



COMITÉ PERMANENT DES MÉDECINS EUROPÉENS  
STANDING COMMITTEE OF EUROPEAN DOCTORS



# Handling health data in the context of medical research



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# Introducing CPME

- CPME represents national medical associations across Europe. We are committed to contributing the medical profession's point of view to EU institutions and European policy-making through proactive cooperation on a wide range of health and healthcare related issues.
- CPME believes the best possible quality of health and access to healthcare should be a reality for everyone. To achieve this, CPME promotes the highest level of medical training and practice but also the provision of evidence-based, ethical and equitable healthcare services.




## Handling health data in the context of medical research: Where do we stand ?

- Priorities of the European Commission
- The EU **General Data Protection Regulation (GDPR)**, adopted in April 2016 (*Implementation date: 25 May 2018*)
- The WMA **Declaration of Taipei on Ethical Considerations Regarding Health Databases and Biobanks (DoT)**, adopted in October 2016 (*and endorsed by CPME on 8 April 2017*)
- Conclusions : potential next steps





# European Commission's Priorities



## Priorities for healthcare

- ✓ *Enabling all to benefit from telemedicine and mHealth through actions in the context of Digital Single Market*
- ✓ *Creating European infrastructure to exchange data*
  - ✓ Legal and technical arrangements for exchange
  - ✓ For European Reference Network
- ✓ *Align EU standardisation activities in ehealth*
- ✓ *Electronic patient access to health records*
- ✓ *Secondary use of health data (Big Data)*

tp 10.7.2015



## **Study on Big Data in Public Health, Telemedicine and Healthcare**

Final Report  
December 2016



# The EU General Data Protection Regulation (GDPR)

Key data protection principles under the GDPR:

- **Purpose limitation:** data should only be collected for legitimate and defined purposes and not further processed in a manner that is incompatible with those purposes;
- **Data minimisation:** data collection should be limited to what is directly relevant and necessary to accomplish the specified purpose(s);
- **Privacy by design:** privacy and data protection compliance must be integrated from the start into the design specifications of technologies;
- **Privacy by default:** measures must be taken to ensure that data are not accessible to an indefinite number of persons without the individual's intervention.



# The GDPR

- Nevertheless, the GDPR introduces a **research privilege**:
  - **“Article 5 - Principles relating to processing of personal data**
    1. Personal data shall be:
      - (b) collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes; **further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes shall, in accordance with Article 89(1), not be considered to be incompatible with the initial purposes** (‘purpose limitation’); (...).”



# The GDPR

- Notion of **broad consent** in the context of scientific research:
  - *(Recital)* “(33). It is often not possible to fully identify the purpose of personal data processing for scientific research purposes at the time of data collection. Therefore, data subjects **should be allowed to give their consent to certain areas of scientific research when in keeping with recognised ethical standards for scientific research.** Data subjects should have the opportunity to give their consent only to certain areas of research or parts of research projects to the extent allowed by the intended purpose.”



# The GDPR

- Member States will play an **important role** in the implementation of these provisions:
  - *(Recital)* “(156). The processing of personal data for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes should be subject to appropriate safeguards for the rights and freedoms of the data subject pursuant to this Regulation. (...) **Member States should provide for appropriate safeguards for the processing of personal data for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes.**”





# The GDPR

- **Self-regulation** could be used to ensure a proper implementation of the regulation:
  - **“Article 40 - Codes of conduct**
    2. **Associations and other bodies** representing categories of controllers or processors **may prepare codes of conduct**, or amend or extend such codes, for the purpose of specifying the application of this Regulation, such as with regard to:
      - (a) fair and transparent processing;
      - (b) the legitimate interests pursued by controllers in specific contexts;
      - (c) the collection of personal data; (...)”



## The WMA Declaration of Taipei on Ethical Considerations Regarding Health Databases and Biobanks (DoT)

- The Declaration of Taipei is an extension of the **Declaration of Helsinki** on ethical principles for medical research involving human subjects;
- Nevertheless, the **unique features of health databases and biobanks** justified the need for specific guidelines;
- While keeping the **principle of ‘informed consent’**, it is recognised that, in some cases, it can be difficult to obtain it;
  - Need for a practical solution in those cases
- If medical research is often not the problem, the re-use of health data for commercial purposes might fall under the terminology of ‘research’ (**problem of delineation**).



# The DoT

- While the use of Big Data presents many opportunities, it also raises new challenges.
- The DoT provides a practical solution to respond to these new challenges by introducing a three-step mechanism which includes:
  - **Reasoning** to start and maintain a database to be checked by an ethics committee (ethical review);
  - **Initial consent** (usually not complete when compared to informed consent) is required;
  - **Governance process** to determine if additional safeguards and/or consent is needed (ethical review by an ethics committee).



## Conclusions: potential next steps

- The **GDPR** offers a **research privilege** and enables the re-use of data for secondary purposes. As such it **does not offer strong protection** for health data, but shifts the debate on ethical standards to Member States. In this context, **self-regulation** is an option.
- The **‘consent plus governance’ solution** of the WMA Declaration of Taipei provides **complimentary safeguards** to the GDPR when it comes to the re-use of personal data for research purposes. It might therefore serve as ‘regulation’ to fill the vacuum.
  - The WMA Declaration of Taipei could be used as a starting point to develop an **EU code of conduct for the medical profession** on the **ethical use of health data for research purposes**.



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# Thank you for your attention

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