

How does the pharmaceutical industry use patient data?



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*useMYdata workshop – Commercial uses of patient data
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Discussion points today



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- **Why is industry interested in patient data?**
 - **What are the sources of patient data?**
 - **Levels of identifiability used by the pharmaceutical industry?**
 - **How is patient data managed in the pharmaceutical industry?**
 - **Other key considerations**

Sequential process of drug development ... to date



- Long and uncertain process
- Evidence centred on randomised controlled trials
- Series of decision points and handovers

New drug development lif cycle

– iterative and distributed



- **Discovering targets and leads**
 - Not only in the lab but in real world settings
- **Evidence and evaluation**
 - Data collection and continuous assessment
 - Interventional, observational
- **Regulatory review and decision making**
 - Adaptive and more complex
- **Treatments as combinations and/or services**
 - Personalised, diagnostics and devices
 - Advanced therapies – cell and gene-based
- **Value definition**
 - Adaptive
 - More complex

Examples of issues where RWD can be used in the drug development lifecycle



How many people suffer from the condition and also have co-morbidities x and y?

What drugs are currently used in the treatment of the condition and to what extent are clinical guidelines being followed?

Given efficacy and tolerability results from the early trials, how might current treatment pathways be affected with our new drug?

How costly are the specific areas of unmet need that a drug with this target product profile might address?

In designing the Phase III trial, what are the underlying rates of adverse events we expect to see in the trial population?

Where can we modify the eligibility criteria in the Phase III protocol to reduce possible recruitment problems?

What is the likely budget impact of introducing the new drug across different patient segments?

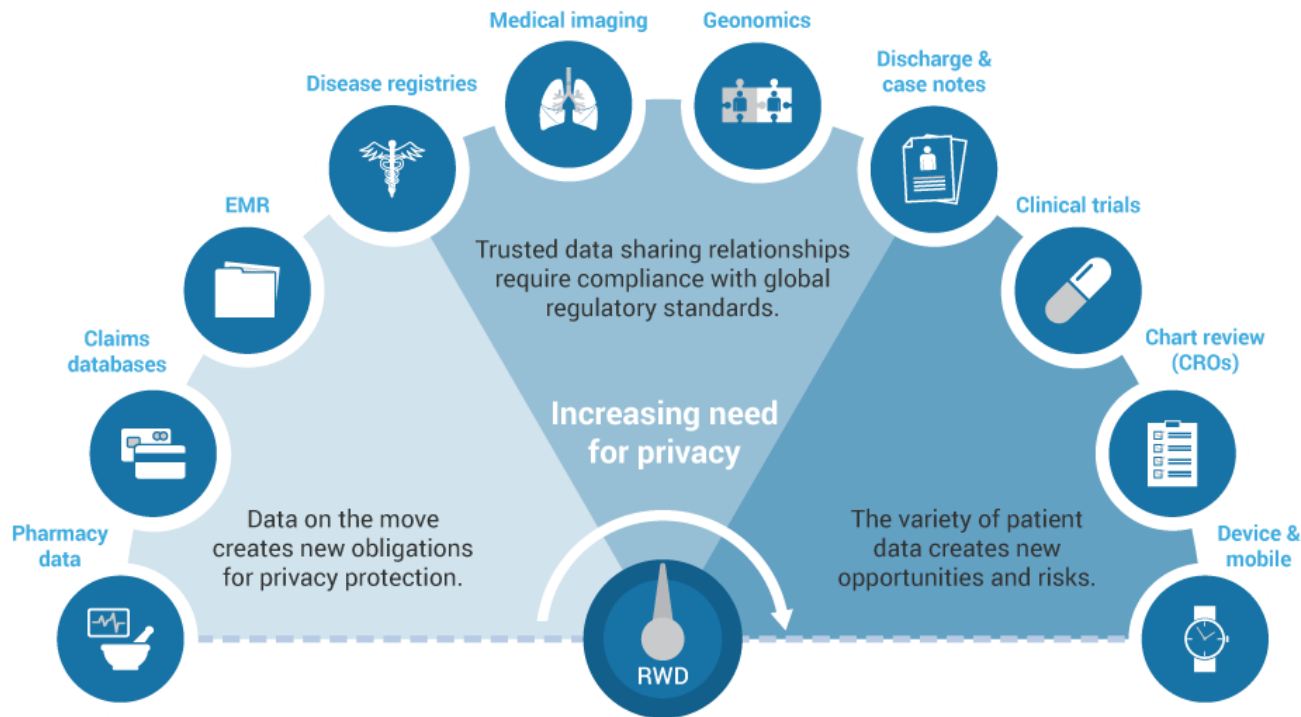
What potential safety issues do we see with the early use of the drug in practice?

How can we run a large clinical trial using electronic medical records to show the relative effectiveness of our drug?

In which patient groups are there compliance issues with the drug?

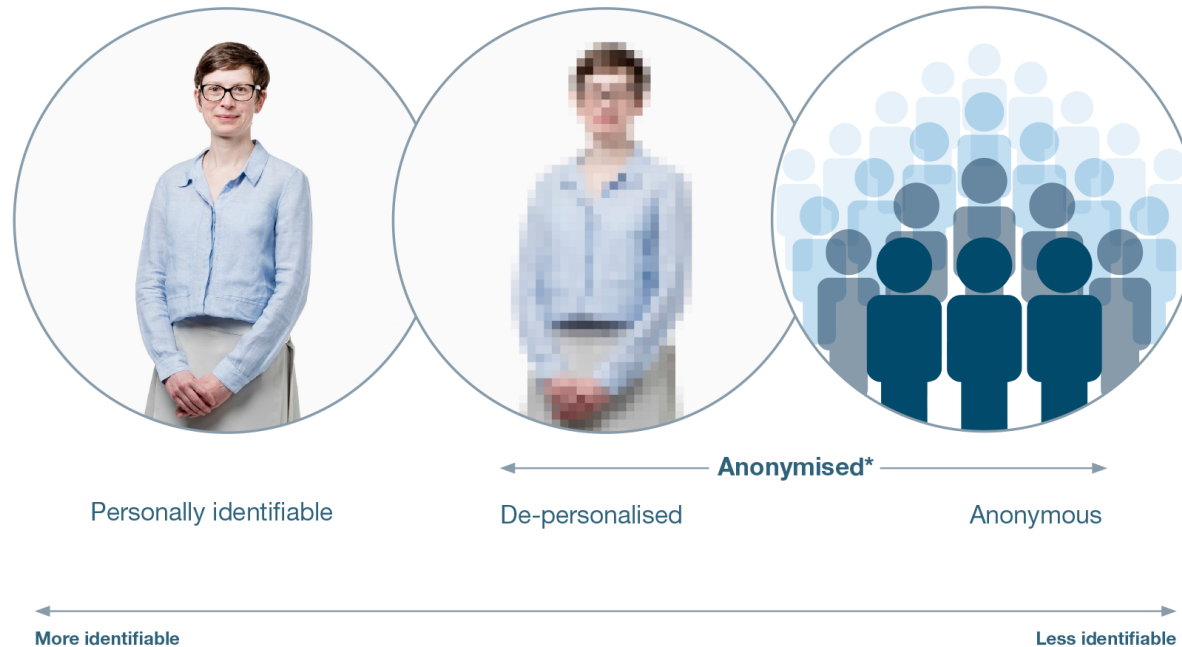
Drug Discovery Today

Sources of patient data



Levels of identifiability used in the pharmaceutical industry

Spectrum of identifiability



Anonymised*

Personally identifiable

De-personalised

Anonymous

More identifiable

Less identifiable

*anonymised in accordance with the ICO code of anonymisation

How is patient data managed in the pharmaceutical industry



- **Regulatory guidance**
 - Good Clinical Practice
- **Data management**
 - Separate and disparate databases
 - Data security
 - Risk management
- **Controlled access**
 - Who has access?
- **Key-coded patient data**
 - Separating patient identifiable information from clinical data about a patient
- **Data protection**
 - UK Data Protection Act and EU General Data Protection Regulation

Other key considerations



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- **Effective informed consent**
 - **Patient privacy**
 - Balancing patient benefits and risks
 - **ABPI Code of Practice**
 - Advertising and promotion of medicines
 - **Sharing Clinical Trial Data**
 - Controlled access, data sharing agreements
 - **Patient engagement**
 - Involve patients in the process
 - **Communication**
 - Transparency on use of patient data throughout drug development lifecycle
 - Highlight use cases to show the benefits of using patient data and how patient risk is managed

THANK YOU!

