# PIONEERING THE DATA TRANSPARENCY ERA
# THE CORE BEHIND

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## WHY NOW?


## CONVERGING FORCES

- Regulatory/Health Authorities
  - EMA publish clinical-trial data and enable access to full data https://www.clinicaltrialsregister.eu/ (ABPI monitoring) revising EU directive to include data
  - FDA http://www.clinicaltrials.gov/ JANUS
  - NCI funded research publish data with the publication
- Patients
  - Patient advocacy groups
  - Informed and active patients
- Consortiums, other
  - CEO Roundtable LSC Task Force
  - NICE and the AllTrials campaign to make all clinical trial data available for public scrutiny

EMA DRAFT GUIDANCE

## DETAILS

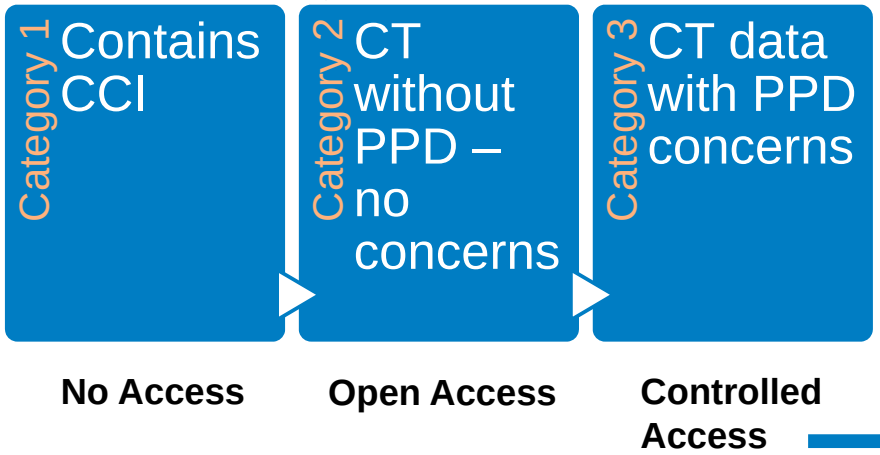
- Clinical trial data is not commercially confidential information
- Measures against inappropriate secondary analysis that protect public health
- Ensuring that transparency is a two-way street

*Raw CT data*: For the purpose of the policy, raw CT data shall mean individual patient data sets, individual patient line-listings, individual Case Report Forms (CRFs), and documentation explaining the structure and content of data sets (e.g. annotated CRF, variable definitions, data-derivation specifications, data-set definition file). It also includes supporting documents, such as test outputs (if not contained in the statistical analysis plan (SAP)), Statistical Analysis Software logs and SAS statistical programs (if code not included in the SAP).



EMA DRAFT GUIDANCE

## DETAILS




- Identified researcher
- Natural or legal person established in EU
- Legal agreement with requestor
  - No new marketing outside of EU
  - Make analysis public

Press release

## European Medicines Agency to push ahead in 2014 towards publication and access to clinical trial data

The European Medicines Agency (EMA) has now reviewed all comments received on its draft policy on publication and access to clinical trial data. While the comments received showed that there is large support for the Agency's plans to allow access to clinical trial data submitted as part of marketing authorisation applications, they also highlighted that there is a need for further analysis and clarification of certain aspects.

The Agency will continue to work with stakeholders, including industry, academia and civil society organisations, to further clarify and fine-tune the proposed rules to achieve the broadest possible consensus. This work will be guided by a set of key principles that were agreed with the Agency's Management Board on 12 December 2013. The policy on publication of and access to clinical-trial data and an implementation plan will be discussed at the March 2014 Management Board meeting.

The key principles include a stepwise approach for implementation with, as a first step, preparation for the publication of clinical study reports redacted as appropriate, the development of a methodology for de-identification of patients, and the definition of a standard format for the submission of data. The principles also foresee the introduction of preliminary steps prior to data access designed to address the risk of possible unfair commercial use of data while ensuring proactive and non-selective access ('use control' not 'access control').

The Agency reiterates its firm commitment to pursuing the objective of full transparency regarding clinical trial data. The Agency will continue to monitor progress in the Court cases brought by two pharmaceutical companies against the Agency and the on-going discussions on the new European clinical trials legislation. It recognises the need for consistency in the general approach to access to documents by EU institutions and bodies, while recognising the specificity of documents in the possession of the EMA and the Agency's primary duty to protect and foster public health.

The Agency's draft policy has prompted broad debate among an unprecedented range of stakeholders, including the important focus on the benefits to patients, and more generally to society of giving access to clinical trial data and on the best approach to achieve this. It has been the catalyst for various initiatives from the pharmaceutical industry, funding bodies and academia centres in this direction.



## CLINICAL TRIAL DATA TRANSPARENCY

**AN INDUSTRY APPROACH SPONSORED BY SAS**

- Initial Clinical Trial Data Transparency environment with GSK early 2013
- Other Life Sciences companies interested in joining
  - Verbal commitment from multiple other companies
- Need neutral party to coordinate companies around approach and governance

**SAS Support for Industry Coordination**

- ✓ Two GSK-demo Webinars (7/31 and 8/9)
- ✓ Weekly roundtable discussions
- ✓ Clinical Trial Data Transparency Forum (10/17/13)

**Over 140 people from approximately 60 companies engaged*

Invited participant at EFGCP Multi-Stakeholder Roundtable Meeting on Sharing Clinical Trial Data in the Interest of Patients and Research (Brussels)

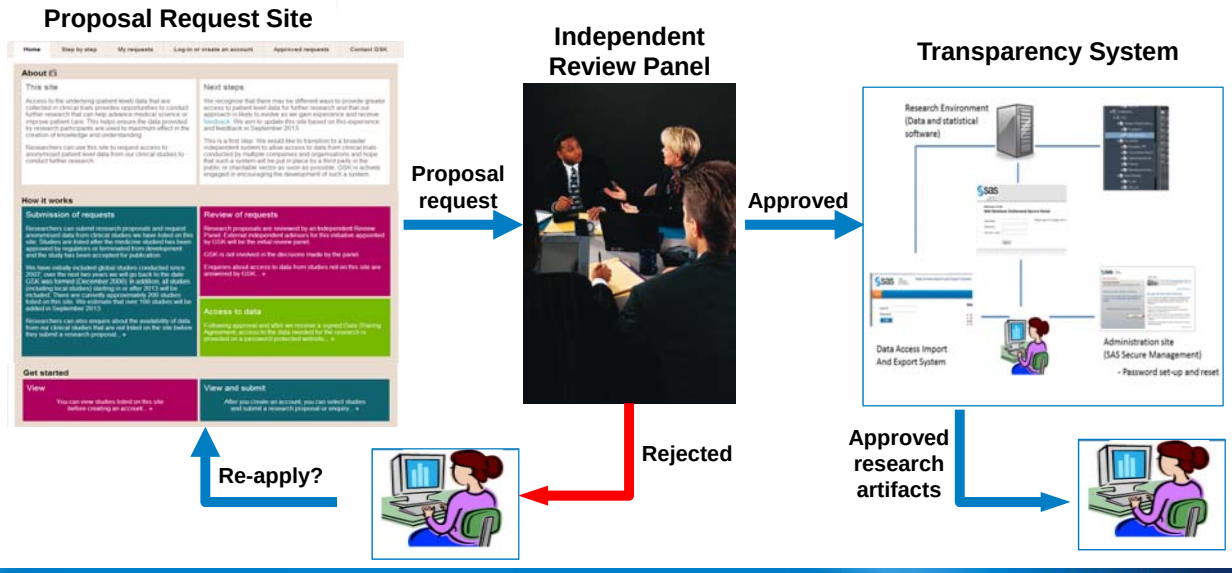
EXPERIENCE TO DATE

## HIGH LEVEL REQUIREMENTS

- Provide repository of research data, programs, output and reports
- Provide researchers access to the content and analytical tools
- Control uploads and exports of content
- Make the environment self-service
- Aggressive go-live timeframe

CLINICAL TRIAL DATA TRANSPARENCY

## BASIC WORKFLOW



CLINICAL TRIAL DATA TRANSPARENCY

## CRITICAL SYSTEM CAPABILITIES

- Proposal request system and approval process
- User registration process
- Data transfer into the transparency system from sponsor systems
- Researcher access to analytical tools
  - SAS
  - SAS Visual Analytics
  - Others as needed, such as R
- Training / Help / Videos / tech support
- Managed extraction of scripts and results from system
  - Data cannot be extracted / exported


Implementation principles
- Hosted by SAS
- Secure data repository
- Easily accessible to researchers
- Ongoing system monitoring and support



DATA TRANSPARENCY

## SAS CLINICAL TRIAL DATA TRANSPARENCY

- Single external interface
- Data segregated by company but accessible by researcher
- Single process for researcher request that can span multiple companies' data
- Single independent review board and process
- All tools available within secure environment
- Needs consensus
  - how far back to go
  - data standards
  - data deidentification
  - tools available
  - import/export process