

# Access to Patient Level Data from Clinical Trials

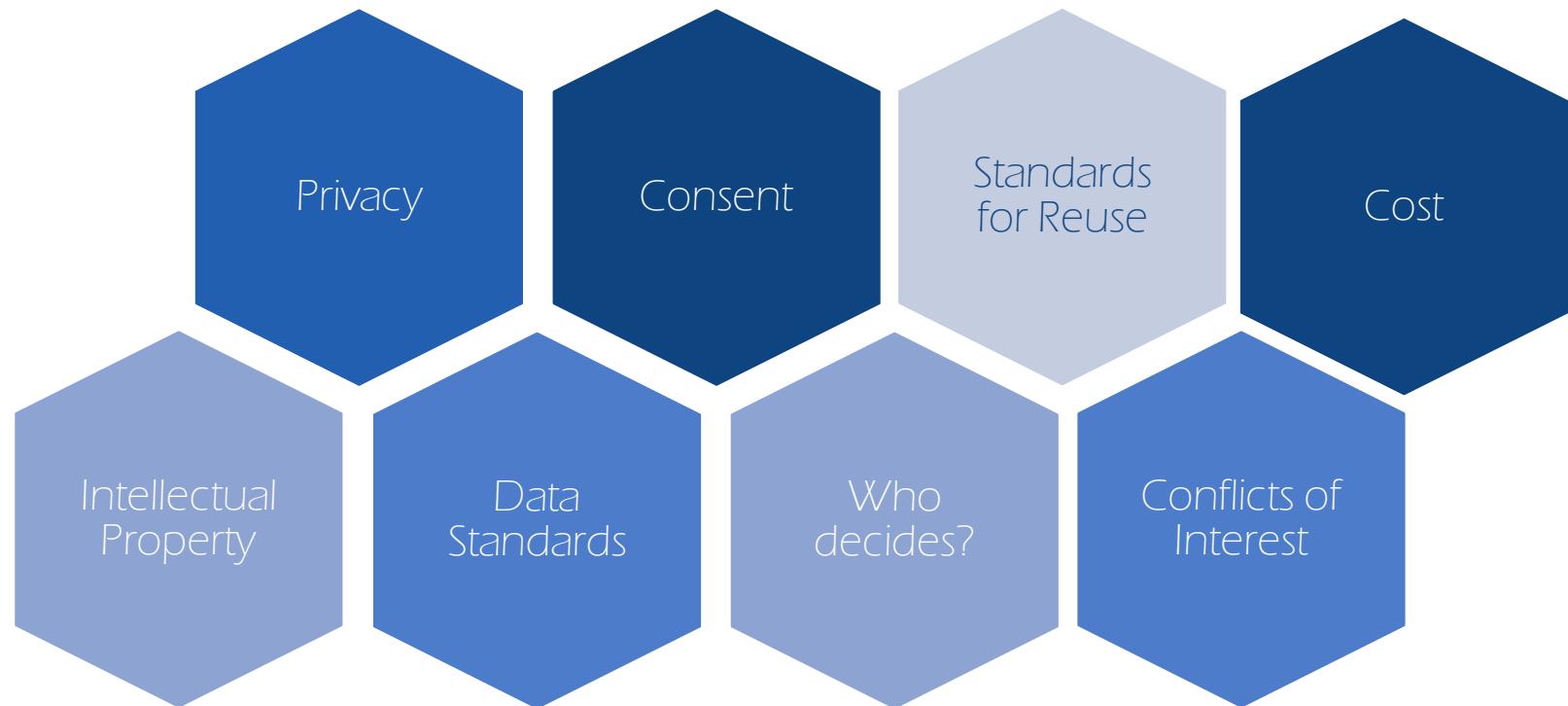
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**MEDICAL DISCOVERY INSTITUTE**

# Why Make Patient Level Data Available

- **Maximizes the contribution of clinical trial participants to new knowledge and understanding**
- **Confirm/refute findings**
- **Hypothesis generation**
- **Methodology development**
- **Transparency in clinical trial reporting**
- **Builds trust**

# Issues Providing Patient Level Data

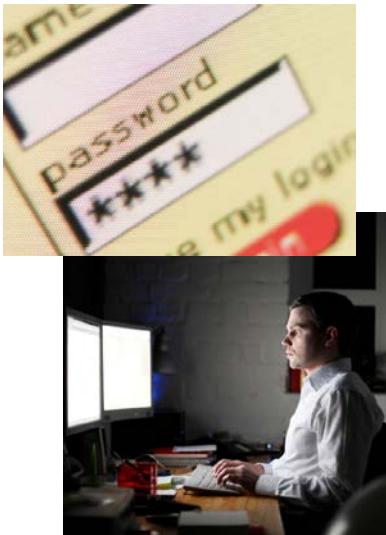


# My Biggest Concerns

- **Protecting privacy and confidentiality**
- **Ensure the data are used for valid scientific investigation**
- **Erroneous claims of benefit or risk**
- **Practicalities and cost of anonymising data in formats investigators can utilize effectively**

# Can Patient Privacy/Confidentiality be Protected?

- **Access to data is provided in a secure password protected internet site**
- **Controls in place to prevent data being downloaded or transferred**
- **Analytical software provided (e.g., “R” and SAS)**
- **Data can be combined and analyses downloaded**
- **Data sharing agreements**
- **Aligned with informed consent**



# Possible Solution

## 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**

## Investigators



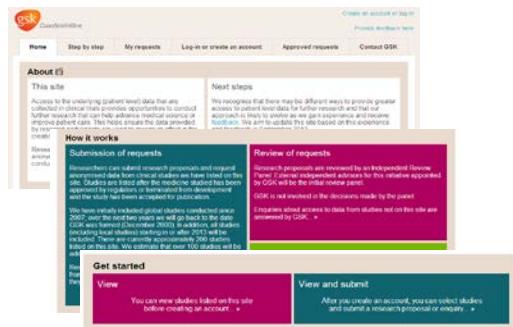
**Submits scientific  
proposals and  
analysis plans**

**Agreements to protect  
privacy, and publish  
the results**

# GSK Took First Step

In May, 2013 GSK launched a system with three components to provide greater access to patient level data from clinical trials

1



GSK Request Site

2



Independent Review Panel

3



GSK Access System

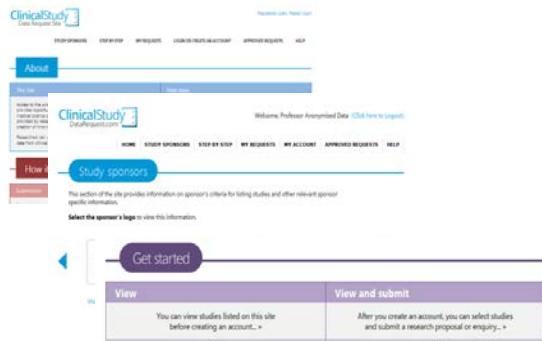
# Next Step

A multi-sponsor request site in January, 2014

(Pfizer and Johnson & Johnson retain autonomous sites)



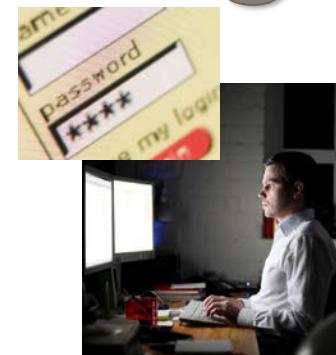
1



2



3



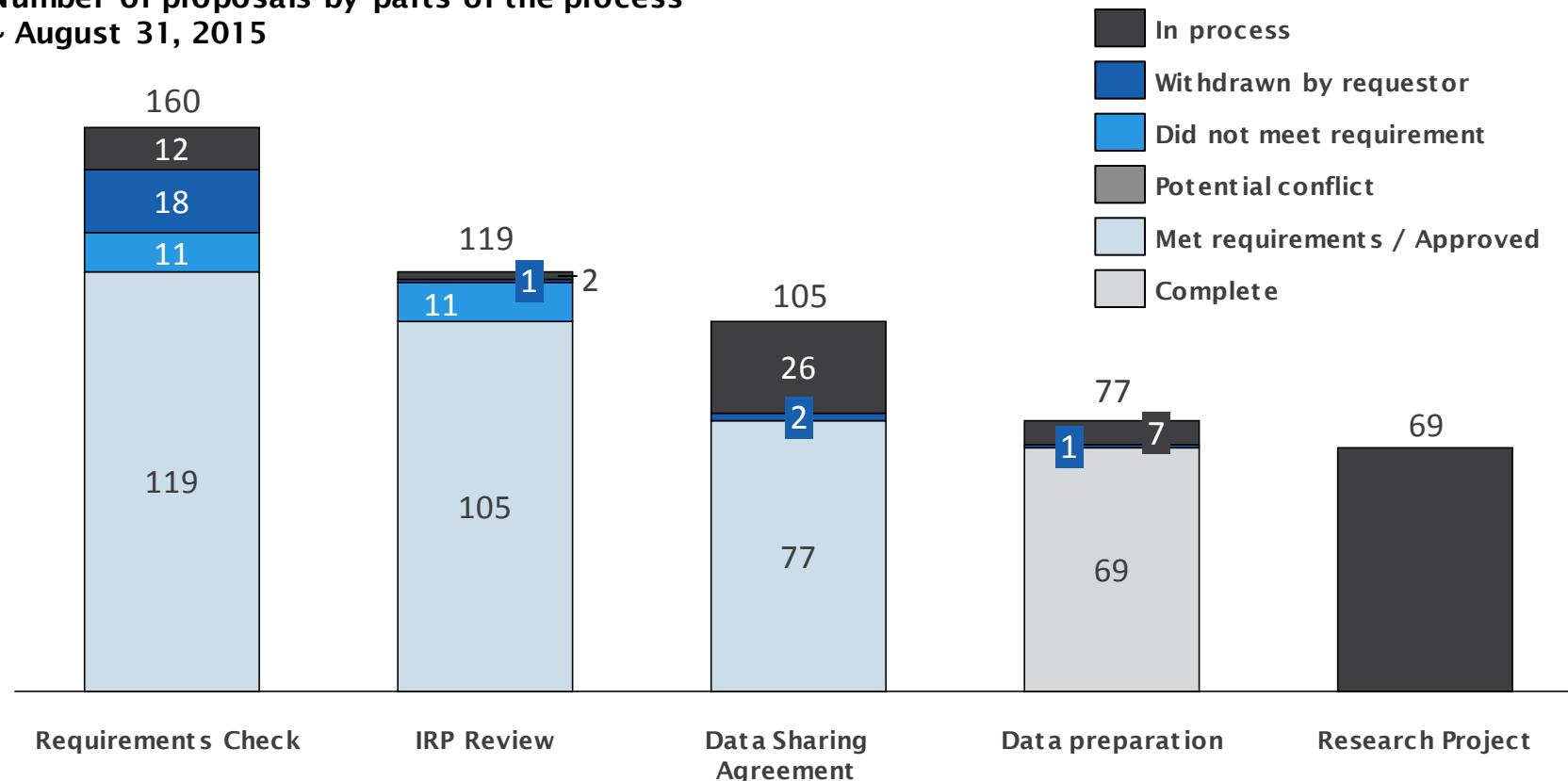
**Multi-sponsor Request Site**

**Independent Review Panel  
(same panel)**

**Multi-sponsor Access  
System (available 2014)**

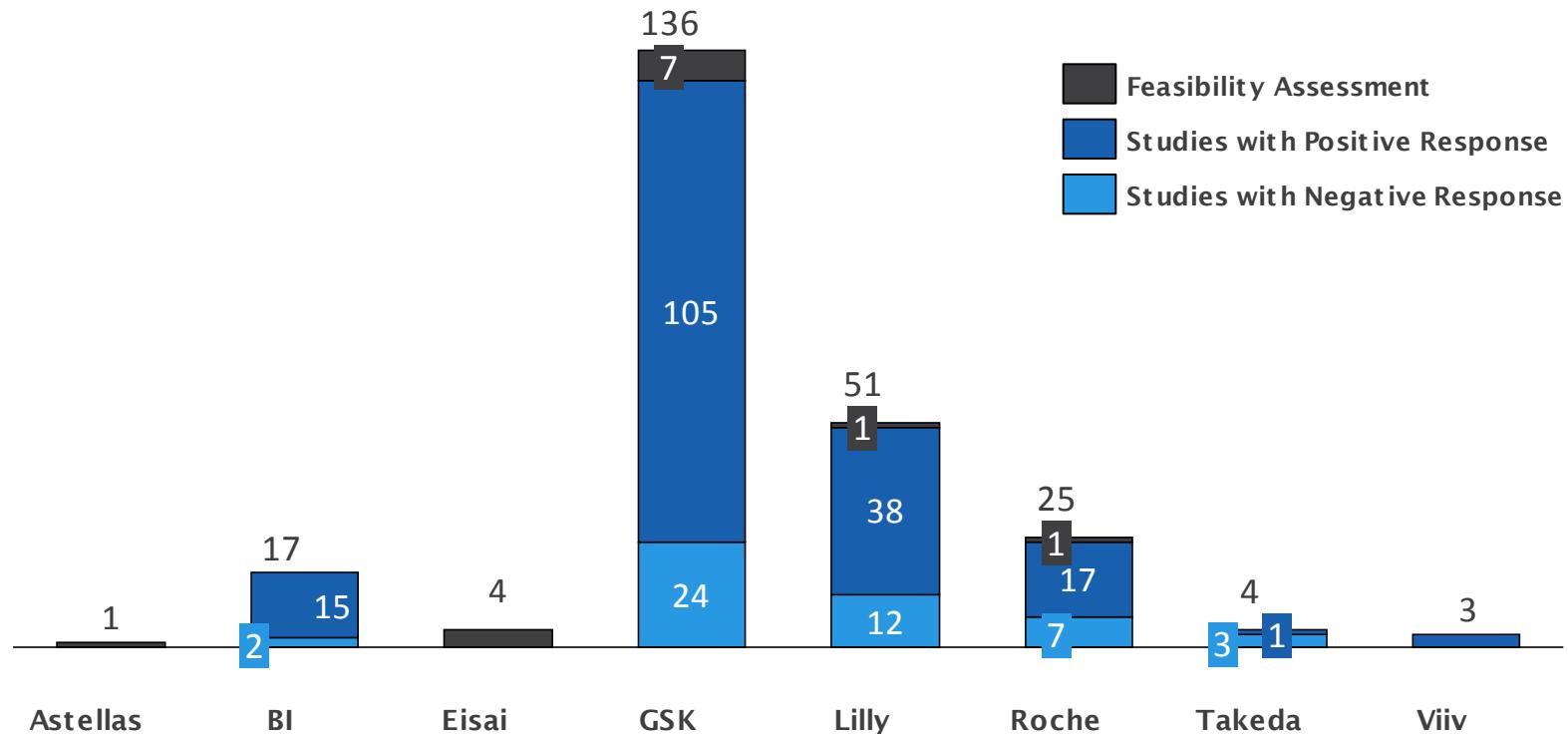
# Research Proposals Requested Access to Patient Level Data

Number of proposals by parts of the process  
~ August 31, 2015

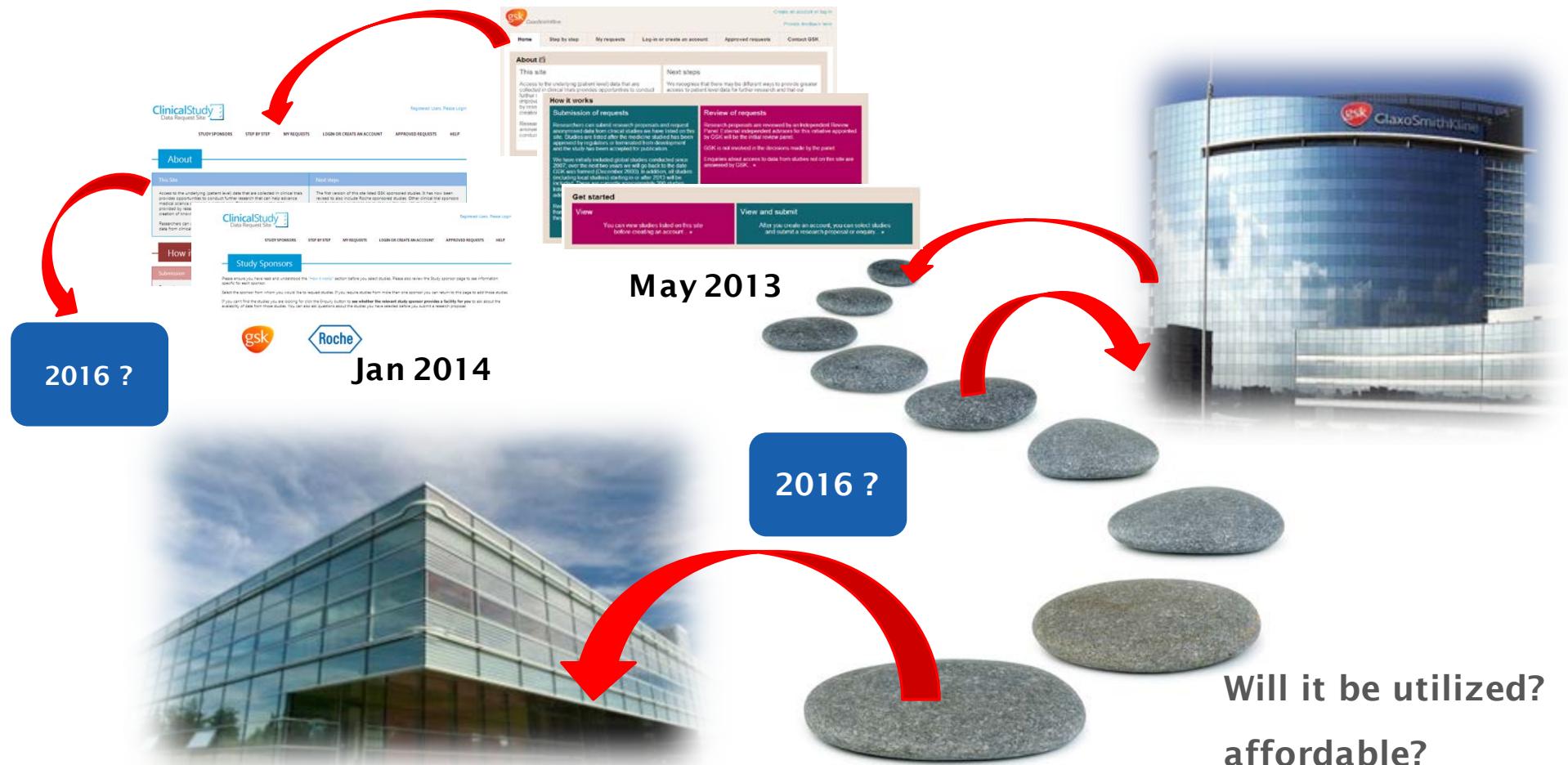


# Non-Listed Studies

Number of non-listed studies for which enquiries were received  
~ June, 2015



# Progress to Independent Custodian Accommodates Multiple Parties



# References

The NEW ENGLAND JOURNAL of MEDICINE

## SPECIAL REPORT

### Access to Patient-Level Data from GlaxoSmithKline Clinical Trials

Perry Nisen, M.D., Ph.D., and Frank Rockhold, Ph.D.

N ENGL J MED 369;5 NEJM.ORG AUGUST 1, 2013

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 Ruyse, Sc.D., John Hughes, B.Sc., and Bartha M. Knoppers, Ph.D.

N ENGL J MED 371;22 NEJM.ORG NOVEMBER 27, 2014

The New England Journal of Medicine