What do EU hospitals need to comply with GDPR in medical studies?

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Disclosure

Speaker name: **Jürgen Bühse**

I have the following potential conflicts of interest to report:

- [ ] Consulting
- [ ] Employment in industry
- [ ] Stockholder of a healthcare company
- [ ] Owner of a healthcare company
- [ ] Other(s)

☐ I do not have any potential conflict of interest
Typical contractual situation before GDPR concerning data protection

One declaration of consent including various declarations concerning data protection
Privacy related communication relationships in the context of medical studies

- PAT: Patient
- GP: General Practitioner
- SP: Specialist Practitioner
- EMP: Employee
- Sponsor
- Rep: Representative
- Mon: Monitor

Data flow:
- Data for medical treatment
- Patient data
- Employee data

Graphical representation of communication flows between different stakeholders in medical studies.
Typical contractual situation after GDPR concerning data protection
minimum contractual requirements

DECLARATION OF CONSENT AND PRIVACY POLICY

- between patients and clinics
- between patients and partner institutions (university)
- between patients and sponsors
- between clinic employees and their employer
- between employees of the clinic and partner institute
- between employees of the clinic and sponsors
Minimum contractual requirements

Sufficient contractual guarantees
- Any institution that forwards patient- or employee data must receive from the recipient of the data sufficient contractual guarantees for the security of the data and the maintenance of the rights of the persons concerned.

Ensurance of compliance
- For all data recipients outside the EU, the data recipients must ensure the compliance with the EU Standard Contract clauses (Set II).
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