What is ClinicalStudy??
ClinicalStudyDataRequest.com (CSDR)

- Where did CSDR come from?
- Who is involved in CSDR?
- What does CSDR aim to do?
- How does CSDR work?
- Where is CSDR going?
GSK’s Vision for Data Sharing

Research sponsors

Anonymised patient level data provided after completion of the project and publication

Independent Data Custodian

Undertakes scientific review of proposals
Reviews expertise and management of any conflicts of interest
Manages privacy

Researchers

Submits scientific proposals and analysis plans
Agreements to protect privacy, and publish the results
Companies sharing data on CSDR (n=13) and counting ......
CSDR Aims

• Maximise the research value of clinical trial data
• Provide multi-sponsor solutions to data sharing
CSDR Data Access Model

- Research Proposal submitted
- Independent Review Panel
- Data Sharing Agreement signed (Data Holder(s) & Researcher)
- De-identified datasets / documents package uploaded
- Analyses performed within SAS secure website
- Publication generated
Data Requester

1. Identifies studies of interest
   • Raises an enquiry if study not listed

2. Develops and submits Research Proposal

3. Reviews and signs Data Sharing Agreement
   • DSA between Research Institute and Data Holder

4. Generates publication based on research findings
   • Includes acknowledgement of data source
   • Sends copy to Data Holder(s) for information / review*
Wellcome Trust Role in CSDR

Independent, not-for-profit, global charitable foundation dedicated to improving health

Spend ~£800M/year supporting research in science, humanities, public engagement and the application of research

Providing IRP Secretariat for CSDR
CSDR Independent Review Panel

Provides **scientific** and **ethical** review of access requests, in order to:

- Protect patient confidentiality
- Ensure appropriate secondary uses of data
- Review scientific and analytical robustness of research proposals
- Assess the competence of the data requestor
- Maintain public trust
Data Holders (Pharma Companies)
Role & Activities

- Updates Study List / Responds to Enquiries
- Reviews RP for feasibility
- Creates data package
- DSA signoff
- Data upload and SAS access set up
- Responds to questions
- Receipt of publication
- Close out of the RP
# Metrics


<table>
<thead>
<tr>
<th>Number of Research Proposals submitted up to 30 June 2015</th>
<th>Proposal Submitted</th>
<th>Proposal Reviewed</th>
<th>Data available</th>
<th>Project on-going</th>
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<tbody>
<tr>
<td>In process</td>
<td>16</td>
<td>7</td>
<td>23</td>
<td>64</td>
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<tr>
<td>Withdrawn by the requestor</td>
<td>15</td>
<td>0</td>
<td>2</td>
<td>0</td>
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<tr>
<td>Not agreed (yet)</td>
<td>10</td>
<td>8</td>
<td>0</td>
<td>0</td>
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<tr>
<td>Met requirements</td>
<td>104</td>
<td>89</td>
<td>64</td>
<td>0</td>
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<tr>
<td>Total</td>
<td>145</td>
<td>104</td>
<td>89</td>
<td>64</td>
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</tbody>
</table>
### Disease areas being researched on CSDR

<table>
<thead>
<tr>
<th>100 Research Proposals</th>
<th>Number</th>
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</thead>
<tbody>
<tr>
<td>Cancer</td>
<td>23</td>
</tr>
<tr>
<td>Infectious diseases</td>
<td>20</td>
</tr>
<tr>
<td>Cardiovascular diseases</td>
<td>14</td>
</tr>
<tr>
<td>Autoimmune diseases</td>
<td>11</td>
</tr>
<tr>
<td>Central nervous system</td>
<td>10</td>
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<tr>
<td>Other</td>
<td>17</td>
</tr>
<tr>
<td>Co-morbidities</td>
<td>5</td>
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</tbody>
</table>
CSDR Findings

Of 100 research proposals:

- **2** aimed to **confirm original trial results**
- **98** aimed to conduct completely **novel analysis**
- **20** aimed to develop/validate new **statistical methods**
- **20** conducted **systematic reviews**
- **49** aim to find **predictive factors** (precision medicine)
Other CSDR Activities

Data Sharing, Year 1 — Access to Data from Industry-Sponsored Clinical Trials

Brian L. Strom, M.D., M.P.H., Marc Buyse, Sc.D., John Hughes, B.Sc., and Bartha M. Knoppers, Ph.D.

Year 2 Update: Early 2016
The Future

LONG TERM
• One-stop shop for clinical trial data
• Single, federated portal
• Discoverable
• User-friendly
• Cost-effective?

MEDIUM TERM
• Continue to learn, develop new tools & partnerships
• MRCT/WT/Arnold Working Groups

SHORT TERM
• Additional Data Holders join CSDR.com
• Scope x-platform collaborations
Useful References

Questions?