This Webinar has been organized with support from EFSPI Data Sharing working group:

Chrissie Fletcher  
Katherine Tucker  
Christoph Gerlinger  
Sally Hollis  
Rebecca Sudlow  
Janice Branson

With acknowledgements to Tony Cornelius and Julia Saperia (PSI) for their organisational support
Data Privacy aspects of Anonymization – What statisticians should know

Nicola Orlandi (Head Data Privacy Pharma)
Janice Branson (Biostatistics Head Immunolgy and Derm Unit)

Basel, 21 June, 2017
Agenda

1. Why a systematic approach to anonymization is important for pharmaceutical companies
2. Legal requirements and industry standards
3. Possible approach
Agenda

1. Why a systematic approach to anonymization is important for pharmaceuticals companies
2. Legal requirements and industry standards
3. Possible approach
A new era for the use of health data

• Secondary use of individual patient data for health research plays an increasing role in modernizing our healthcare systems, driving medicines innovation and fostering better patient outcomes.

• Pharma is accessing an unprecedented depth and breadth of clinical data. This significantly expands research potential, but also creates re-identification risks.

• Pharmaceutical companies are called to share results of analysis in a transparent manner.

• Individual and societal expectations as well as privacy regulations mandate the responsible use of personal data.

• A strong need for a systematic approach to privacy management and de-identification of health data is key in view of optimizing value of health data for scientific research and responding to the demand of transparency.
The potential of big data analysis for improving health outcomes for patients

**CLINICAL TRIALS**
Bringing innovation to patients through simpler, faster and better clinical trials

**PATIENT EXPERIENCE**
Empowering the patient through better diagnosis, treatment and access

**PROVEN OUTCOMES**
Emphasizing outcomes through ongoing data analysis and insight creation

- **Digital solutions to improve trial administration and enhance patient experience and outcomes**
- **Digital innovation and solutions to aid in patient care and to help identify and deliver on big trends**
- **Collaboration to drive continuous innovation from insights through the assessment of de-identified patient data**
Many in the healthcare sector are interested in big data analysis

Government agencies (FDA, PCORI, CMS, VA)

Payers

Accountable care organizations

Industry

Hospital systems, pharmacies

Academia, medical societies

Data utility must be preserved

CMS, Centers for Medicare and Medicaid Services; FDA, US Food and Drug Administration; PCORI, Patient-Centered Outcomes Research Institute; VA, US Department of Veteran Affairs
Increasing demand for transparency

• Regulatory decisions to authorize a drug to be placed on the market, are granted based on the results of clinical trials

• There’s an increasing demand from stakeholders for additional transparency, not only about Agency’s deliberations and actions, but also about clinical data on which regulatory decisions are based

A few past cases blaming the Pharma Industry for withholding data:

- 1999- Avandia/GSK anti diabetic drug
- 2004-Vioxx/Merck
- 2012-Tamiflu Case/Roche
A systematic approach to de-identification of data is key to unlock full value of RWE and respond to transparency expectations.

- Better results of treatments and understanding of side effects
- Targeted interventions for the better impact
- RWD will complement clinical trial data to drive medicine innovation and shape future research
- Better quality of care and increased efficiency, best practices identification, sustainable healthcare systems
- Improve accountability
- Build trust among industry and investigators
- Strengthens science literature integrity.

Individuals and society as well as privacy regulators expect us to use personal data in a responsible manner.
Agenda

1. Why a systematic approach to anonymization is important for pharmaceuticals companies

2. Legal requirements and industry standards

3. Possible approach
What is anonymization?

Anonymization is a process where all direct or indirect identifiers are removed from Personal Data so that the dataset by itself will no longer identify an individual Data Subject and is also unlikely to allow any individual Data Subject to be identified in combination with data from other sources.

If done correctly and personal data has been collected in line with applicable data protection law in the first place, the resulting data is no longer subject to data protection, it can be processed without the data subject’s consent and without regard to other data protection restrictions.
For various reasons it is hard to achieve full anonymization.

Privacy laws as well as Industry Standards recommend to adopt a sound risk based approach by acknowledging that certain identification risks may remain despite all efforts to minimize them.
Current EU approach focus on efforts necessary to re-identify a person

<table>
<thead>
<tr>
<th>«means reasonably likely to be used» (Recital 26 of the GDPR) to re-identify an individual</th>
</tr>
</thead>
</table>

- Recital 26 GDPR account should be taken of all objective factors

- Art. 29 Working Party criteria for assessing the robustness of an anonymization process

- The European Court of Justice has confirmed the «relative approach» (ECJ C.582/14)
Current CH/EU approach focus on efforts necessary to re-identify a person 2/2

Swiss law asks whether it is possible only with disproportionate efforts to re-relate the data to a particular person. If yes, data is considered anonymous, even if a theoretical possibility of re-identification remains.

One has to determine whether someone reasonably likely

- has access to information or techniques that permit the (direct or indirect) identification of the Data Subject (objective element)
- has a reasonable interest in undertaking the effort to make use of such means (subjective element)
- can relate the data at issue to the person so that it is possible to link that data to other information known or otherwise likely available on the real person (reference data test)
US Health Information Portability and Accountability Act (HIPAA)

- HIPAA provides for a very specific process to limit the ability to identify a Data Subject from a clinical dataset.
- It is based on the removal of specific identifiers (e.g., by way of redaction).
- When US clinical data is de-identified according to this process, it may be disclosed to a third party.
- De-identification requires the removal of all 18 of the identifiers listed by.

The de-identification as per the above HIPAA rules is not sufficient for Anonymization standards in the EU or in Switzerland because it does not fully address the risk of indirect identification of a Data Subject.
Industry Standards, EMA

- guidance to the pharmaceutical industry on anonymization of clinical reports, in the context of publication of clinical data (policy 0070).

- purpose of achieving adequate anonymization while retaining a maximum of scientifically useful information on medicinal products for the benefit of the public.

EMA recommends a risk-based approach. The risk of identification and re-identification needs to be very low for publications; a higher risk could be acceptable for non-public data sharing because robust governance arrangements to prevent identification can be established (EM 90915 2016). Such arrangements include, but are not limited to security, privacy and contractual controls (technical, organizational and legal measures).
Agenda

1. Why a systematic approach to anonymization is important for pharmaceuticals companies

2. Legal requirements and industry standards

3. Possible approach
Anonymization: a possible approach

**Approach**
When performing anonymization of health data for the purpose of Secondary Use, one can follow a **risk-based** and **relative approach**, in line with Swiss and EU laws and with industry standards, considering all circumstances that may result in a (re-)identification of a Data Subject.

**Techniques**
It is not necessary to mandate the use of one particular technique. When deciding which anonymization technique/s shall apply, aim for choosing the maximum degree of anonymization that is reasonably acceptable with a view to the context of Secondary Use.
Anonymization: a possible approach

<table>
<thead>
<tr>
<th>Measures to maintain anonymization</th>
</tr>
</thead>
</table>

- Purpose of mitigating the remaining risks of (re-)identification of Data Subjects to the extent reasonably possible.
- Have to be determined on a case-by-case basis taking into considerations all circumstances, such as the ongoing technical developments (e.g., new methods of big data analysis) or potential new uses of the anonymized Data.

<table>
<thead>
<tr>
<th>Data sharing agreements</th>
<th>Data protection policies and procedures</th>
<th>Control mechanisms</th>
<th>Re-evaluation assessments</th>
</tr>
</thead>
<tbody>
<tr>
<td>e.g. to oblige third party having access to data to refrain from any attempt to re-identify data, to maintain security, etc.</td>
<td>Applicable to relevant employees in order to ensure that they refrain from any attempt to re-identify</td>
<td>Such as security measures which protect the anonymized data from potential attackers</td>
<td>Perform regular re-assessments to verify whether data can still be qualified as anonymized, identify new risks and take necessary steps</td>
</tr>
</tbody>
</table>
Anonymization: a possible approach

Circumstances for consideration

- To which extent can the Personal Data at issue be anonymized.
- What are the risks of re-identification in light of the envisaged secondary use and with or without the possible anonymization measures.

- Purpose to be achieved
- Maximum secondary analysis usage time
- Sensitivity and nature of original data
- Context of personal data collection
- Envisaged release
- Recipients of anonymized data current controls
- Sample size
- Availability of public information sources

- Link to other databases
- Rare disease and small populations
- People and organization potentially interested in a re-identification
- Agreements in place with recipients
- Application of new technology
- List of all direct and quasi direct identifiers
- (...)
Anonymization: a possible approach

Roles and responsibilities

- Establishing, safeguarding, reviewing the anonymization processes for Secondary Use
- Supervise and monitor the implementation of and the compliance with the process

Process for approval

- Request
- Evaluation of request
- Decision on anonymization methodology

Documentation

- Every assessment, decision and approval shall be documented in a corresponding anonymization report
Thank you