

# What is **ClinicalStudy** ?

DataRequest.com

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**Wellcome Trust**

UCL-Yale Meeting, London, October 9<sup>th</sup> 2015

# 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



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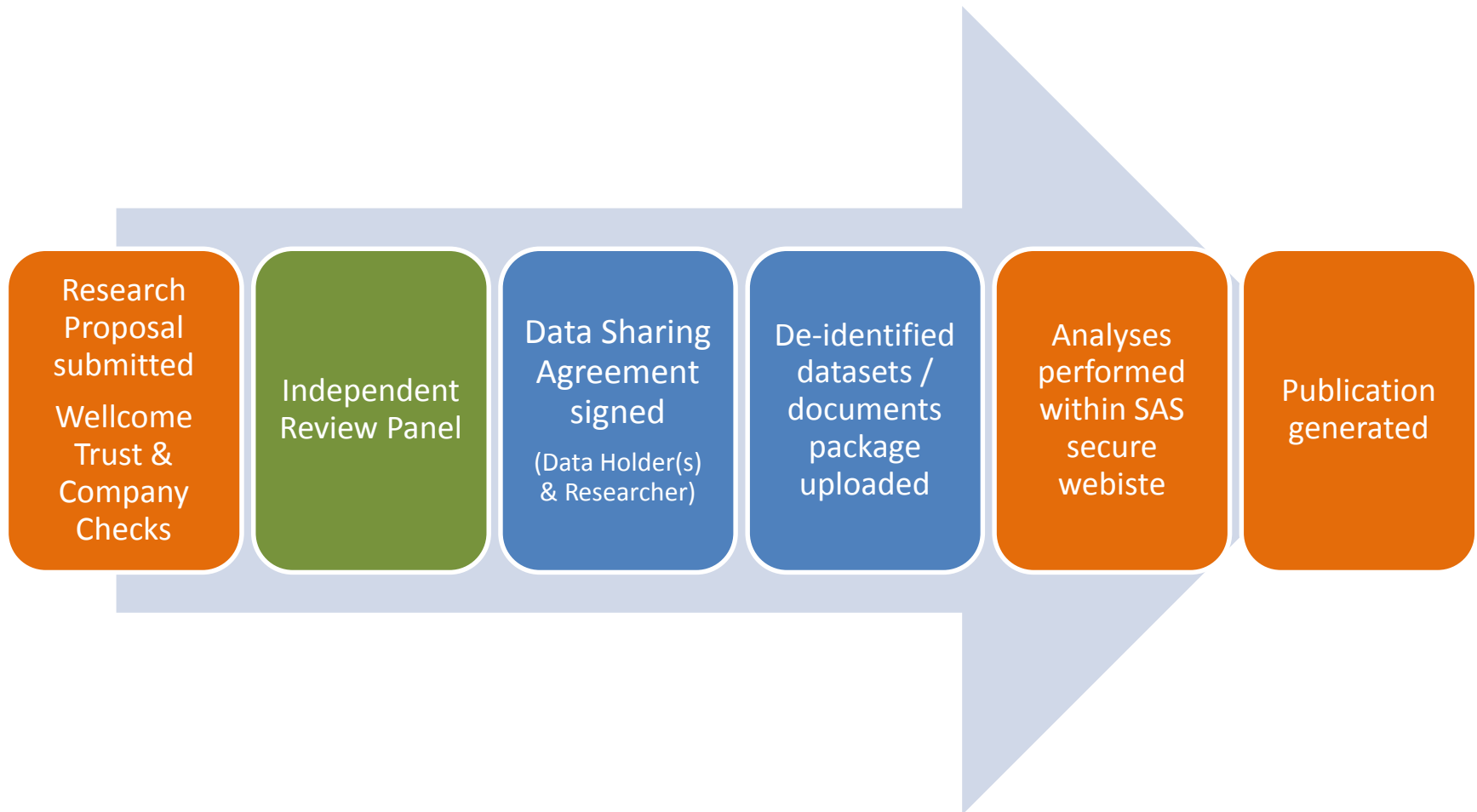
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**(n=13) and  
counting .....**



# CSDR Data Access Model





# 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

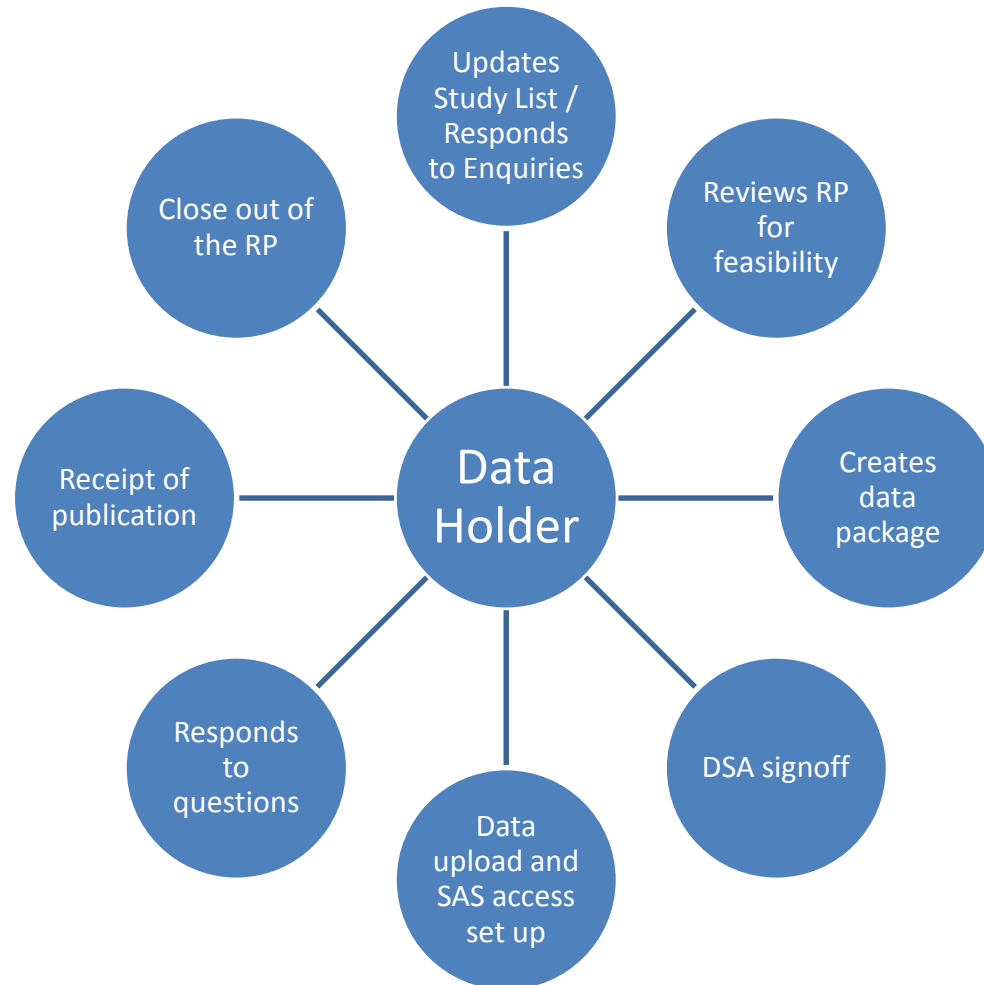


Provides **scientific** and **ethical** review of access requests, in order to:

- 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



# Metrics

## 145 Research Proposals Submitted (2013-2015)

Number of Research Proposals submitted up to 30 June 2015	Proposal Submitted	Proposal Reviewed	Data available	Project on-going
In process	16	7	23	64
Withdrawn by the requestor	15	0	2	0
Not agreed (yet)	10	8	0	0
Met requirements	104	89	64	0
<b>Total</b>	<b>145</b>	<b>104</b>	<b>89</b>	<b>64</b>

# Disease areas being researched on CSDR

100 Research Proposals	Number
Cancer	23
Infectious diseases	20
Cardiovascular diseases	14
Autoimmune diseases	11
Central nervous system	10
Other	17
Co-morbidities	5

# 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



The NEW ENGLAND  
JOURNAL of MEDICINE

PERSPECTIVE

ACCESS TO DATA FROM INDUSTRY-SPONSORED CLINICAL TRIALS

## 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?

## SHORT TERM

- Additional Data Holders join CSDR.com
- Scope x-platform collaborations

## MEDIUM TERM

- Continue to learn, develop new tools & partnerships
- MRCT/WT/Arnold Working Groups

# Useful References

- IoM report : <http://iom.nationalacademies.org/Reports/2015/Sharing-Clinical-Trial-Data.aspx>
- WT report : <http://www.wellcome.ac.uk/About-us/Policy/Spotlight-issues/Data-sharing/Access-to-clinical-trial-data/index.htm>
- Link to shared website: <https://clinicalstudydatarequest.com/Default.aspx>
- *NEJM* Paper: <http://www.nejm.org/doi/pdf/10.1056/NEJMp1411794>



# Questions?



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