GDPR – the view of the Ethics Committee

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genae
Disclosure

Speaker name:

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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: co-founder of genae

☐ I do not have any potential conflict of interest
Medical data

Data leaks always will exist...

NEWS

270,000 patient records breached in Med Associates hack
by Jessica Davis | June 20, 2018

The healthcare billing claims vendor discovered a hacker accessed an employee workstation on March 22.

NEWS

California medical device manufacturer reports breach of 30,000 consumers
by Jessica Davis | April 17, 2018

NEWS

Patient data exposed for months after phishing attack on Sunspire
July 18, 2018

A victim to a targeted phishing attack may have exposed sensitive patient data.
Personal data

However lots of data is shared voluntarily...
Personal data

However lots of data is shared voluntarily...
Clinical trial data

Source: clinicaltrials.gov; active studies
Clinical trial data

Source: clinicaltrials.gov; active medical device studies
GDPR & clinical trials

Researchers use anonymized patient data wherever possible, however most of the time coded

**Anonymized** versus **pseudonymized**

- No identifiable information
- Coded information
Clinical research & GDPR challenges

- Clinical research more data intensive than ever
- Additional data sources: wearables, biobanking, genomics, direct EHR access
Clinical trials & GDPR: self evident?

1. Processing should be lawful, fair and transparent to the data subject (lawfulness, fairness and transparency)

2. Collection for specified, explicit and legitimate purposes and not processed in a manner that is incompatible with those purposes (purpose limitation)

3. Data should be adequate, relevant and limited to what is necessary for the processing purpose (data minimization)
Clinical trials & GDPR: self evident?

4. Data should be accurate, kept up to date and inaccurate data should be erased or rectified without delay (accuracy)

5. Data should be kept for no longer than necessary to fulfil the purpose, with some exceptions for archiving and research (storage limitation)

6. Data should be kept secure and protected against accidental or illegal loss or access (integrity and confidentiality)
GDPR changes to study documents

- Contracts between research organizations, investigators and third parties
  Primary and future use described in detail
- Protocols should include sections on GDPR compliant data storage and handling
  Timing of pseudonymization, archiving
- Informed consent documents
  Describing why limitation of GDPR rights
- Future/secondary use of data and/or samples
  Publication and consultation
Informed consent

- The responsible person for the data processing is to be named
- The name and contact details of the Data Protection Officer are to be added
- Subjects are to be informed that they can object to the usage of their data at the local/country data protection agency
- Subjects are to be informed that they have the right to know what’s collected and can request a deletion/change

Based on the recommendation from the German Arbeitskreis medizinischer Ethik-Kommissionen
Summary

Be specific about the GDPR in your study documents
Name the people responsible for the collection and processing the data
Verify with the applicable Ethical Committee(s) on their expectations/template documents
Ensure all named parties are aware...
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