

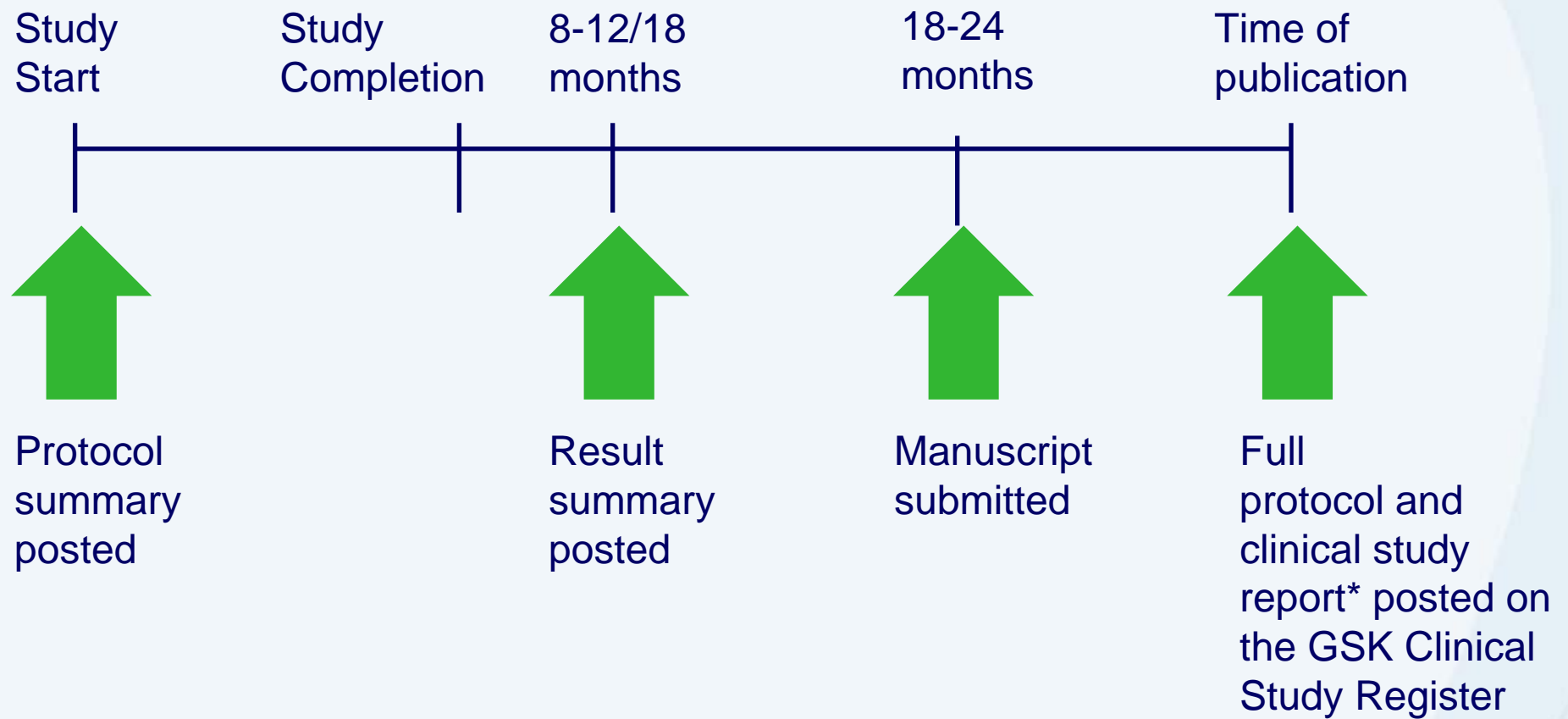


Access to Anonymised Patient Level Data from GSK Clinical Trials

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GSK Publicly Discloses Clinical Research Information

All human subject research studies that evaluate investigational or approved medicinal products – (phase I-IV, meta-analyses, observational studies)



* CSR posted after approval or termination of the medicine

Result Summaries and Publications Have Limitations

Publicly disclosed results:

- Summarise data from the study population with statistics to compare treatment groups
- Do not include the primary data from each research participant

Primary Efficacy Results: Total Population			
Emetic Episodes Day 1 To Day 5	Dose 1	Dose 2	Dose 3
Treatment Response, n (%)			
Complete (0 Episodes)	7 (19)	8 (22)	10 (31)
Major (1-2 Episodes)	10 (28)	14 (39)	10 (31)
Minor (3-5 Episodes)	0	1 (3)	0
Failure (>5 Episodes/Rescued)	19 (53)	13 (36)	12 (38)
p-value (stratified for centre)			
Dose 2 vs Dose 1	0.848		
Dose 2 vs Dose 3	0.467		

Benefits of Greater Access to Patient Level Data

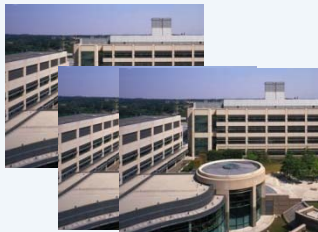
- Enables the identification of trends and associations that may provide greater insight or help develop hypotheses and theories for further research
- Enables the review of results from clinical trials to validate the results
- Helps ensure the data provided by research participants are used to maximum effect in the creation of knowledge and understanding
- Strengthens trust in clinical research through enhanced openness and transparency

Main Issues

- Protecting the privacy and confidentiality of research participants
- Ensuring the data are used for valid scientific investigation
- Practicalities of anonymising data and providing data in ways that enable external researchers to understand and navigate the information

A 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

Researchers



Submits scientific proposals and analysis plans

Agreements to protect privacy, and publish the results

How can we Realise this Solution?

The aim of GSK's initiative is to help realise a broader solution with an Independent Data Custodian



Overview of the GSK process

- Researcher submits a **research proposal** via request website
 - <https://clinicalstudydata.gsk.com>
- Proposals **reviewed** by an Independent Review Panel
- **Data sharing agreement**
- Access to **anonymised** data and documents with **personally identifiable information redacted**: (*raw dataset, analysis & reporting dataset, protocols with any amendments, annotated case report form, reporting and analysis plan, dataset specifications & CSR*).
- Access provided in a **secure IT environment**

Available Clinical Studies will Build

GSK1550188, A randomised, single-blind, placebo controlled, dose ascending, single dose study to evaluate the safety, tolerab...
Medicine: belimumab, Condition: Systemic Lupus Erythematosus, Phase: Phase 1, GSK Clinical Study ID: BEL114243.

A study to evaluate the potential incidence of orthostatic hypotension in elderly hypertensive patients following administrat...
Medicine: carvedilol, Condition: Hypertension, Phase: Phase 1, GSK Clinical Study ID: CFD109701.

COR111096, A Randomized, Double-Blind, Active-Controlled, Parallel Group, Multicenter Study Comparing the Proportion of Subje...
Medicine: carvedilol, Condition: Hypertension, Phase: Phase 3, GSK Clinical Study ID: COR111096.

Evaluation of the immunogenicity and safety of GlaxoSmithKline Biologicals' HPV vaccine 580299 when administered as a 3-dose ...
Medicine: CERVARIX, Condition: Cervical Cancer; Papillomavirus Infection; Papillomavirus Vaccines, Phase: Phase 3, GSK Clinical Study ID: 110168.

Safety and reactogenicity of GSK Biologicals' DTPa-IPV/Hib (Infanrix™-IPV/Hib) in infants
Medicine: Combined Diphtheria, Tetanus, Acellular Pertussis, Inactivated Polio, Haemophilus influenzae Type b C, Condition: Diphtheria, Tetanus, Pertussis, Polio, Hib, Phase: Phase 3, GSK Clinical Study ID: 112065.

- Researchers can submit research proposals and request data from clinical studies we have listed on the site
- Studies are listed after the medicine studied has been approved by regulators or terminated from development and the study has been accepted for publication

- We have included global studies conducted since 2007; approximately 200 studies are listed
- Over the next two years we will add global studies going back to the formation of GSK
- We will also include all studies (including local studies) we start in or after 2013
- We estimate that over 100 studies will be added in September 2013

Researchers Submit Research Proposals Using an On-line Form with these Items

Section A: Research Plan

Title

Lay Summary

Study Design

Studies Selected and Study Populations

Primary and Secondary Endpoints

Statistical Analysis Plan

Publication Plan

Section B: Information about the Research Team

Name

Post or Position

Employer, Company, Research Institution or Affiliation

Education, Professional Qualifications and Memberships

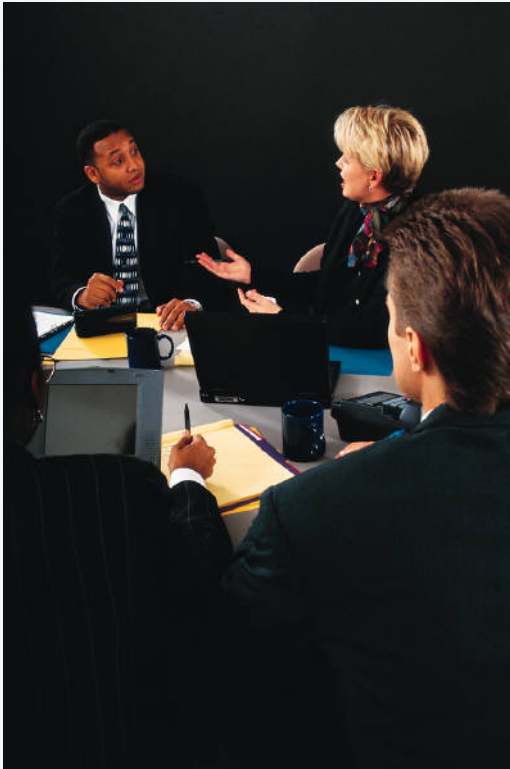
Section C:
Funding of the Proposed Research

Section D:
Potential Conflicts of Interest (Col) and management of Col

Section E:
Other Information

Research Proposals will be Reviewed by an Independent Panel

The panel will consider:



- The scientific rationale and relevance of the proposed research to medical science or patient care
- The ability of the proposed research plan (design, methods and analysis) to meet the scientific objectives. This is a high-level review
- The publication plan for the research
- Real or potential conflicts of interest that may impact the planning, conduct or interpretation of the research and proposals to manage these conflicts of interest
- The qualifications and experience of the research team to conduct the proposed research (a statistician with a degree in statistics or a related discipline should be part of the research team)

Researchers can Ask us About the Availability of Data from GSK Studies not Listed Before they Submit a Research Proposal

Enquiry Form

Please complete this form in English.

To find out if we can provide data from our studies that are not listed on this site please search the [GSK Clinical Study Register](#) and provide the GSK Study Identification Number and the study title below. Alternatively, provide other reference information so we can identify the study. For example, a [clinicaltrials.gov](#) identification number or publication reference.

Where we are able to provide access, we will do so if the Independent Review Panel approves your submitted research proposal and we receive a signed Data Sharing Agreement.

GSK Study Id. No.

Study Title

Other Reference Information

Add Another Study

GSK Review of Enquiries



Have the studies been published or accepted for publication?

Are the studies of terminated or authorised medicines (in approved indications)?

Do we have the data? (e.g. many observational studies use data from third party databases)

Do we have the legal authority to provide the data? (e.g. the medicine may have been out-licensed to another company)

Can we effectively anonymise the data? (e.g. for studies of rare diseases we will consider this on a case by case basis)

Are there any practical constraints? (e.g. there may be issues related to the size of genetic databases)

What resources are required to retrieve and anonymise the data and documents?

Our Intent is to Provide Access to Data Where we Can



Where we are able to provide access, we will do so if the Independent Review Panel approves the submitted research proposal and we receive a signed Data Sharing Agreement

*Have you received an answer to a previous enquiry related to this research proposal?

Yes No

Please provide the enquiry Reference Name and Number

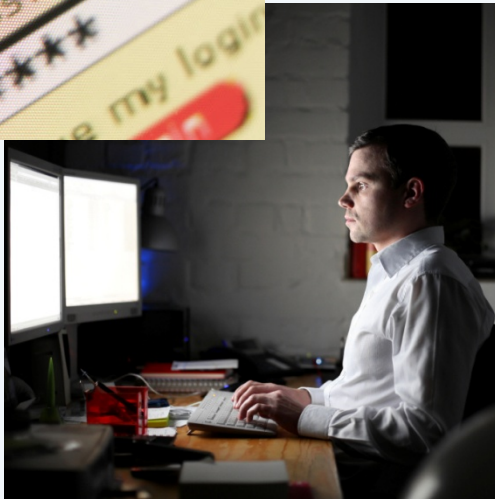
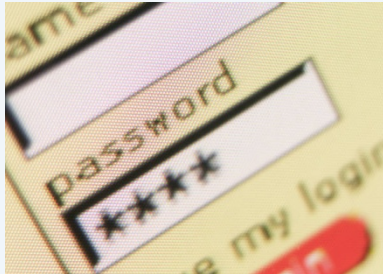
A Data Sharing Agreement will be put in place

The Data Sharing Agreement includes requirements to:



- Only use the data for the agreed purpose
- Not to attempt to establish the identities of research participants
- Inform regulatory authorities and GSK of any safety concerns as soon as they are identified
- Post and seek publication of the research
- Provide GSK with a copy of the manuscript after submission to a peer reviewed journal
- Allow us to use any invention that comes out of the research and negotiate any further rights in good faith

Access to Data is Provided in a Secure Password Protected Internet Site

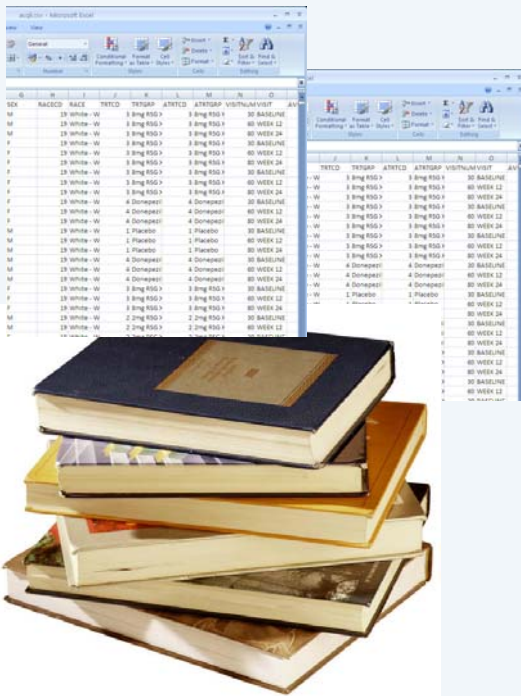


- Controls in place to prevent data being downloaded or transferred
- Analytical software provided (e.g. “R” and SAS)
- Data can be combined and analyses downloaded

This helps to protect the privacy and confidentiality of research participants and helps ensure the data are used for the agreed research purpose

Data and Documents Provided for Each Study

- Raw dataset
- Analysis-ready dataset
- Protocols with any amendments
- Annotated case report form
- Reporting and analysis plan
- Dataset specifications
- Clinical study report (appendices which include patient level data are not included)



Helpline support will be available to help researchers understand and navigate the data

Summary

- We have taken **a first step** and established a system where researchers can request access to anonymised patient level data from our studies
- We recognise that there may be different ways to provide greater access to patient level data for further research and that **our approach is likely to evolve as we gain experience and receive feedback**
- We would like our initiative to transition to a broader **independent system** to allow access to data from clinical trials conducted by multiple companies and organisations and hope that such a system will be put in place by a third party in the public or charitable sector as soon as possible. GSK is actively engaged in encouraging the development of such a system.