

# Access to Patient Level Data from Clinical Trials

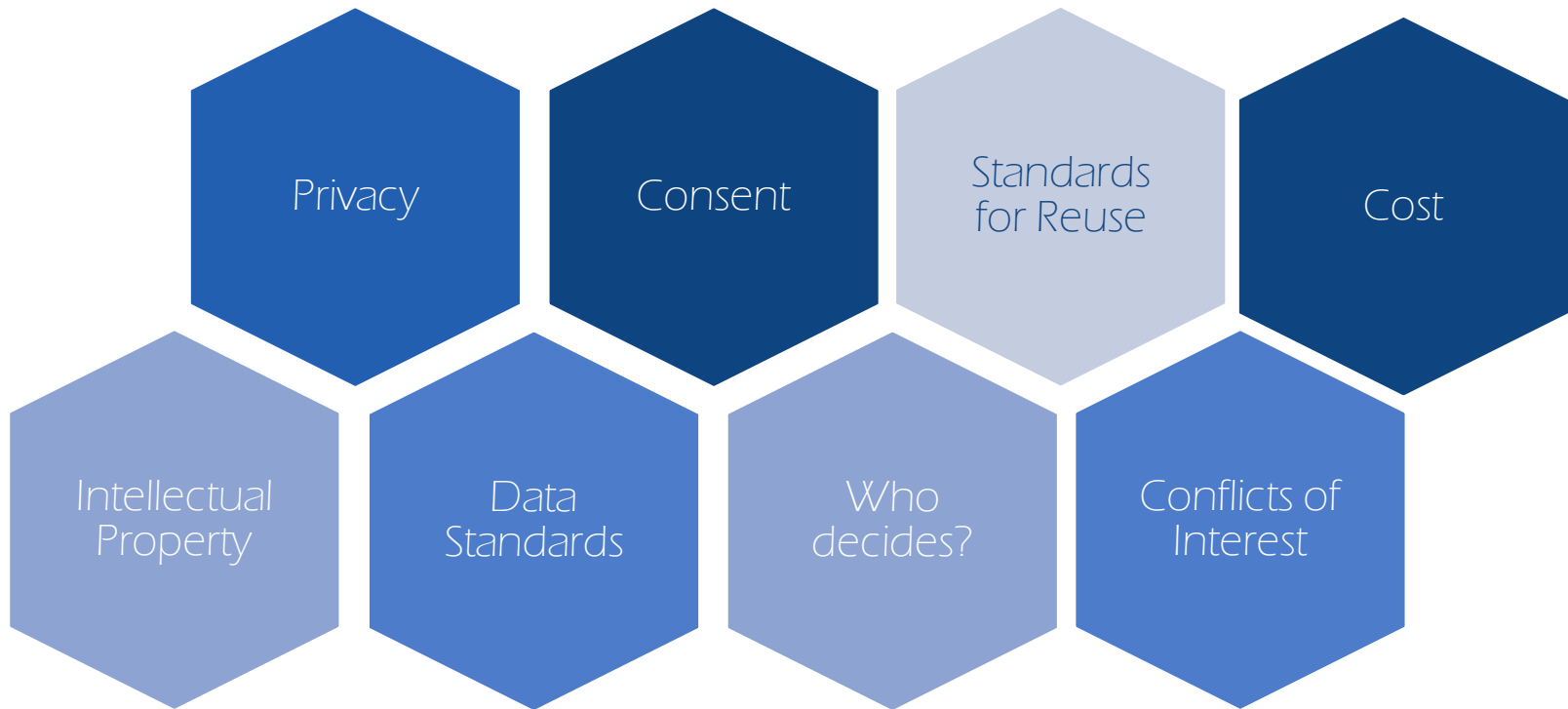
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**MEDICAL DISCOVERY INSTITUTE**

# 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**



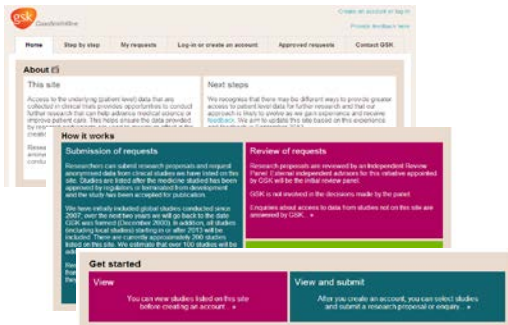
**Submits scientific  
proposals and  
analysis plans**

**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



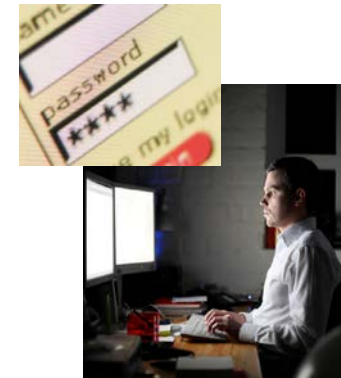
**GSK Request Site**

2



**Independent  
Review  
Panel**

3



**GSK Access System**

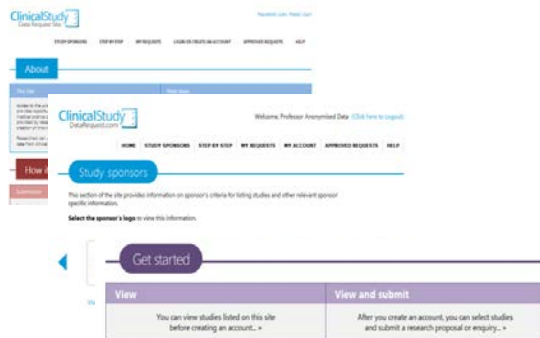
# Next Step

A multi-sponsor request site in January, 2014

(Pfizer and Johnson & Johnson retain autonomous sites)



1



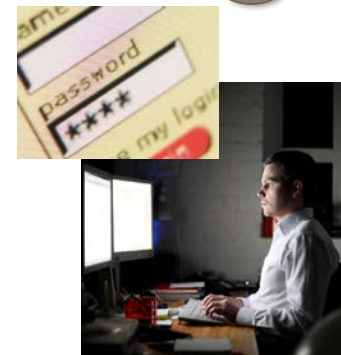
**Multi-sponsor Request Site**

2



**Independent Review Panel  
(same panel)**

3

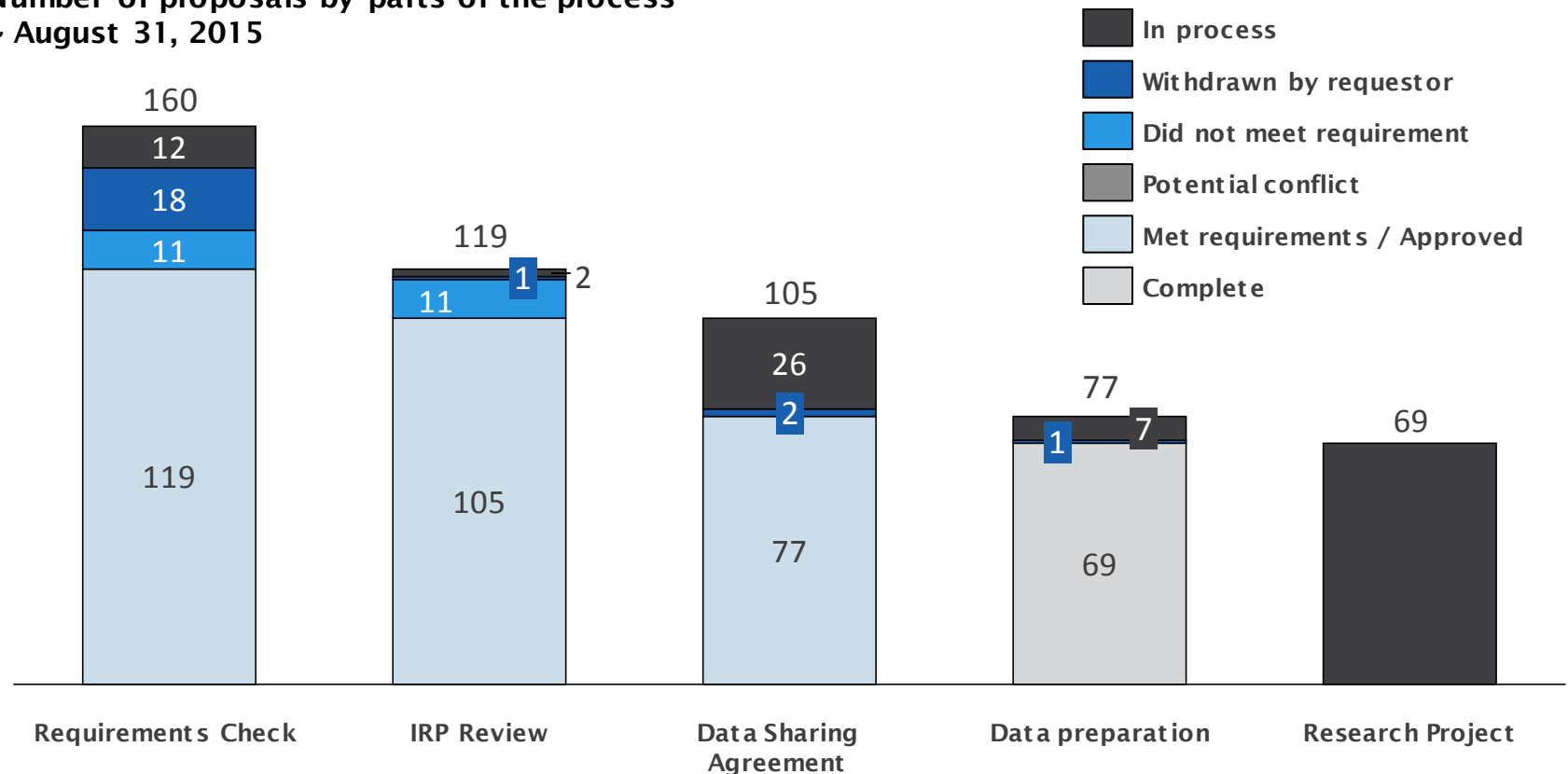


**Multi-sponsor Access  
System (available 2014)**



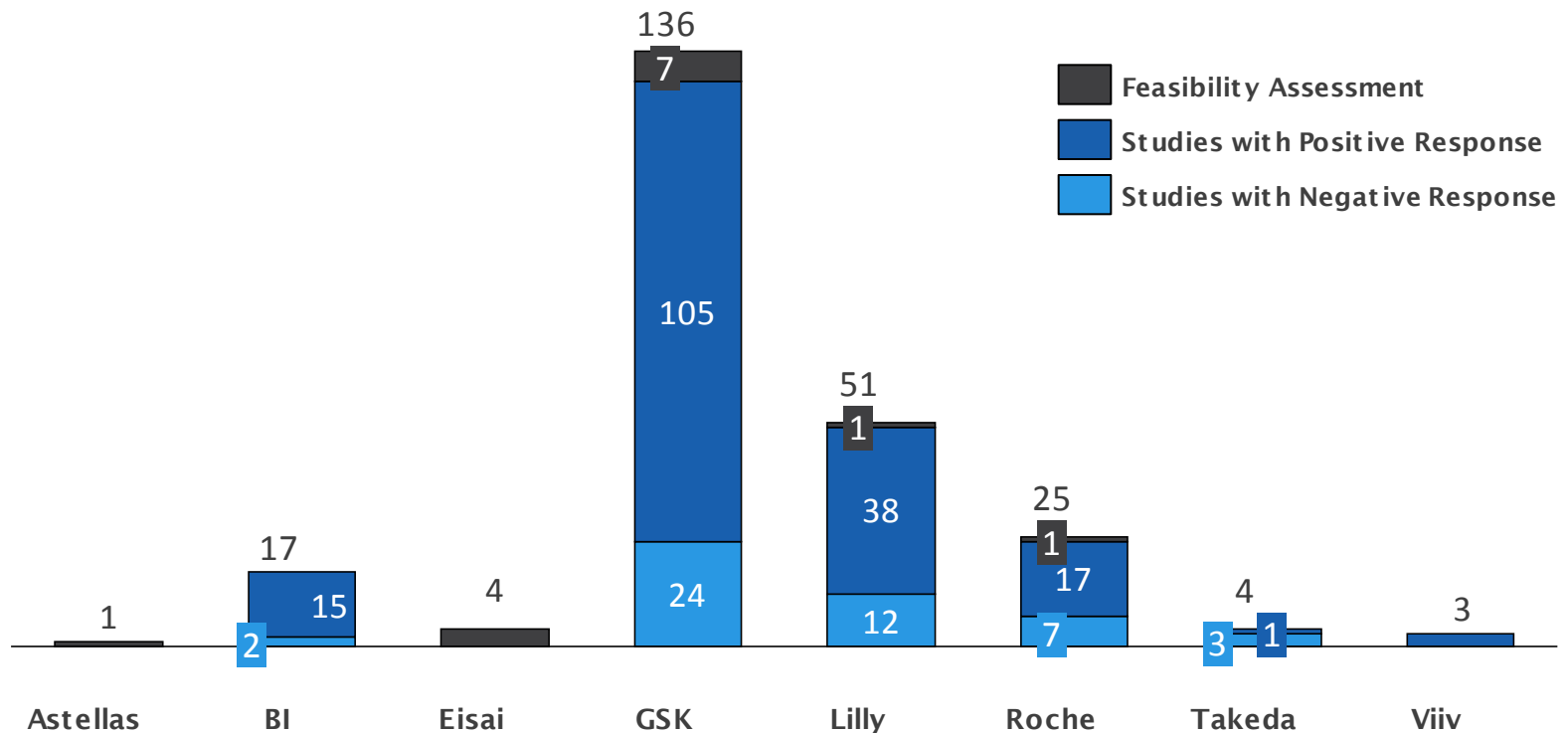
# Research Proposals Requested Access to Patient Level Data

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

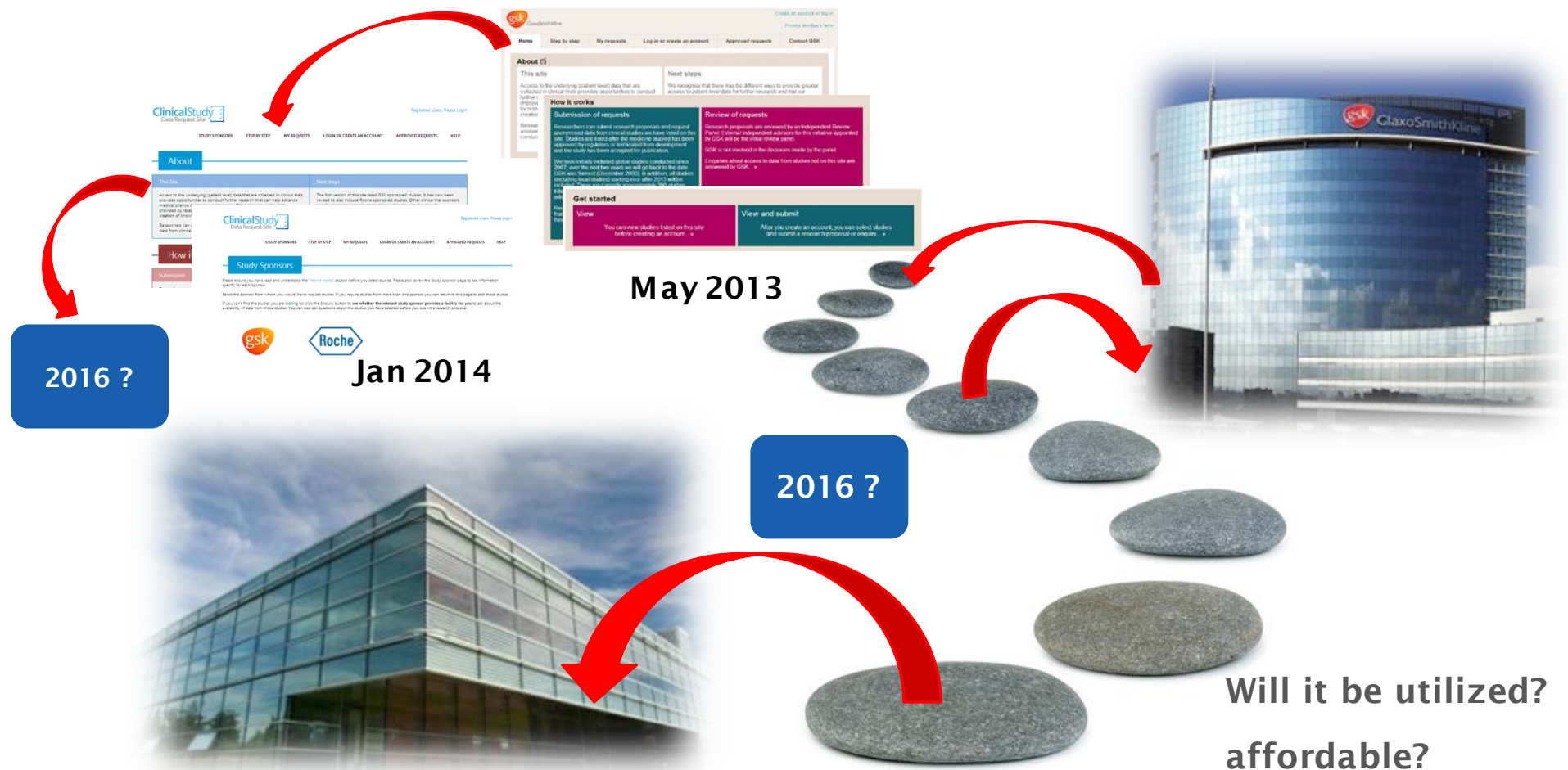


# Non-Listed Studies

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**