

Working Party for Information Security and Privacy (WPISP)
Working Party on the Information Economy (WPIE)



Joint WPISP-WPIE Roundtable

**The Economics of Personal Data and Privacy:
30 Years after the OECD Privacy Guidelines**

Use of health data in Pharmaceutical Research & Development

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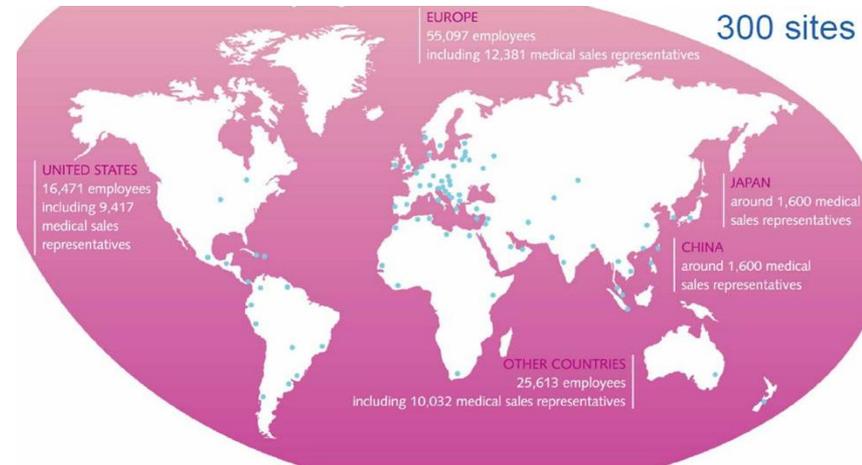
Because health matters

A project-based organization

- Discovery Research
 - Identify promising research targets for therapeutic innovation
 - Discover and propose new compounds for development

- Development
 - Turns compounds into medications
 - Project team is formed: researchers, clinicians, pharmacists, toxicologists, representatives from regulatory affairs and marketing
 - Task: develop the compound all the way to marketing
 - Several clinical trials are needed

- □ International R&D teams
 - Located in over 25 centers on 3 continents
 - Trials in over 300 sites



- Designed to verify the efficacy and safety of a compound for use by human beings
 - Takes place after in vitro and animal studies (preclinical testing)
 - The compound is compared either to a placebo or to existing treatments
 - Determine whether it is more or less effective
 - Determines the effective dose
 - Determines possible toxicity, nature and frequency of adverse events
- □ A mandatory step to get approval of a drug
- Also used to define patient categories
 - Responders vs. non-responders

Clinical trials organization

- Clinical trials are driven by our company (sponsor)
 - Trials are designed by us
 - Medical part of the study is led by one of our clinical study directors independent physician who will lead the
 - Trials are conducted by several physicians or hospital teams in several sites at the same time
 - A protocol (validated by an independent ethical body) describes all details related to collection and analyses of data and samples
- 3 mandatory steps for each study to bring a drug to the market
 - Phase 1: Evaluation of the product's **safety** and internal body evolution
 - Phase 2: Product's **efficacy** testing and optimal **dose** determination
 - Phase 3: **Comparison** of the compound efficacy to a reference treatment or to a placebo

Where do health data come from?

Phase 1 to 3

- Healthcare professionals (HCP) treat patients according to the protocol
 - Any analyses/ examination planned in the protocol is run by a HCP and paid by the sponsor

- Patient results are registered in the hospital/ physician's computer, and also registered on-line by the HCP (or sent by fax) for the sponsor
 - Directly nominative data in the hospital/ physician computer
 - Coded data (identity details replaced by a number – key known by the HCP only)

- There is no connection between the hospital and the sponsor IT systems (yet)!

- Clinical data and preclinical data are merged to prepare a registration file
 - Submitted to public Health Authorities for license to market
 - Individual coded raw data must be provided as well as statistical results

Post-marketing: Phase IV studies

- Trials continue throughout the drug marketing life
- Phase IV trials are carried out after approval of the drug, in conditions close to those of usual medical care
 - Detect possible rare undesirable side effects which had escaped attention in the previous phases (Pharmacovigilance)
 - Define conditions of use for certain groups of at-risk patients
 - Procedure is very similar to phase 1 to 3
 - Requires protocol and approval (but is often simpler), expenses paid by the sponsor, coded results transferred to the sponsor, no connection between HCP and sponsor IT systems
 - Additional safety study or life quality study: more patients, less data per patient

Post-marketing: Epidemiology studies

- Epidemiological studies are very different
 - Use existing data: no additional medical act is done = Retrospective study
- When run by us, data are collected through questionnaires sent to the HCP or collected through dedicated web interfaces
- Already existing databases can be consulted or purchased
 - Hospitals or healthcare organization databases, e.g., the French Cancer registry or a US private health insurance database
 - Individual or agglomerated data
 - Consent for sharing data with a third-party is necessary for transferring coded individual data
 - Anonymous data or agglomerated data can be shared without consent for sharing
- No connection between the hospital and the sponsor IT systems

Recent developments

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- Trend away from “universal” medications towards “personalized medicine”
- Different people react differently to medicines
 - A drug can be efficacious with one person and cause severe adverse reactions to another
- Researchers search for biomarkers that help identify how a patient will react to a certain drug
 - Biomarkers are typically genetic or imaging markers
 - The presence of certain genes or the identification of certain signs on medical images will help to find the right drug for the right patient

- In order to study which biomarkers are linked with which reaction of a patient there is a need to analyze how genetic data correlates with diseases and drugs
 - In clinical trials, more and more genetic data will be collected for this purpose
 - Genetic data will need to be stored in electronic patient records in order for the doctor to prescribe the right medication
 - Notification of adverse events to health authorities will therefore also include more and more genetic data

Pilot project to use EHR

- Recent pilot projects are exploring the possibilities to use electronic health records
 - for clinical research and pharmacovigilance
- They follow exactly the same privacy rules as current clinical trials
 - The sponsor has never direct access to patient data, only to pseudonymized data
- Data would be automatically pseudonymized and transferred to the sponsor
- Adverse events would be directly detected and transferred to the sponsor/ the health authority after approval by the doctor

Questions ?

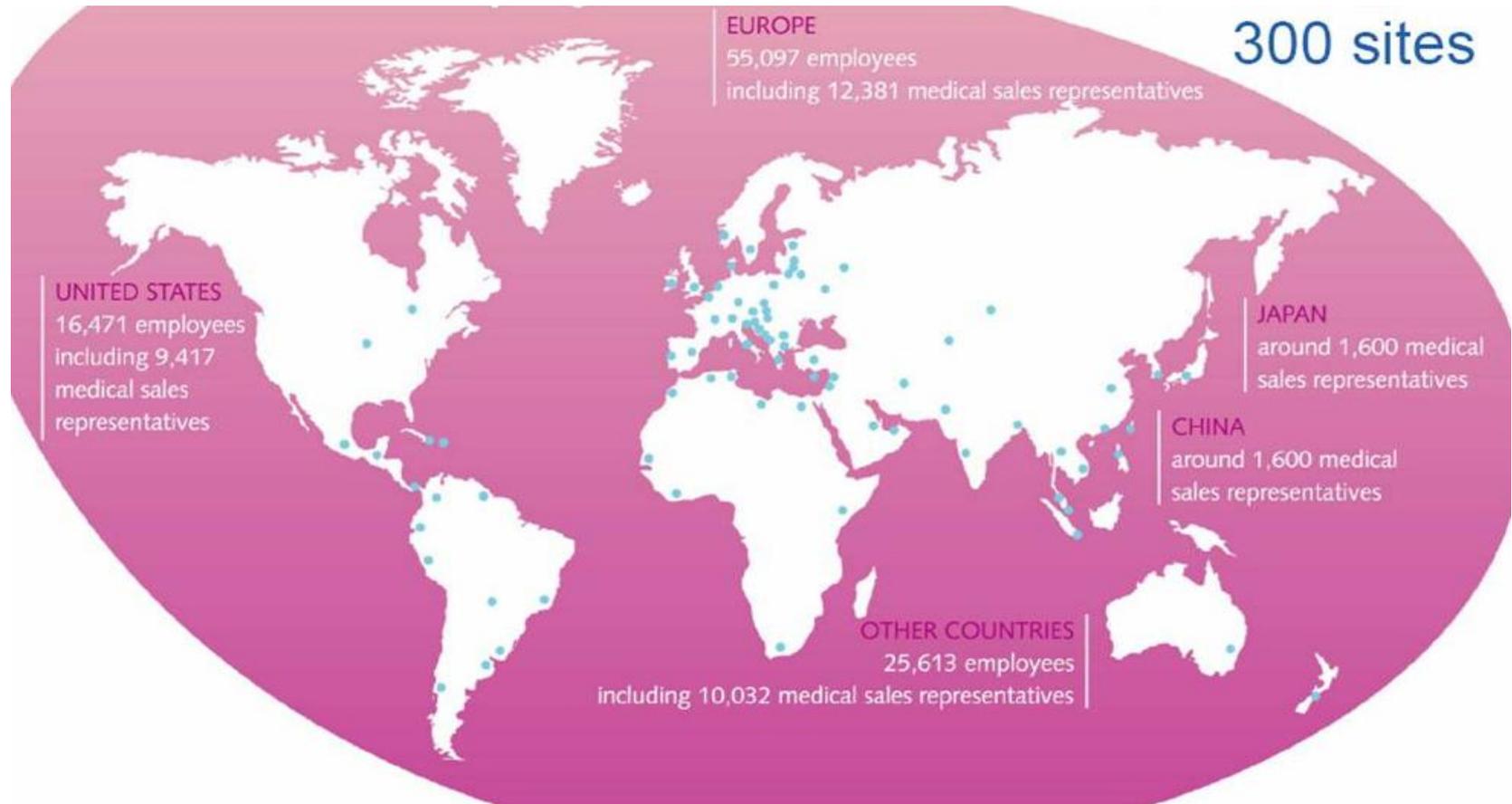
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Sanofi-aventis in the world in 2008



Clinical trials phases details

- Phase I:
 - At this point, the compound is tested mainly on a limited number of healthy subjects*, who may receive compensation and are under strict medical supervision. The compound is tested over a short period of time. The purpose is to evaluate the product's safety, how it evolves within the body, the tolerance threshold and adverse events.
(* Patients are recruited to phase I studies especially in cases such as cancer therapies.)
- Phase II:
 - Testing involves larger groups of patients. The purpose is to test the product's efficacy and determine optimal dosage regimen. These studies are usually comparative: one of two groups of patients is administered the product whereas the other group is given a placebo.
- Phase III :
 - Testing involves large number of patients, with the purpose of comparing the therapeutic efficacy of the compound to a reference treatment (if there is one) or to a placebo (when there is no alternative therapy). Such studies involve generally many study centers in several countries. In most cases, neither the patient, nor the medical profession are aware of what each patient is being treated with (double blind trial): this is to avoid any bias or prejudiced opinion on either side regarding efficacy or adverse events.