

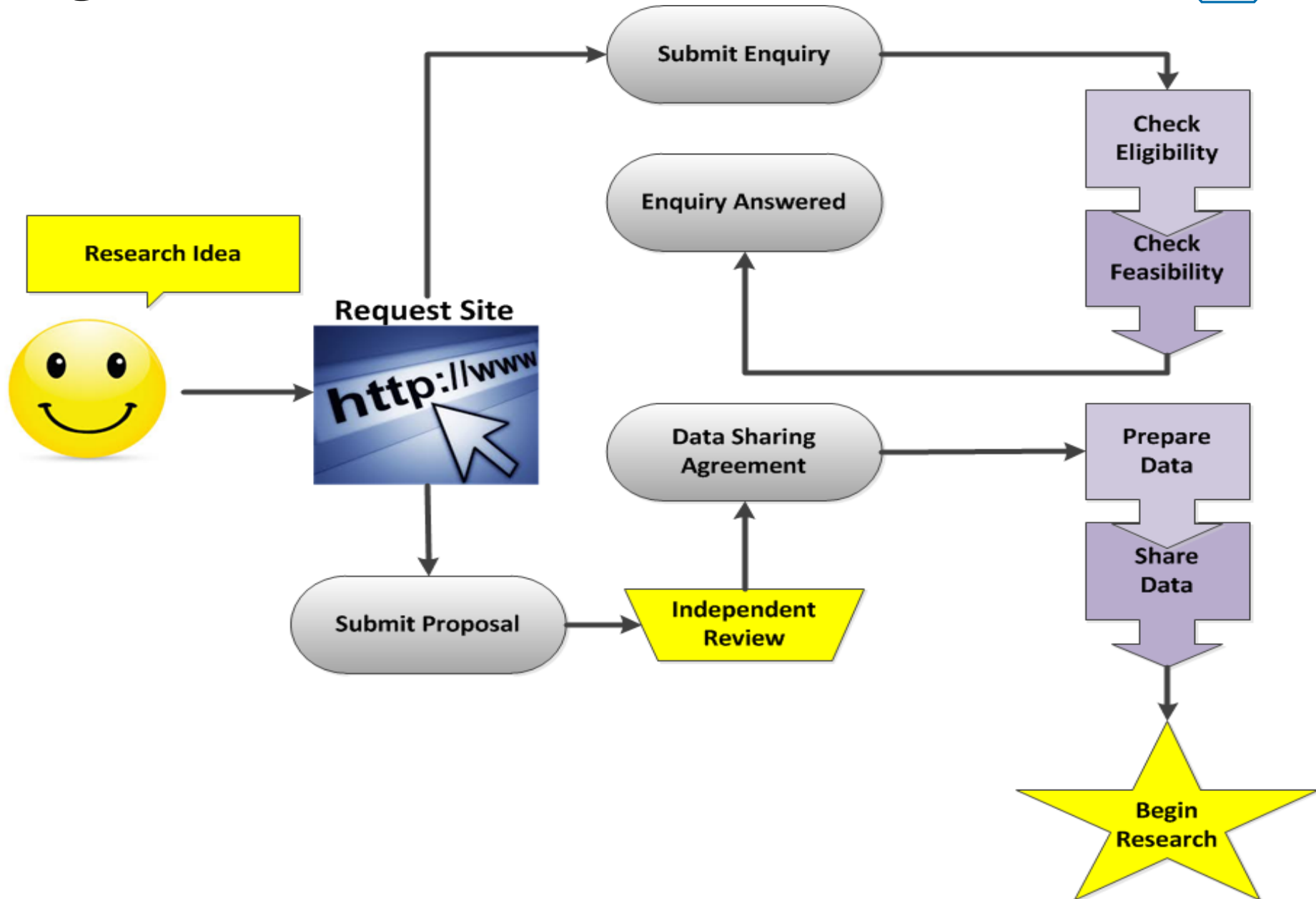
A Day in the Life of a Data Sharing Specialist

PhuSE, October 2014

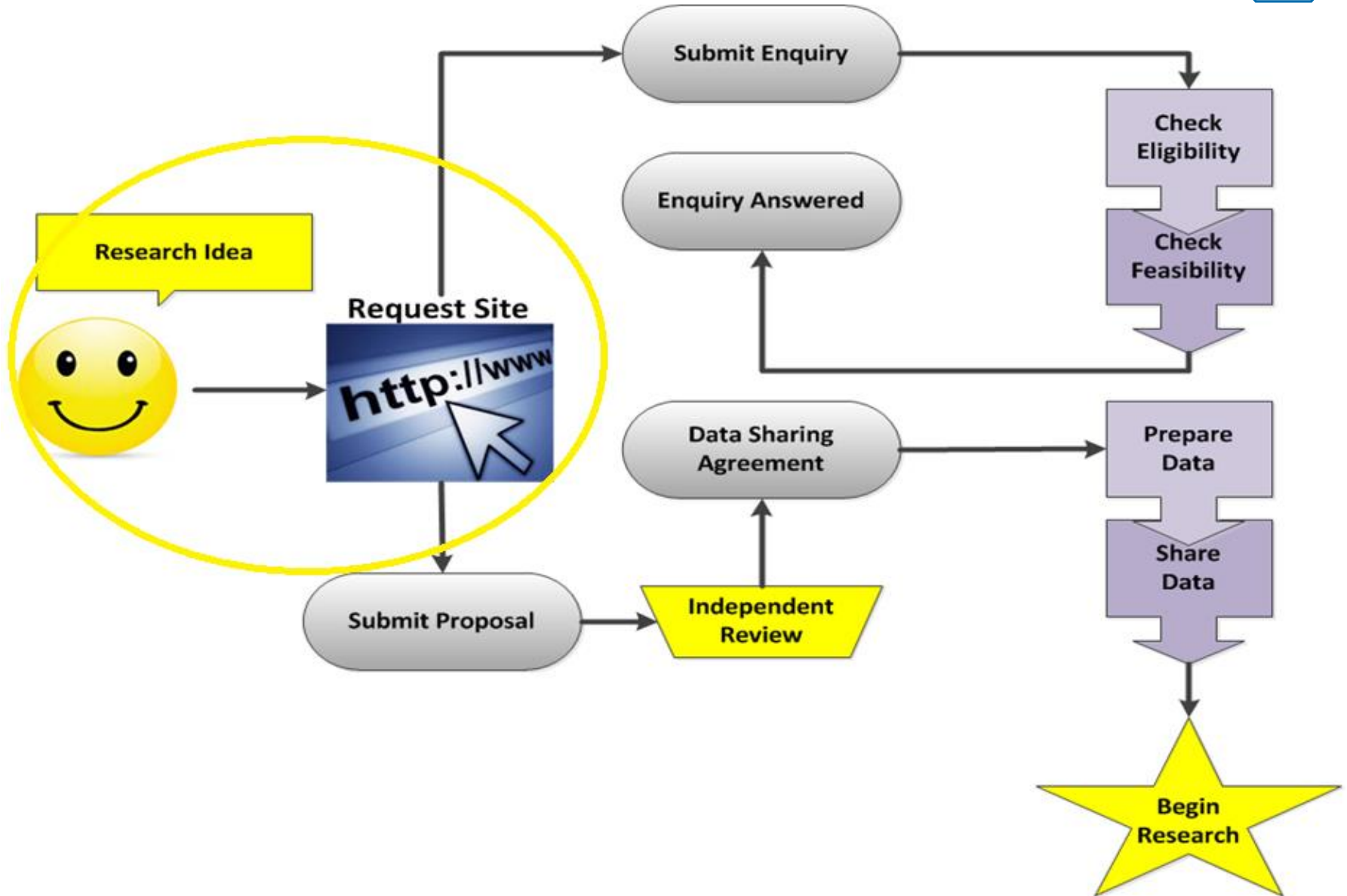
Kelly Mewes, Data Sharing Specialist.



Agenda



The Request Site



ClinicalStudyDataRequest.com website and the Partnering and Opportunity Management System



Registered Users, Please Login



Welcome Box, Roche (Roche) [Change User](#)
Current Group: Enquiry [My Profile/Privileges](#)
[My Home Group](#)

Powered by
ideaPoint

[HOME](#) [STUDY SPONSORS](#) [STEP BY STEP](#) [MY REQUESTS](#) [LOGIN OR CREATE AN ACCOUNT](#) [APPROVED REQUESTS](#) [HELP](#)

About

This site

Access to the underlying (patient level) data that are collected in clinical trials provides opportunities to conduct further research that can help advance medical science or improve patient care. This helps ensure the data provided by research participants are used to maximum effect in the creation of knowledge and understanding.

Researchers can use this site to request access to anonymised patient level data and supporting documents from clinical studies to conduct further research.

Next steps

Study sponsors who have committed to use this site are **Bayer, Boehringer Ingelheim, GSK, Lilly, Novartis, Roche, Sanofi, Takeda, UCB** and **Viiv Healthcare**.

Other clinical trial sponsors and funders are invited to join with the aim of transitioning to a fully independent system which allows access to data from clinical trials conducted by multiple companies and organisations. It is hoped that such a system will be put in place as soon as possible.

If you are a study sponsor interested in listing studies on this site, contact information is provided [here](#).

REQUESTS



1023 - Test Enquiry

[Details](#) [Team](#) [Comments](#) [Attachments](#) [Conversations](#) [Correspondence](#) [History](#) [Checklist](#)



This is detailed information related to this opportunity including information from the external submitter and data that we are tracking internally related to this opportunity. If you have rights to edit this information, you will see a small pencil icon. Click on the pencil icon to edit.

Management Fields

Group: Enquiries (Enquiry)	Submitted Date: 02 Jun 2014 8:37 AM
Institution:	Decision Date:
ENQUIRY_DSAIDSC(s): DSAIDSC, Test (Test)	Days Elapsed: 93
Box, Roche (Roche)	Origination Site: External Portal
	Visibility: Normal
	Internal ID:
External Submitter(s):	Agreement Date:
	Created Date: 02 Jun 2014 8:37 AM
Other External Contact(s):	Modified Date: 02 Jun 2014 8:37 AM
Internal Submitter(s):	Linked Enquiries:
Other Internal Contact(s):	
Staff Submitter(s):	
Clinical Studies:	

Status/History

Internal Status: Submitted

External Status: Submitted

How the site works

Step by step guide

How to select studies and submit a **Research Proposal**

Proposal



How to submit an **Enquiry** about sponsor studies not listed on this site or ask other questions

Enquiry



Partnering and Opportunity Management System



- We can track requests through each stage until close out and access all details of each request.
- We record the outcome of our feasibility assessment here.
- All communication is done through this system with standard email templates available for each stage of the process.
- We can also send messages through a conversations tab and attach documents as required.
- The Independent Review Panel use this system to record the outcome of their decision.

Details

Team

Comments

Attachments

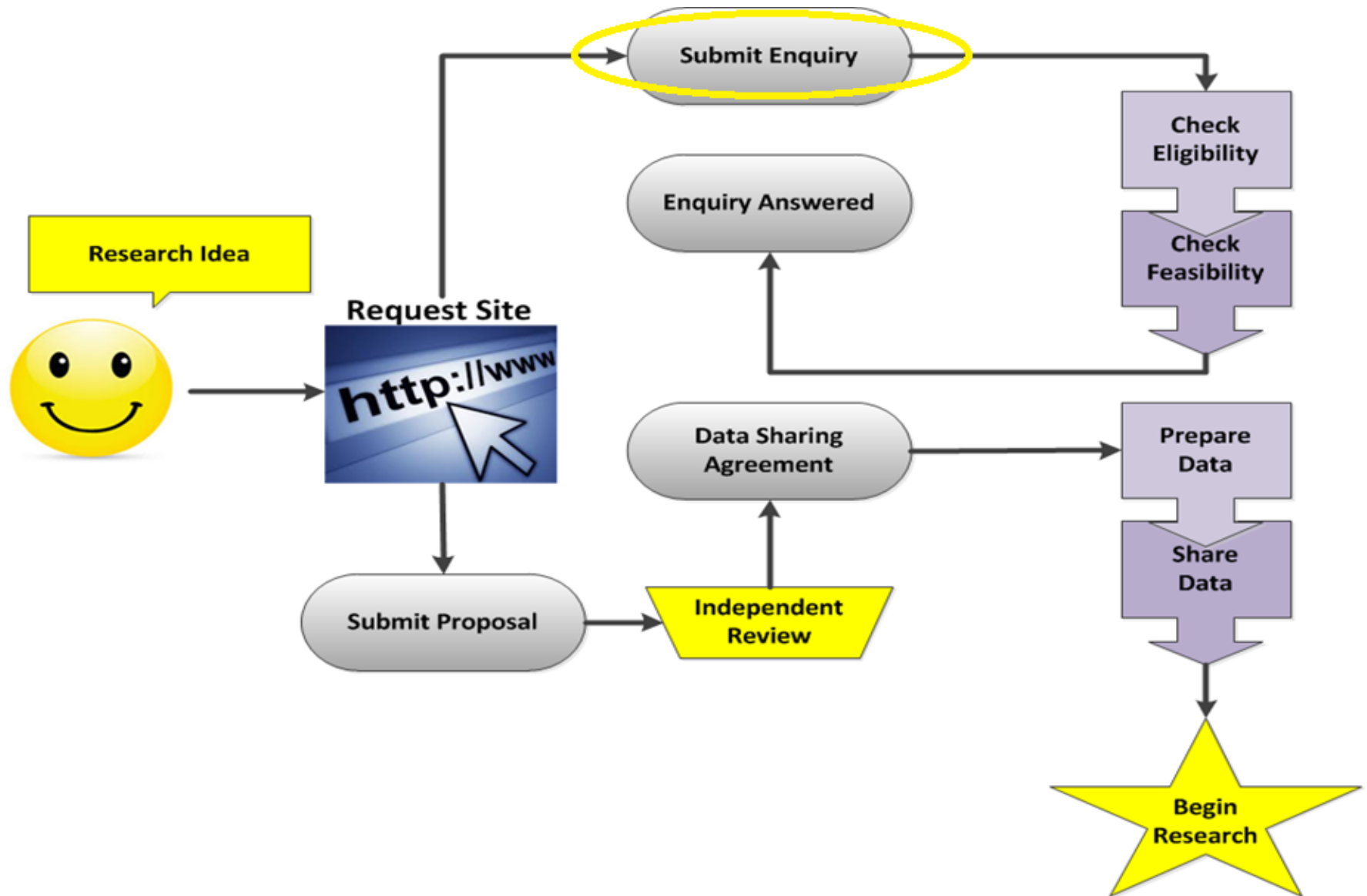
Conversations

Correspondence

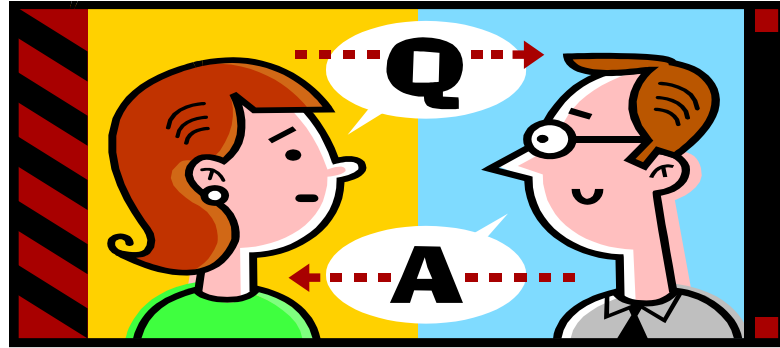
Checklist

Panel Decision Form

Enquiries.

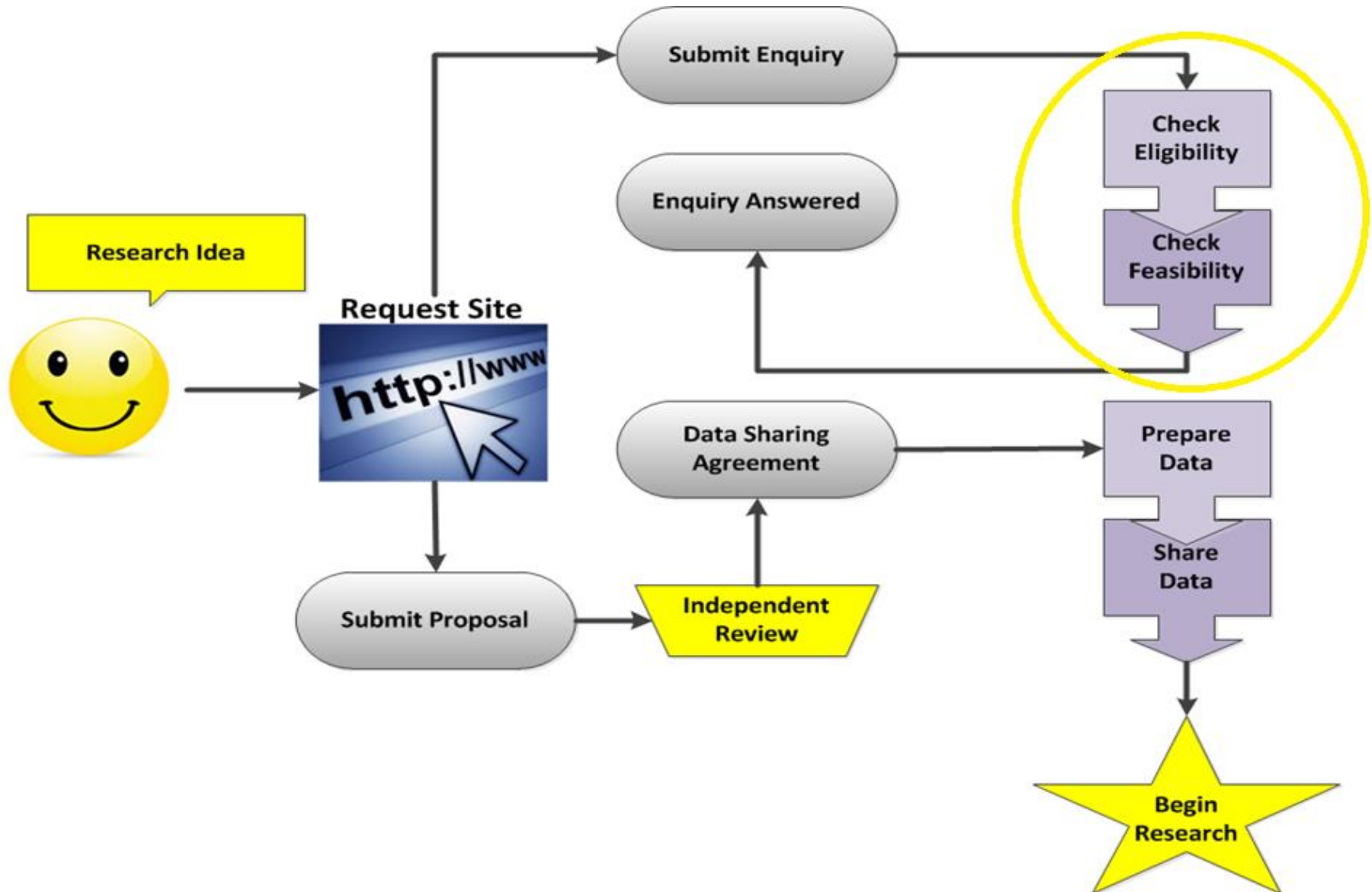


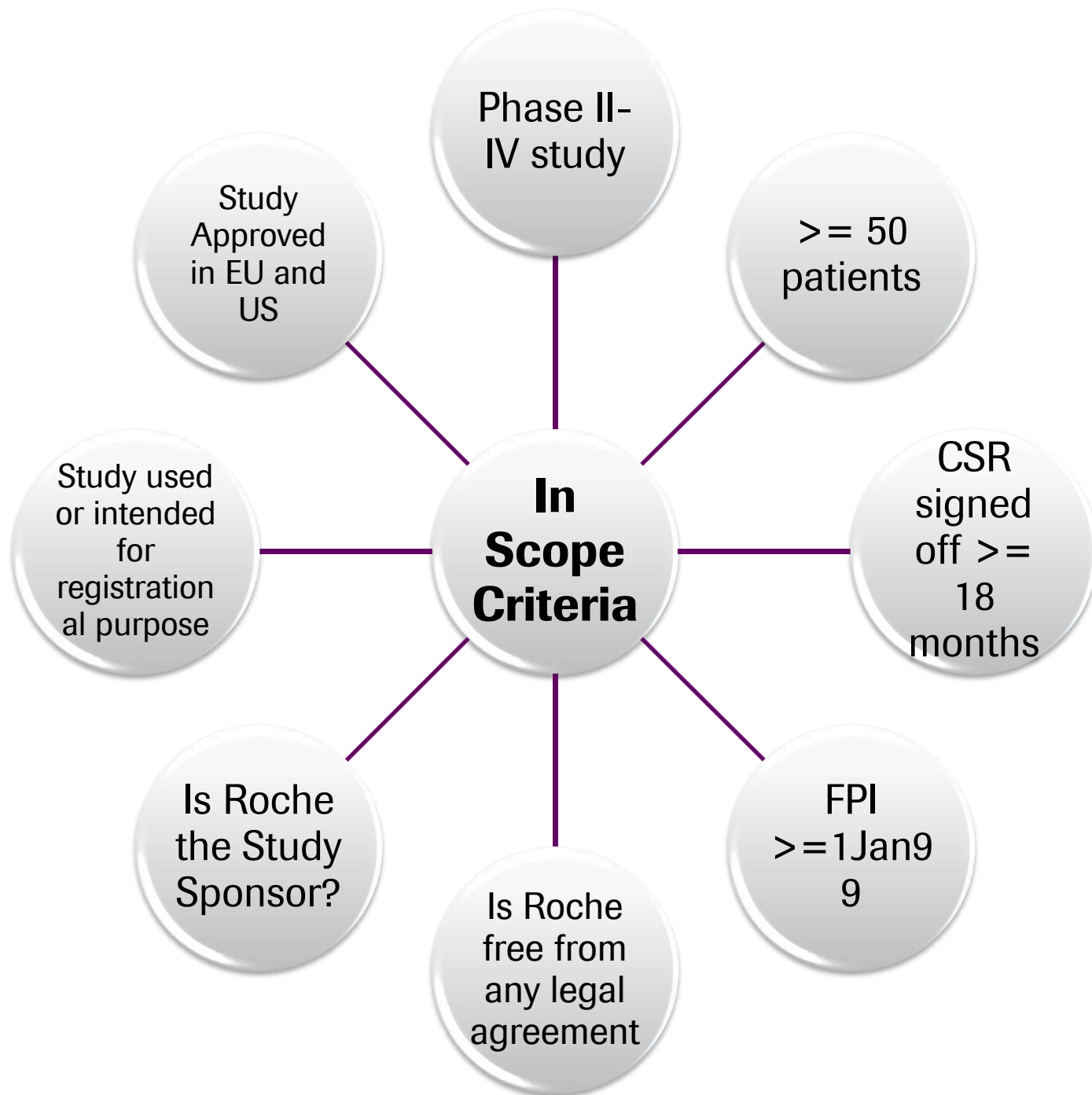
Enquiries



- Enquiries can be
 - General questions
 - Specific queries on studies
- We start by reviewing the enquiry and completing a checklist of completeness.
 - Does it make sense ?
 - Have they picked the correct sponsor ?
 - Do we need further information ?
- We will then either respond for general queries or for study specific queries we start the feasibility check on every study requested.

Eligibility and Feasibility Assessment

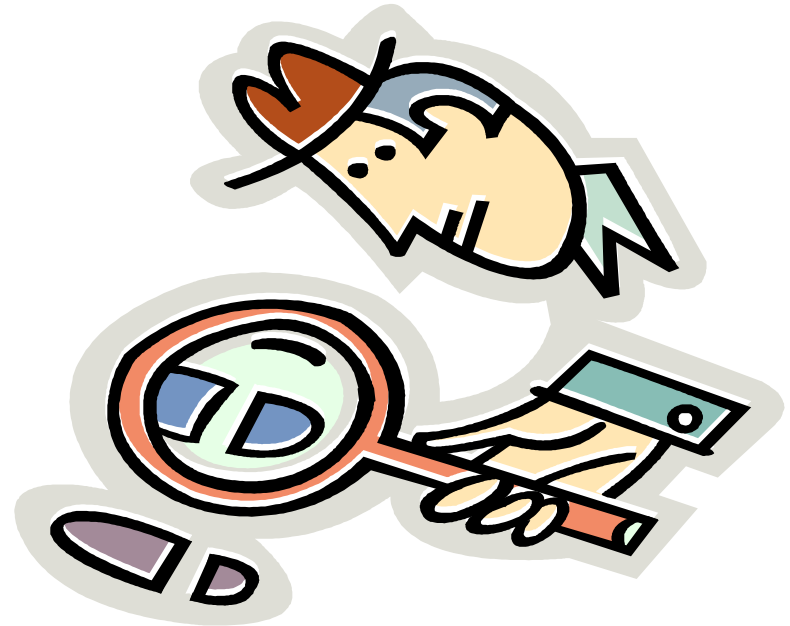




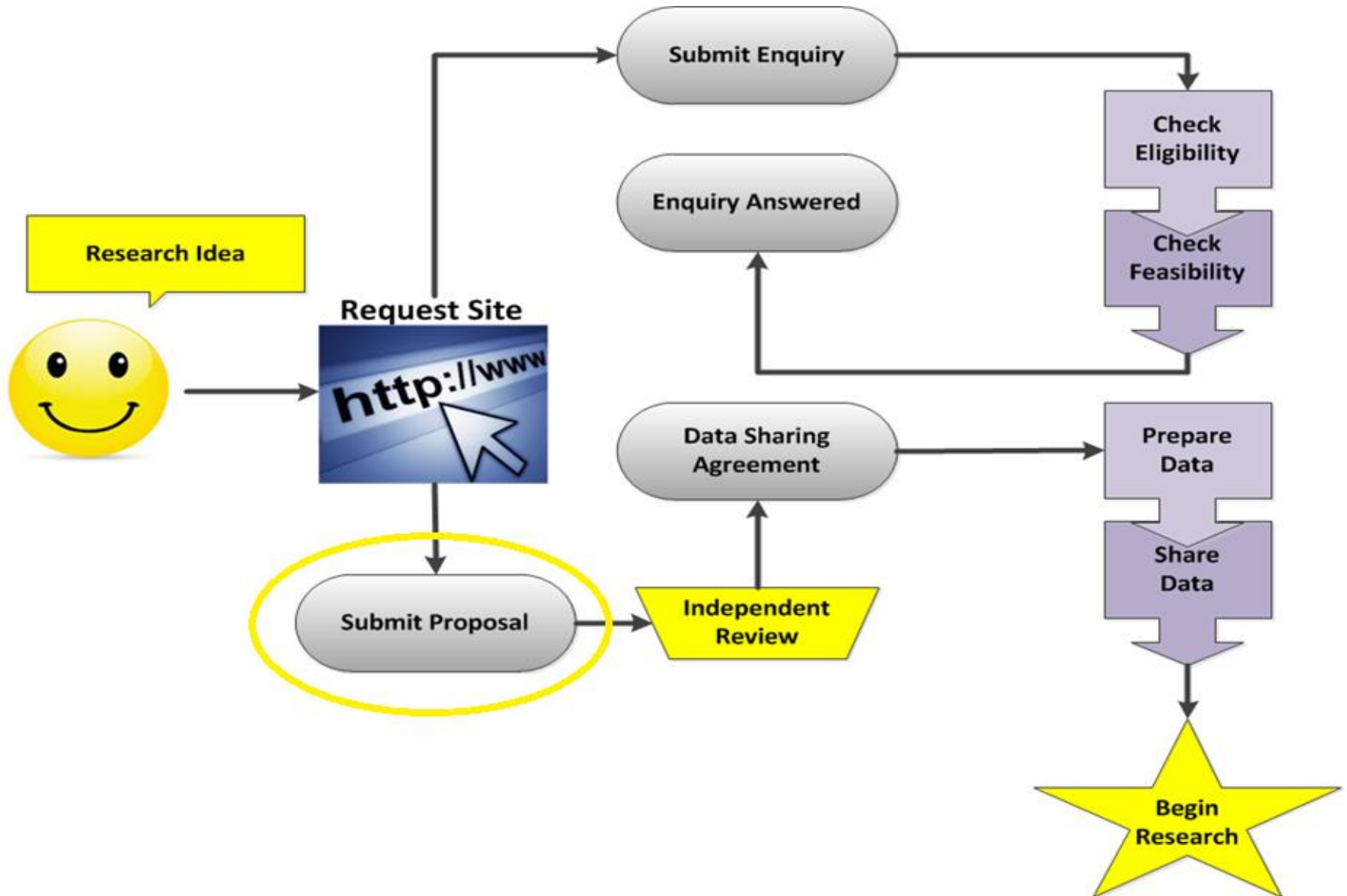
Study Feasibility Check



- Once passed the in scope criteria we locate the data and documentation.
- For studies that have been submitted to the FDA as an electronic submission this is simple as we have all the documents and data ready in one package.
- If not this can be challenge.
- Supply the correct datacut.
- Search other systems for documentation, no simple report available.
- Supporting documentation includes
 - Dataset specifications
 - Annotated CRF
 - Protocol
 - Reporting and analysis plan
 - CSR



Proposals



Proposals



- Proposals received so far can be very simple to the very complicated !
- Feasibility assessment :

Research Proposal complete ,
understandable, in English?

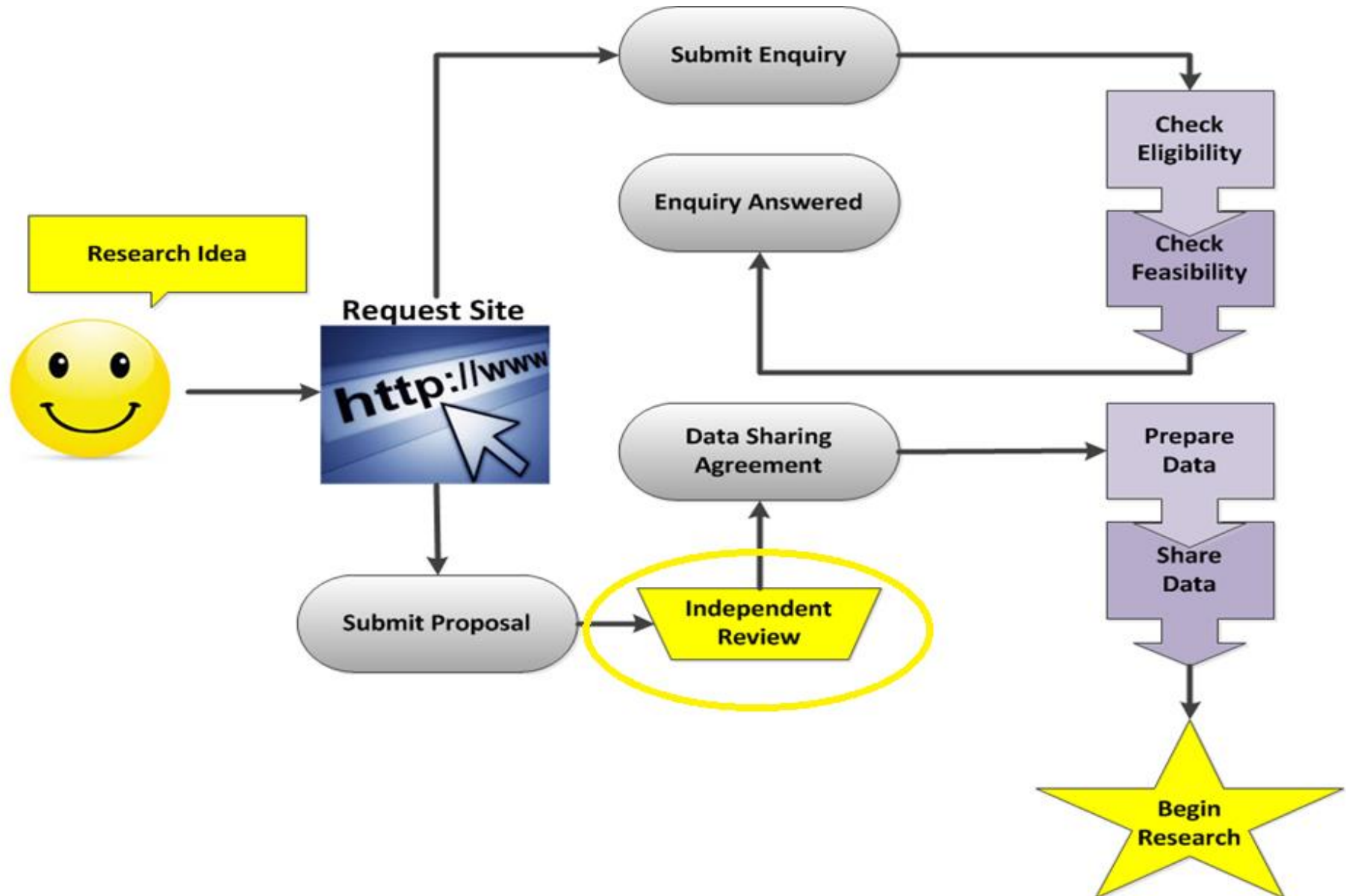
Qualified statistician?

Research Proposal relate to data from clinical studies
which are listed on the request site and are the
requested datasets and documents available?

Research Proposal related to the
medicine or disease researched
in the selected studies?

Research proposal align with
the sponsors' requirements?

The Independent Review Panel.



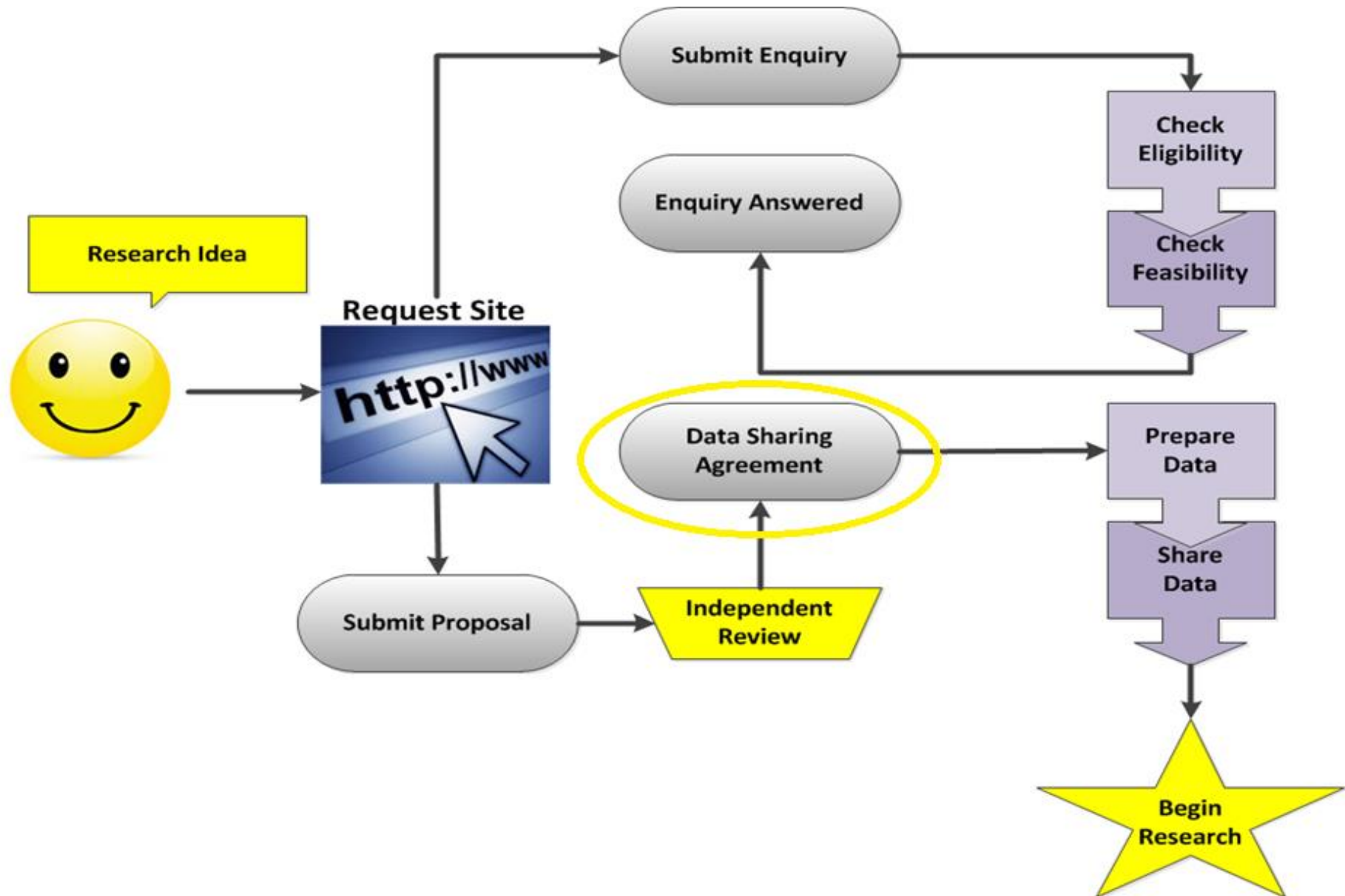
The Independent Review Panel.



- Once passed the feasibility stage we locate all required data and documentation.
- The proposal is then passed to the Independent Review Panel who review proposals based on the following criteria:
 - The scientific merit of the proposed research to medical science or patient care.
 - The ability of the proposed research plan to meet the scientific objectives. This is a high-level review.
 - The publication plan for the research.
 - Real or potential conflicts of interest
 - The qualifications and experience of the research team to conduct the proposed research.



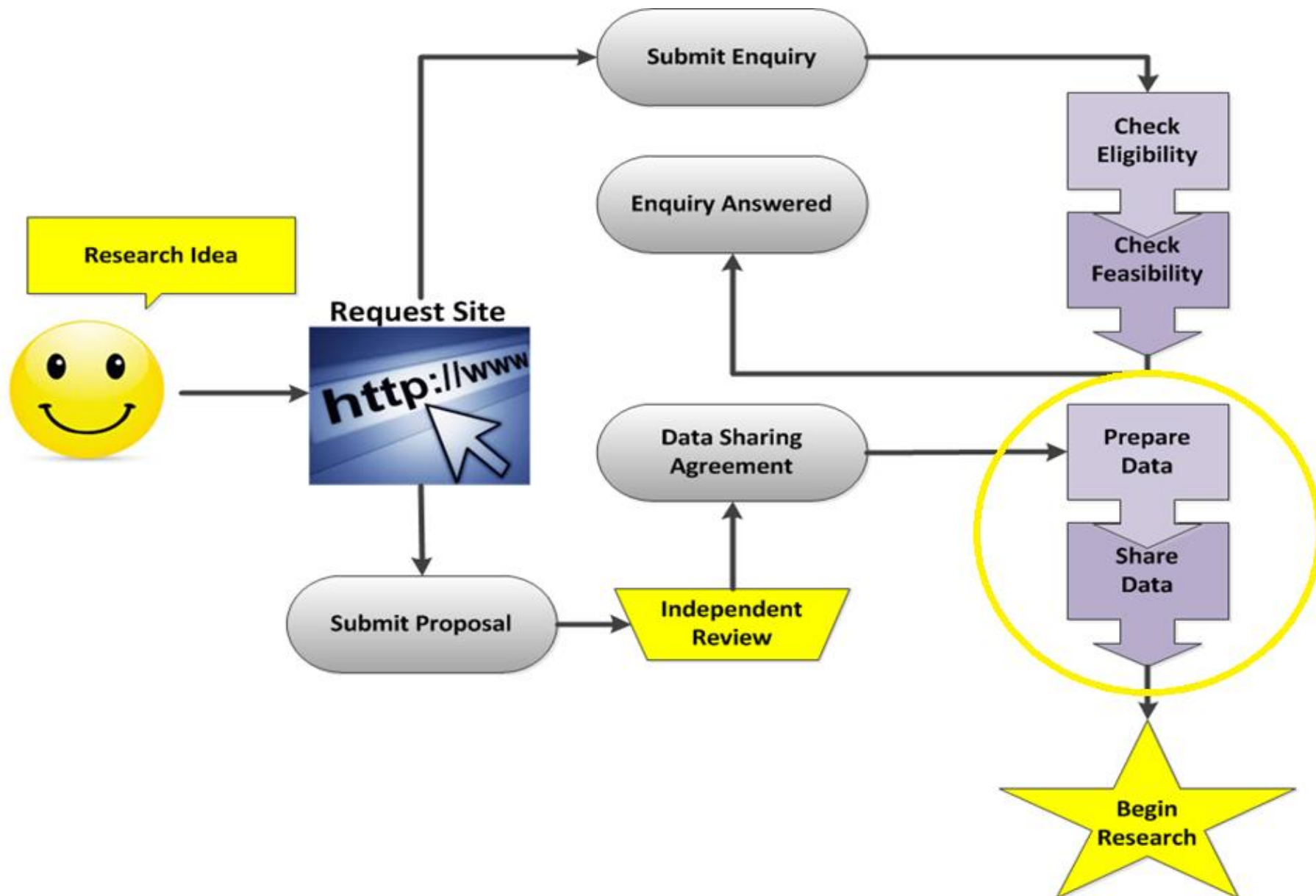
The Data Sharing Agreement



The Data Sharing Agreement

- Following approval by the IRP, access is provided after the relevant study sponsors receive a signed Data Sharing Agreement.
- This includes requirements for the research team to follow certain stipulations such as
 - Only use the data for the agreed research purpose and not download or transfer the data for future use.
 - Protect the privacy and confidentiality of research
 - Obtain any regulatory or ethics approvals
 - Inform any safety concerns as soon as they are identified.
 - Publication of the research in a peer reviewed journal.





Data Package Creation including Dataset Anonymisation.



- To create anonymised datasets we remove any personally identifiable information.
 - Remove original patient id and centre number and replace with new random id and centre.
 - Remove verbatim text, comments.
 - Remove all dates and replace with study day, replace DOB with age.
- Separate project area on computing environment for data to be anonymised.
- Store pdf copies of the supporting documentation there.



The Programming Part !



- Internal macro created for standard anonymisation.
- Requires preprocessing of the data to fit into the macro.
- Some examples or preprocessing are

Ensuring dates are correctly named to be identified

Removal of specific identifying parameters from vertical structure datasets

The Programming Part continued ..



- Even with macros and standard programs a manual review of each and every dataset is required.
- Each project and study has different variations so unless this review is performed patient identifiers can be missed.
- Balance between anonymisation and still keeping the data medically relevant.
- Free text considered a high risk as a patient identifier
- Growing in confidence over time.
- Team discussions for resolutions.

The SAS bit !



- Data and supporting documentation is loaded into the SAS CTDt portal to be shared.
- Based on SAS Drug Development.
- ‘Locked’ box approach.
- Researchers access their research area where the requested studies are listed.
- Own working environment to create programs, store outputs and data.
- SAS, R-studio and Open Office tools available.
- Controls on exports and downloads to ensure data is not taken out of the system.

What skills are needed to work in data sharing ?

- Experienced in liaising with and knowledge of other functions and the Pharma organisation and its processes.
- Therapeutic knowledge of clinical trials.
- Investigative ability to research and link patient level datasets, study documentation and regulatory knowledge.
- Good communication skills as you will spend a lot of time liaising with other groups both internally and externally to your company.
- Analyst skills, to make decisions and be proactive.
- Ability to improve processes, working practices, make recommendations and implement as the role of data sharing evolves



Questions?



Doing now what patients need next

Back Up Slides

Providing Data to Collaborations with Roche Involvement



- We have also created an internal process for project teams in Roche who need to provide data to existing collaborations.
- In these cases we provide a data anonymisation service but all other steps are managed by the project teams as below
 - Agreement with third party researcher over planned analyses, future sharing of results of analyses with Roche and plans to publish.
 - Identification of studies and datasets that need to be provided, including any study specific issues.
 - Overall accountability for ensuring Data Sharing Agreement is created and signed off
 - Confirmation that Roche are the owners of the data and are able to share those
 - Sending the data and documents and responding to any queries from the third party

The Impact of Data Sharing on You

- For studies which statisticians and programmers work on now....
 - the audience for CSRs and datasets will change
- For development projects you will work on in the future...
 - you will be able to use information from many more sources
- End-game for studies and data is no longer regulatory submission
- Tomorrow's Data Leaders will be:
 - those who know where the **relevant data are located**, how to **access** it, how to **aggregate** it, how to **analyze** it for meaning and how to **effectively communicate** insights

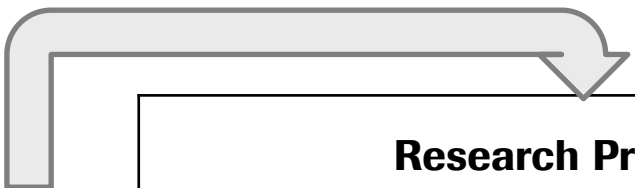


Data Sharing Requests so far (CSDR.com)



Jan – 09 Oct 14

Patient Level Data requests from CSDR.com



Received Total	Enquiries	Research proposals	Research Proposals				Access Provided Research Begun
			In Progress	Rejected before IRP review	Proposal Answer- ed	IRP Approved	
15	6	9	3	1	2	3	1

Patient Level Data requests direct to Roche teams:

Support for 5 Roche requests (i.e. project teams sharing data externally):

- providing advice
- data anonymisation/de-identification service
- data sharing agreement support