

GDPR – the view of the Ethics Committee

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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
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- 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

Patient data exposed for months after phishing attack on Sunspire

July 18, 2018

Victim to a targeted phishing attack may have exposed sensitive patient data, including Social



NEWS

California medical device manufacturer reports breach of 30,000 consumers

by [Jessica Davis](#) | April 17, 2018

Personal data

However lots of data is shared voluntarily...



Personal data

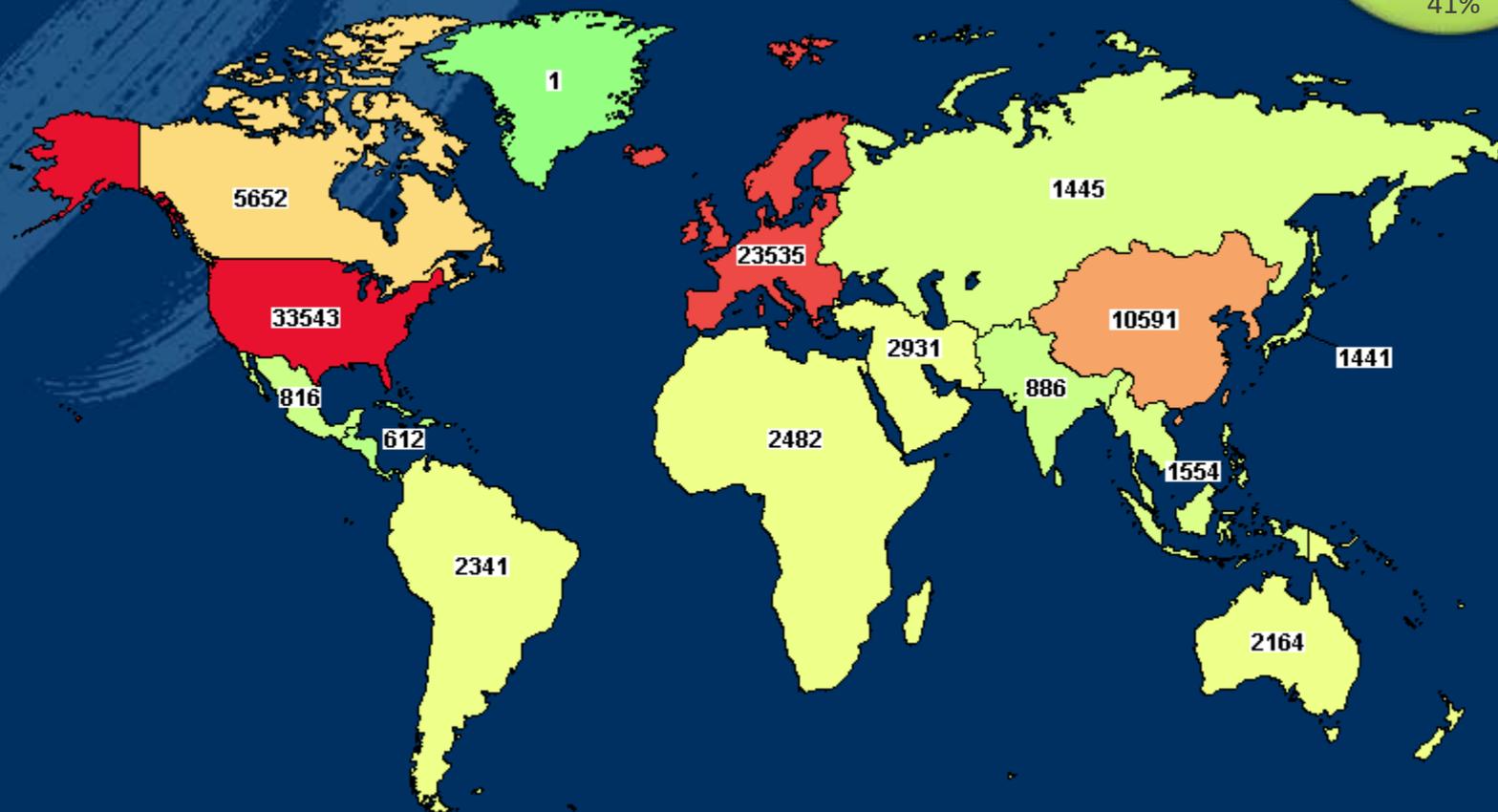
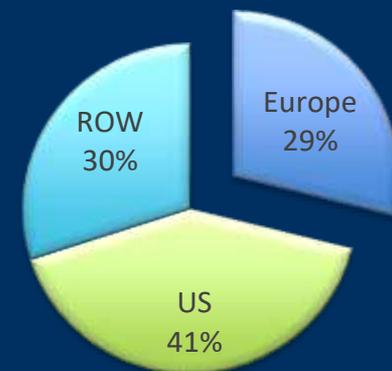
However lots of data is shared voluntarily...

A screenshot of a Facebook post and its associated hashtag data. The post is from a user whose name and profile picture are redacted with blue bars. The post text is "#ImSick" followed by a sad face emoji. Below the post are three reaction icons: a thumbs up, a sad face, and a shocked face. To the right of the post is a list of three hashtags with their respective post counts:

- #sick: 10,782,741 posts
- #sick 🤒: 219,366 posts
- #sickday: 816,823 posts

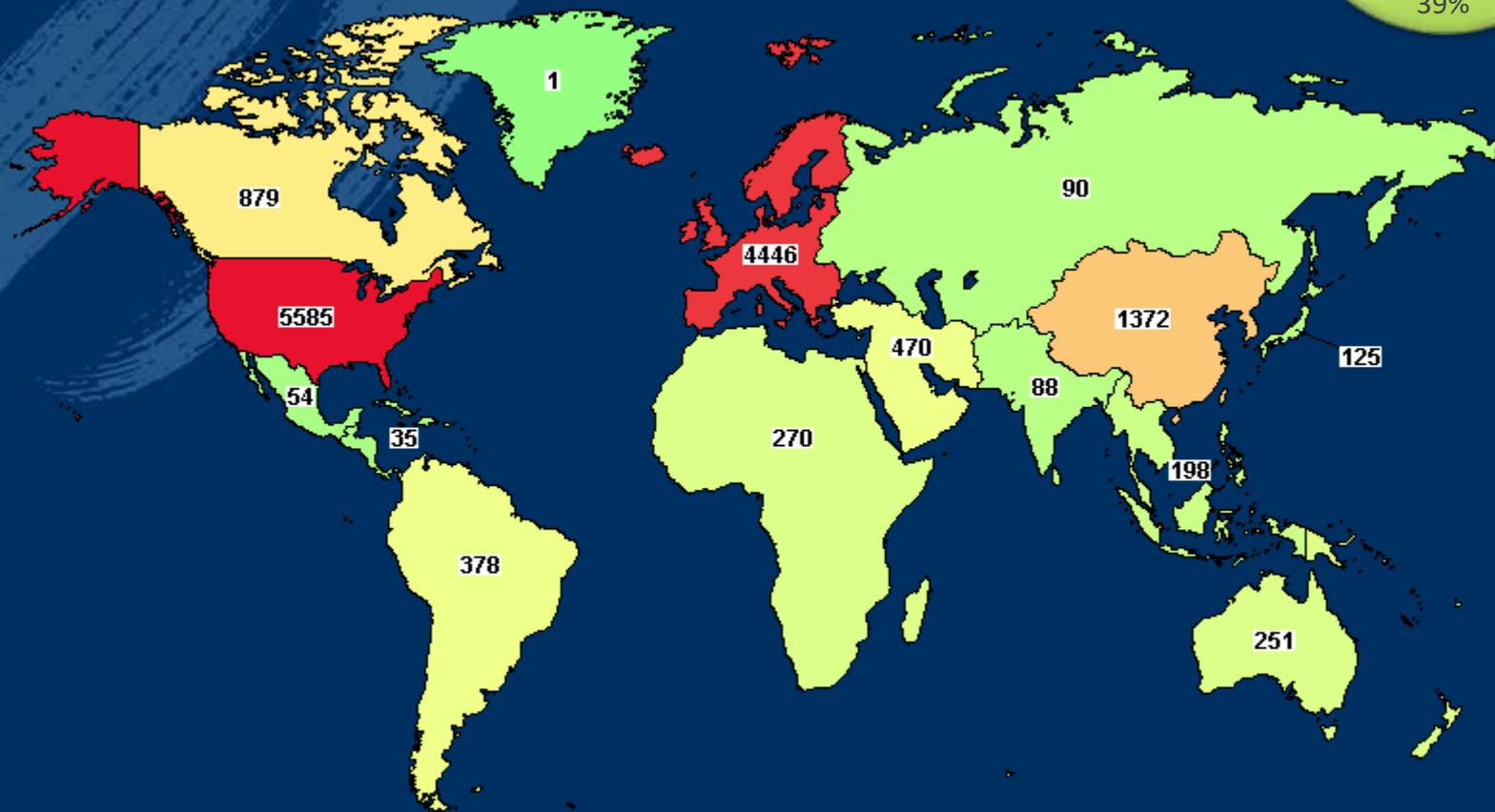
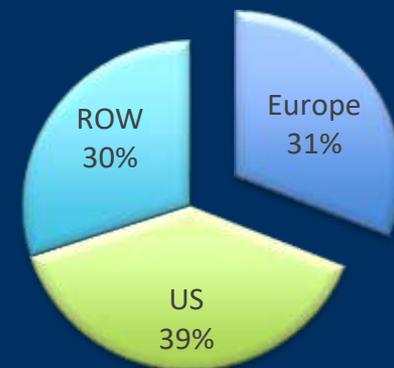
Hashtag	Number of Posts
#sick	10,782,741
#sick 🤒	219,366
#sickday	816,823

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

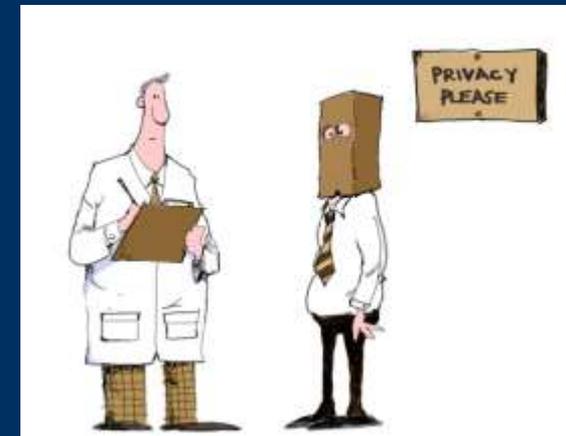
Summary

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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