How does the pharmaceutical industry use patient data?

Bringing medicines to *life*

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useMYdata workshop – Commercial uses of patient data
Thursday 12th October, 2017

Discussion points today

- **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**

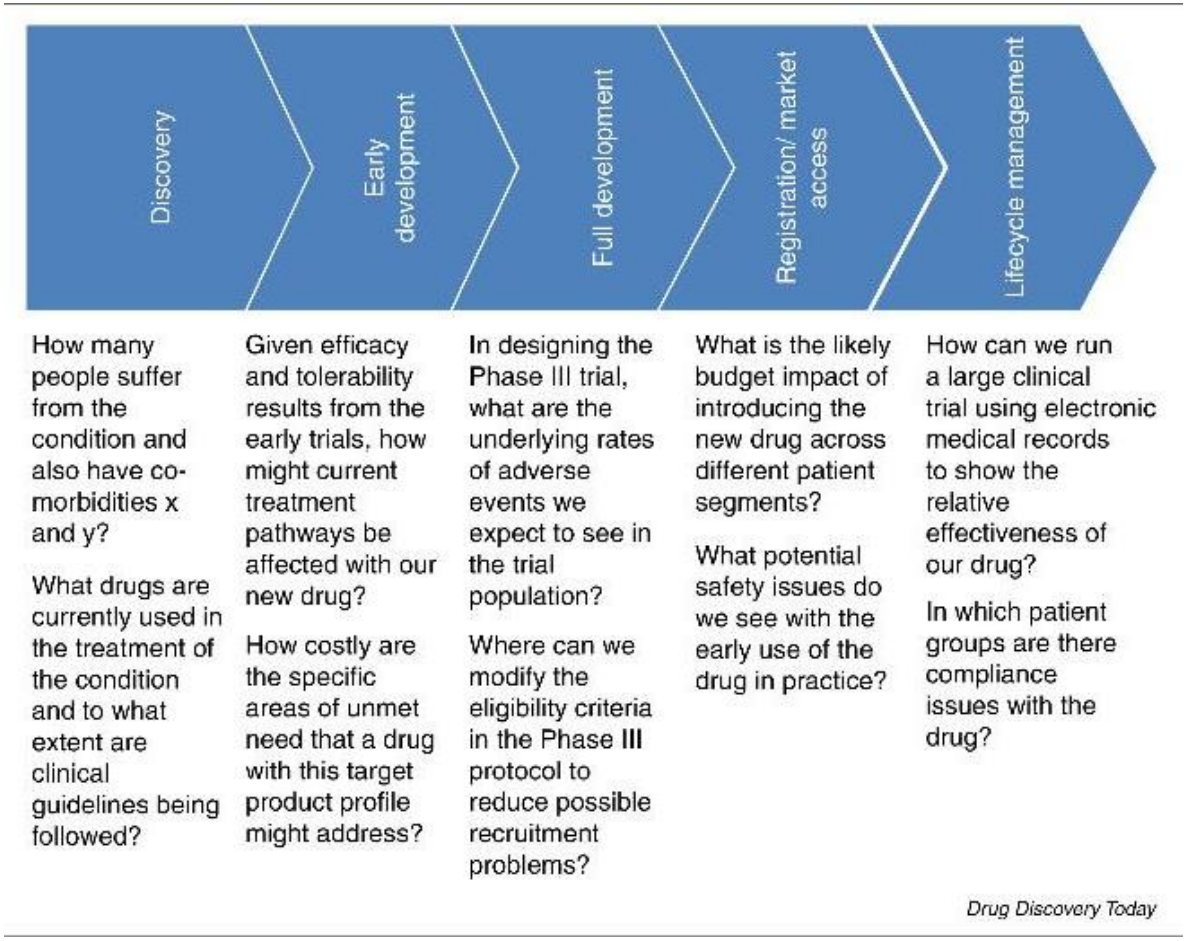
Sequential process of drug development … to date

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

New drug development lif cycle – iterative and distributed

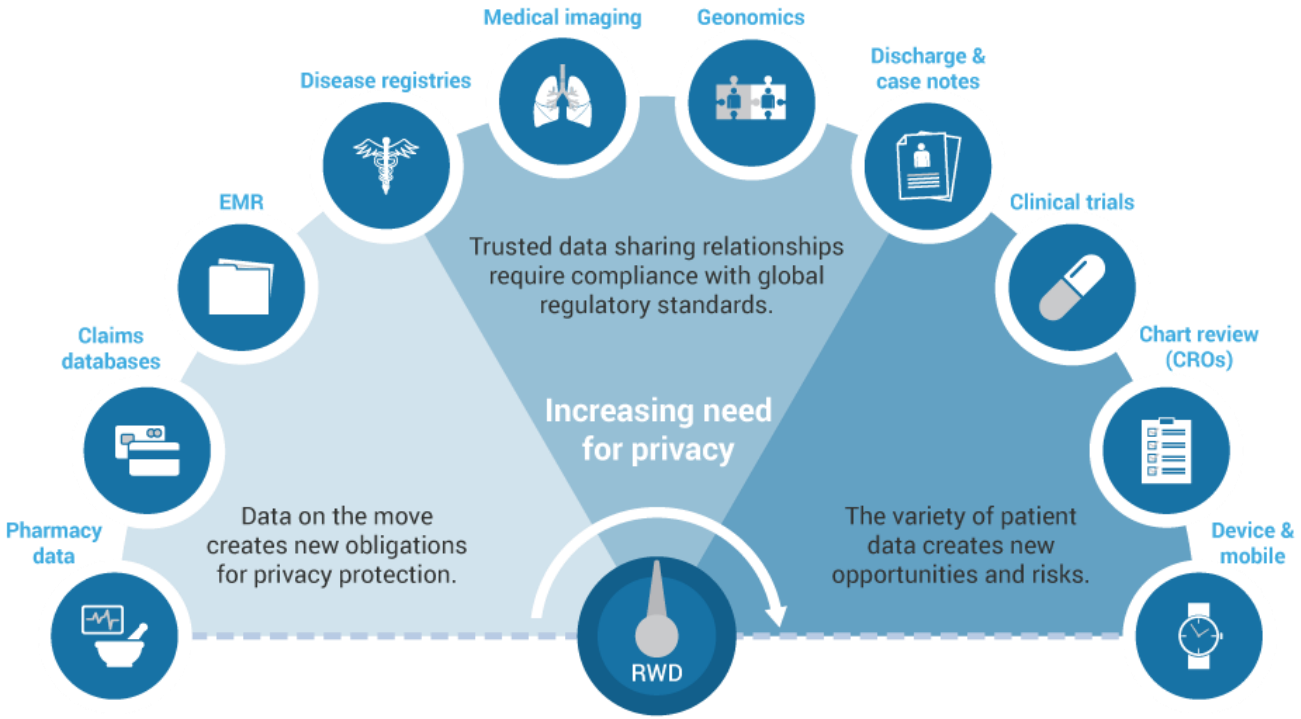
- **Discovering targets and leads**
  - Not only in the lab but in real world settings
- **Evidence and evaluation**
  - Data collection and continuous assessment
  - Interventional, observational
- **Regulatory review and decision making**
  - Adaptive and more complex
- **Treatments as combinations 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

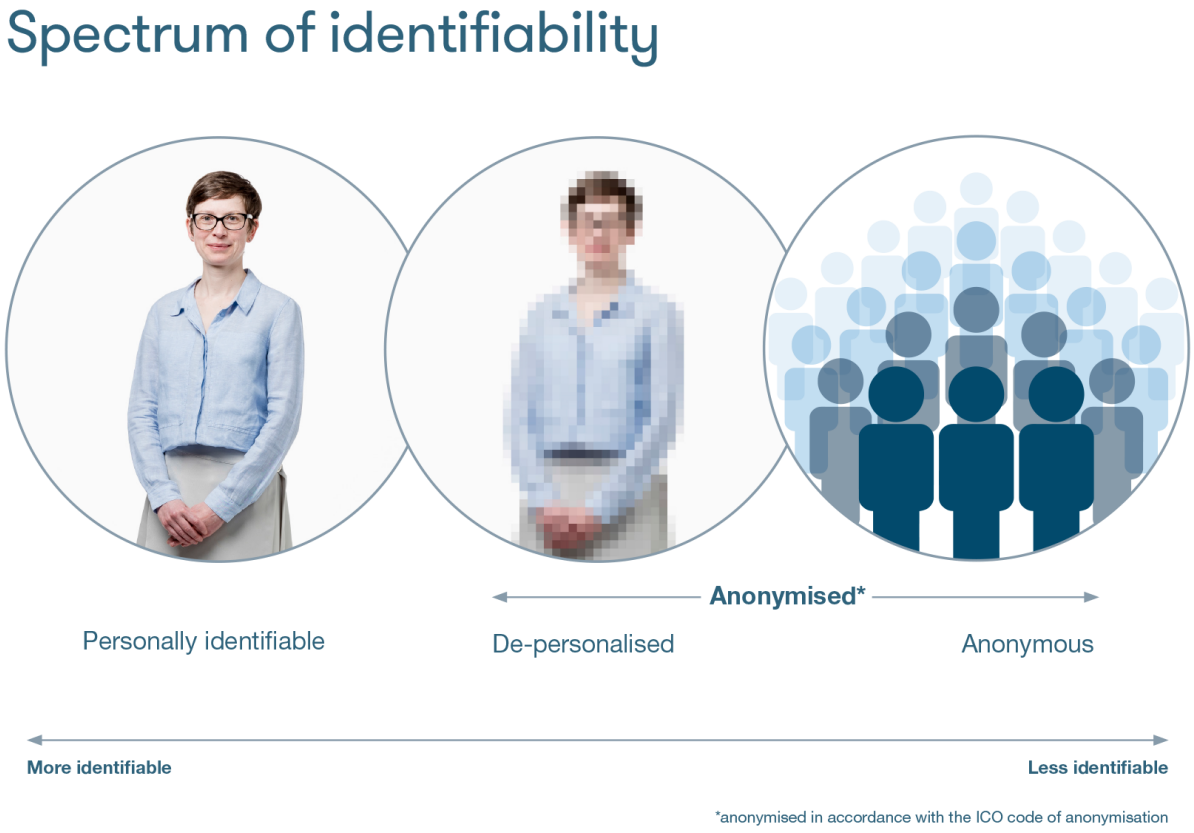


Bate et al. Designing and incorporating a Real World Data approach to international drug development and use – what the UK offers. Drug Discovery Today ,Vol 21, Issue 3, 2016, 400-405

Sources of patient data



Levels of identifiability used in the pharmaceutical industry



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

- **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!

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