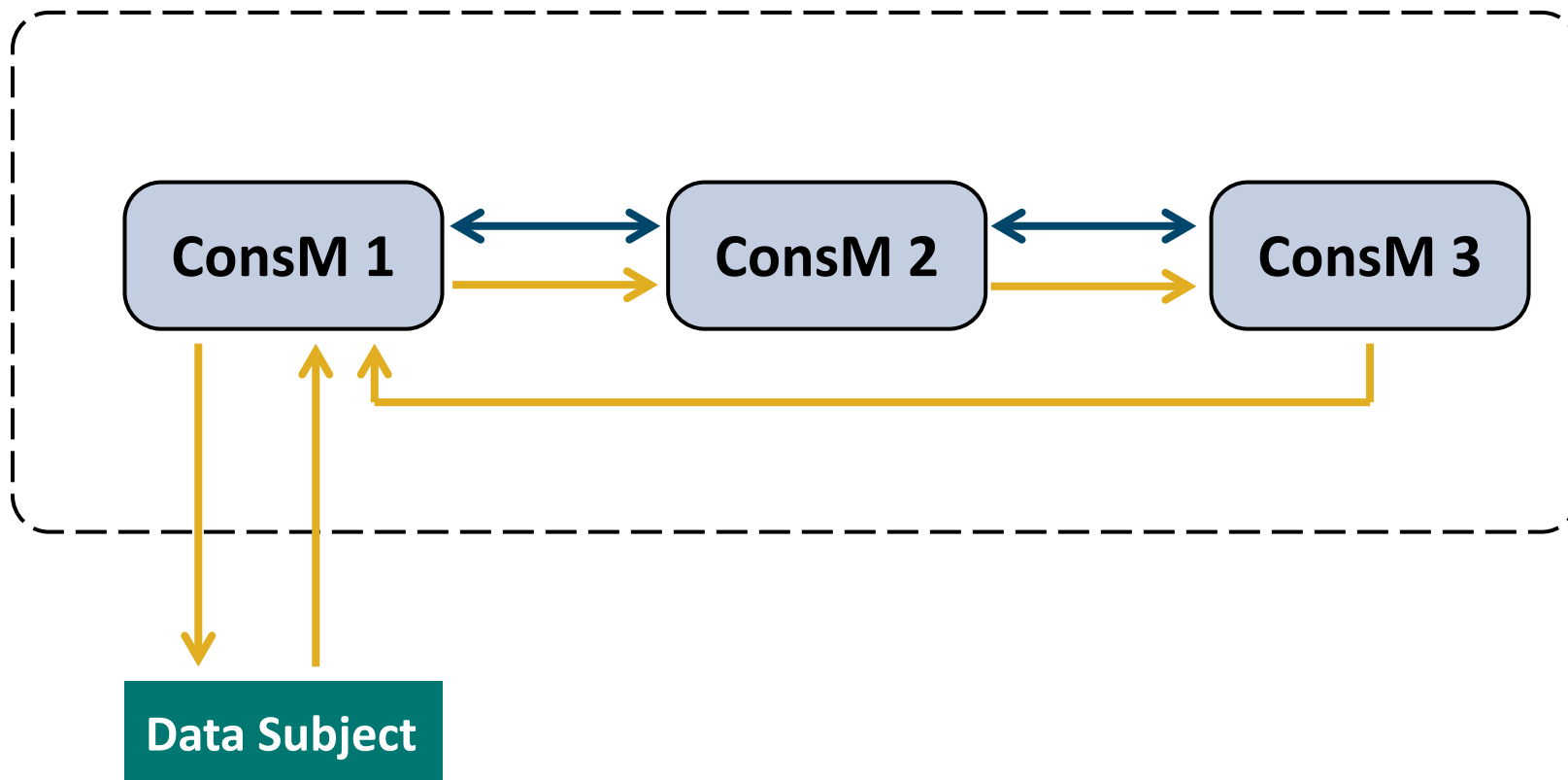
1. Controller-to-controller-agreement (data transfer: DTA)
2. Controller-to-processor-agreement
3. Joint controller agreement

Where does the Consortium agreement stand?

What are the choices in designing the agreement?

Note: the agreement has to reflect the actual data handling!

Be aware of the risks:
joint controllership = joint liability



Criteria for Joint Controllership

Joint decision about purposes and means

- ▶ Each party determines the purpose and means of the processing, e.g. the purpose of one party cannot be achieved without the purpose of the other, each controller is responsible for a certain phase of the processing
- ▶ Mutual acceptance of processing purposes
- ▶ Close relation between processing purposes, not only chain of processing

Not necessary:

- ▶ Overall control
- ▶ Equal rank of control
- ▶ Congruence of purposes
- ▶ Sharing of costs

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