Sanofi's Commitment to Sharing Clinical Trial Data, Information, and Results

Implementation Overview & Best Practices for Internal Data Sharing

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Agenda

- Part 1: Implementation - Data sharing Models
  - Sanofi's commitment to share
  - What data will be shared
  - How it works
  - Where are we with implementation
  - Overview of roles
- Part 2: Best Practices for Data Sharing

Access Models: One size doesn't fit all..

1. **Black Box, or Database Query model:**
   - May be suitable for some types of very sensitive health information

2. **Gatekeeper Model:**
   - PhRMA / EFPIA principles
   - Independent review board
   - Limited access, and broad data
   - Protection of Confidential Commercial Information

3. **Broad Access Model:**
   - Immune Tolerance Network, Sage Bionetworks, and *Project Data Sphere*
   - No Independent Review Panel
   - Responsible-use attestation
   - Broader access, but less data. Data integration. Crowd

Sanofi is Committed to Sharing Clinical Trial Data, Information, and Results

- **Making clinical trial data, information and results available to researchers, promises to advance science and medicine, contribute to improvements in public health and improve knowledge about, and trust in, pharmaceutical product development**
- **It is equally important to protect the privacy of the participants in our clinical trials as well as to maintain incentives for investment in biomedical research**

Sanofi will make clinical study data available for request:

Sanofi Companies* will make clinical study data available for request:

- For drugs and biologics:
  - phase II - IV trials in patients sponsored by a Sanofi Company
  - submitted to the US and EU regulatory agencies as part of the request for marketing authorization for new medicines or a new indication for an approved medicine;
  - approved by both agencies on or after January 1, 2014;
    - For new indications, only studies submitted in the application in support of the new indication
  - the trial results have been published
- For vaccines:
  - phase II-IV studies in healthy volunteers
  - submitted to the US or the EU regulatory agencies as part of the request for marketing authorization for new vaccines or a new indication for an approved vaccine;
  - approved on or after January 1, 2014;
    - For new indications, only studies submitted in the application in support of the new indication
  - the trial results have been published

* Sanofi Companies include: Sanofi, Sanofi Pasteur, and Genzyme Corporation

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What will be Shared with Researchers
in the SAS controlled-access data sharing environment

- **Patient Level Data**
  - Raw Data in CDISC Study Data Tabulation Model (SDTM) format. This is the raw data collected for each patient in the clinical trial mapped to CDISC standards and is analysis ready.
  - Dataset specifications. This is the meta-data which describes the datasets, e.g., variable labels, variable descriptions, code lists, formats.

- **Clinical Documents**
  - Clinical Study Report, which has been redacted by the Sanofi business owner with respect to commercially sensitive information and anonymized to protect patient privacy
  - Protocols with any amendments. This describes the objectives, design, methodology, statistical considerations, and organization of a clinical trial.
  - Annotated case report form. This is a blank case report form with descriptions of the data collected and how they are described in the dataset.
  - Statistical methodology. This describes methods of analysis, procedures for data handling. (included in CSR)

High-level Overview of how it works

- Request access to data via Scientific Proposal
- Technical requirements met – e.g. statistician, publication plan, statistical plan, etc…
- Reviewed for potential conflict of interest or actual or potential competitive risk
- Reviewed by Independent Panel of Experts
- If approved, will sign data use agreement and will have access to the data for 12 months

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Before the data are shared

- De-identify patient level data – to protect privacy
- Expert certification of patient level data

- Redact clinical documents, e.g. CSR for privacy and Commercially Confidential information
- Patent's approval on redacted documents

- Signed Data Sharing Agreement

Where we are with implementation

Phase I - Jan 1, 2014 - Commitment

- Sanofi Policy / Directive
- Sanofi.com website updated
- Sanofi included in data request portal - ClinicalStudyDataRequest.com
- External Communication - Sanofi Press release
- Independent Review Panel

Phase II – Preparing to share (4Q2014)

- Established cross-functional working teams to define end to end processes and accountability
- Implementation of SAS data repository
- Quality Document Package developed

Phase III - Steady State – (4Q2014+)

- Roll-out and training to product specific teams

- Active ongoing involvement in consortia representing Sanofi in the evolution of the multi-sponsor data sharing environment

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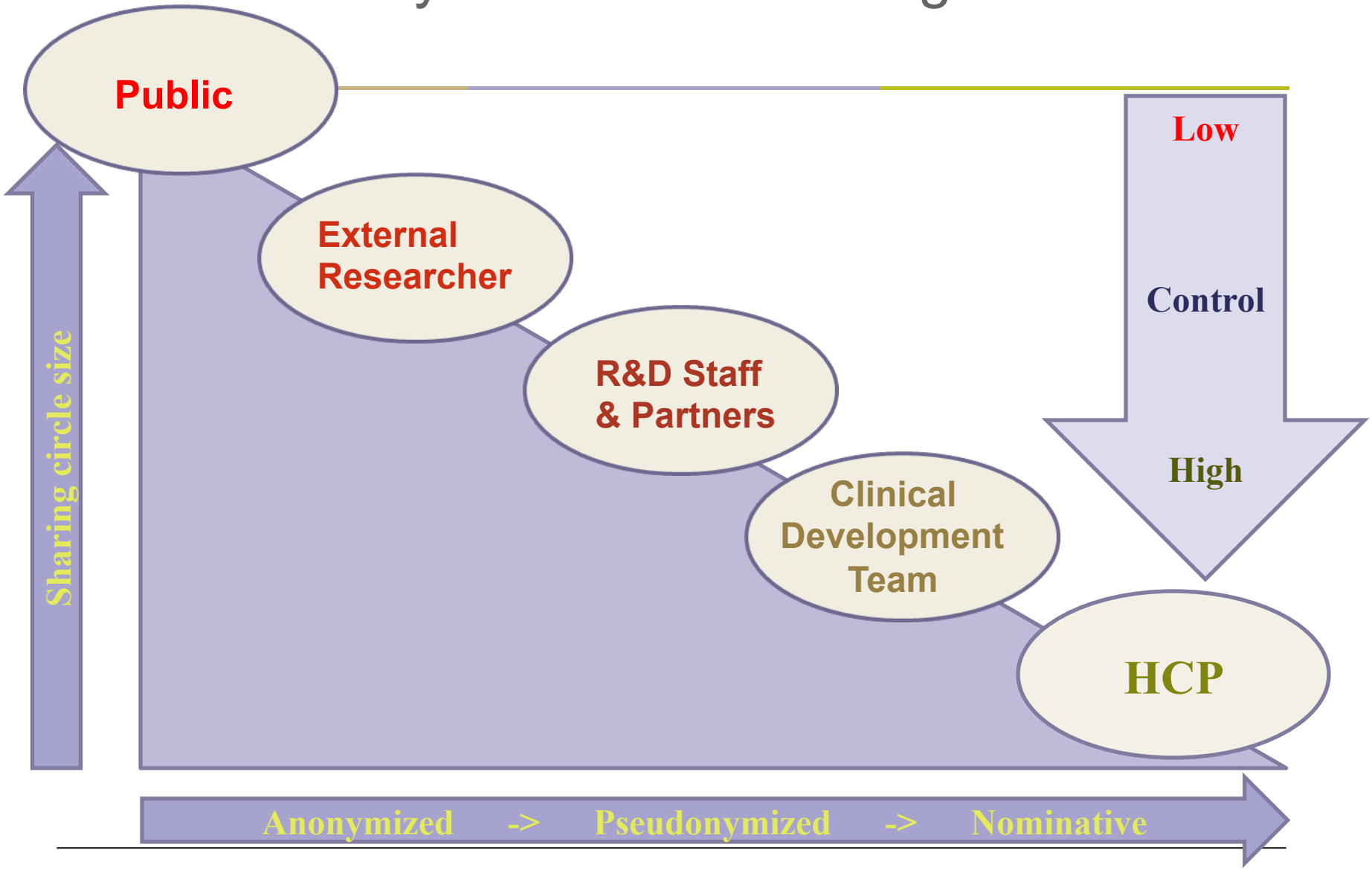
Clinical Data Sharing Role Descriptions

- **Central DSC** – Oversee clinical trial data sharing initiative, coordinate efforts between each company specific DSC to ensure execution of processes, manage the monthly steering committee reviews and ensure escalation process
- **Company Specific DSC** - manage and coordinate efforts between Central DSC and team members to ensure implementation of processes
- **Project Medical Manager / Clinical Lead** - Work with the responsible parties to determine trial eligibility and to support the data preparation processes, de-identification and redaction of clinical data
- **Biostatistician / Programmer** – Work with responsible parties to develop de-identification plan for approved data sets, execute plan including external certification, upload of final data to repository.
- **Medical Writer** - responsible for the redaction of the CSR and its associated appendices that were approved for sharing.
- **Patents / Legal** - Support de-identification and redaction efforts. Review approved datasets and associated documents for commercially sensitive data and conflicts of interest. Preperation of the Data Sharing Agreement.
- **Steering Committee –** with the DSC's and relevant stakeholders, review and approve clinical studies to be shared as well as review and approve requests for data from research proposals

Level of anonymization vs sharing circle



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Internal Clinical Trial Data Sharing

Clinical Trial Team

Study Director, Medical Advisor, Statistician, Clinical Trial manager, Monitor, CRA, Data Manager, Statistical programmer, Medical Writer, Safety Officer, Quality Officer etc.

Clinical Development Team

Scientists from pharmacokinetics, pharmacogenomics, regulatory, IT specialists, etc.

R&D Members

People working in all areas from discovery research, in vivo and in silico testing…

Collaborative project partners

Members of other pharma companies, biotechs, university, public & private research institutions…

Anybody

Who can access the internet!

Control Mechanisms

Clinical Trial & Clinical Development Team

Data: pseudonymized

IS Security : Role based data access on "Need to know" basis

Legal : employment contracts & non-disclosure agreements

Compliance : procedures, training & audit

Other R&D Members

Data: Anonymization + ISS, legal & compliance as above

Collaborative project partners & external researchers

Data : Anonymization, ISS as above + contractual clauses, audit

Anybody

Data : Strongest anonymization and restrictions on which studies can be released

De-Identification of Clinical Trial Data for Further Internal Research

Which datasets

Raw study dataset

Analysis-ready dataset

De-identification process

Removal of 18 identifiers (HIPAA Privacy Rule)

Removing Free Text Verbatim Terms

Replacing Date of Birth with Age

Replacing Original Dates

Removing Other PII (e,g, investigator info & geographic location)

Removing genetic data rich enough to single out a person

⇒ **Other molecular data (including omic data) are retained**

Review and Quality Control

Removal of personally identifiable information

Center ID	Investigator ID (INVID)	Subject ID (SUBID)	Unique Subject ID (USUBID)	Age in years	Age category	Enrollment date	Date of death
001234	279344	22	TJF278401	57	<=89	29DEC2010	27JAN2011
001234	279344	48	TJF278424	92	> 89	10JAN2011	06APR2011

Remove precise geograhical information

Remove INVID

New SUID for each subject

New USUBID for each subject

Remove age above 89

Create age category

Add dummy dates

Calculate duration

Region		Subject ID (SUBID)	Unique Subject ID (USUBID)	Age in years	Age category	Enrollment date	Date of death	Survival time (days)
Europe		1962	TJF278428	57	<=89	19AUG2010	17SEPT2010	29
North America		1978	TJF278443	90	> 89	06JUL2010	30SEP210	86

Questions?