DS13 - Patient Level Data Sharing in pharmaceutical companies

Sophie Buyle, 10 October 2017
Context

Process

Future requirements

How to facilitate the process?

Conclusion

Q&A
**Time line**

<table>
<thead>
<tr>
<th>May 2013</th>
<th>January 2014</th>
<th>March 2015</th>
<th>January 2017</th>
<th>After?</th>
</tr>
</thead>
<tbody>
<tr>
<td>GSK starts initiative</td>
<td>ClinicalStudyData Request.com (CSDR)</td>
<td>The Wellcome Trust took over running the independent review panel for CSDR</td>
<td>External requirements to implement</td>
<td>?</td>
</tr>
</tbody>
</table>
## Different systems

<table>
<thead>
<tr>
<th>CSDR (clinical study data request)</th>
<th>PDS (project data sphere)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Listed studies on a website open to request</td>
<td>Request via website</td>
</tr>
<tr>
<td>Gatekeeper model</td>
<td>Sharing platform</td>
</tr>
<tr>
<td>2 panels review (independent and internal)</td>
<td>Authorised user approval</td>
</tr>
</tbody>
</table>
How it works for the researcher?

- **Multi-sponsor request site**
- **Select** studies that are needed for the research
- **Submit** a research proposal
- **Review** of proposal by independent review panel
- **Agree**: when approved, a data sharing agreement is signed
- **Access** data in secure access system
  - Raw dataset, Analysis-ready dataset, Protocols with any amendments, Annotated case report form, Reporting and analysis plan, Dataset specification, Redacted Clinical Study Report including modular appendices (potentially identifiable information, including patient level data and patient narratives are redacted)
- **Register research, conduct and publish**
# Current requirements

<table>
<thead>
<tr>
<th>Study Type</th>
<th>Interventional human subject research</th>
<th>Non-interventional studies and studies using data or biological samples from previous studies</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Studies that evaluate products</td>
<td>Studies that do not evaluate products</td>
</tr>
<tr>
<td></td>
<td>Studies that evaluate products</td>
<td>Studies that do not evaluate products</td>
</tr>
<tr>
<td>Full Protocol</td>
<td>At the time of results summary posting(^a)</td>
<td>-</td>
</tr>
<tr>
<td>Statistical Analysis Plan</td>
<td>At the time of results summary posting(^a)</td>
<td>-</td>
</tr>
<tr>
<td>Regulatory package</td>
<td>Within 60 days of decision for marketing authorisation(^b)</td>
<td></td>
</tr>
<tr>
<td>Clinical study report (CSR)</td>
<td>Defined by each company at the moment</td>
<td></td>
</tr>
<tr>
<td>Patient Level Data Sharing (PLDS)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

\(^a\)FDA Final Rule, 18 Jan 2017  
\(^b\)EMA POL070, 1st Jan 2015
Redaction of PPD/CCI involves redacting (masking from view with a blue/black bar) specific content and removing certain sections of the CSR with an explanation of what has been removed and why.

Examples:
PPD: investigator CV, subject ID...
CCI: doses/composition of products...

CCI: Commercially Confidential Information
PPD: Patient Personnal Data
Anonymisation of data

- *Standards defined*

- *Data have to be de-identified so that Patient Personal Data (PPD) has been removed*

- *Anonymised datasets to be stored in a central holding repository*
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Companies

Follow requirements but can go beyond with internal guidances to proactively prepare for next steps

Journals

Some journals to require authors to agree to share the data underlying the studies they publish

EMA

- 2019, **clinical trials conducted in the EU** and paediatric trials conducted outside the EU that are part of paediatric investigation plans: All clinical trial-related information generated during the life cycle of a clinical trial to be made available on future EU portal.

- Within 30 days of decision on Marketing authorisation for clinical trials included in a marketing authorisation application in EU (EU CTR, Q4 2018)

NIH

- FDA Final Rule, 18 Jan 2017
- Expand of scope
Facilitators

- Standardised templates and databases will allow external researchers to compare results/conclusions from different trials

- Facilitate process to ensure data sharing to a maximum extent

- Exchange with other companies should empower the process
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Conclusion

- **Initiative is an expanding one and new requirements will keep on coming**

- **Sharing patient level data has the potential to increase public understanding and interest**

- **Pharmaceutical companies adapting to external requirements**

- **External environment is encouraging multiple models to co-exist**
Questions...
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