Towards better sharing of data & samples collected during trials in resource-limited countries

Les Pensières, 5 November 2015

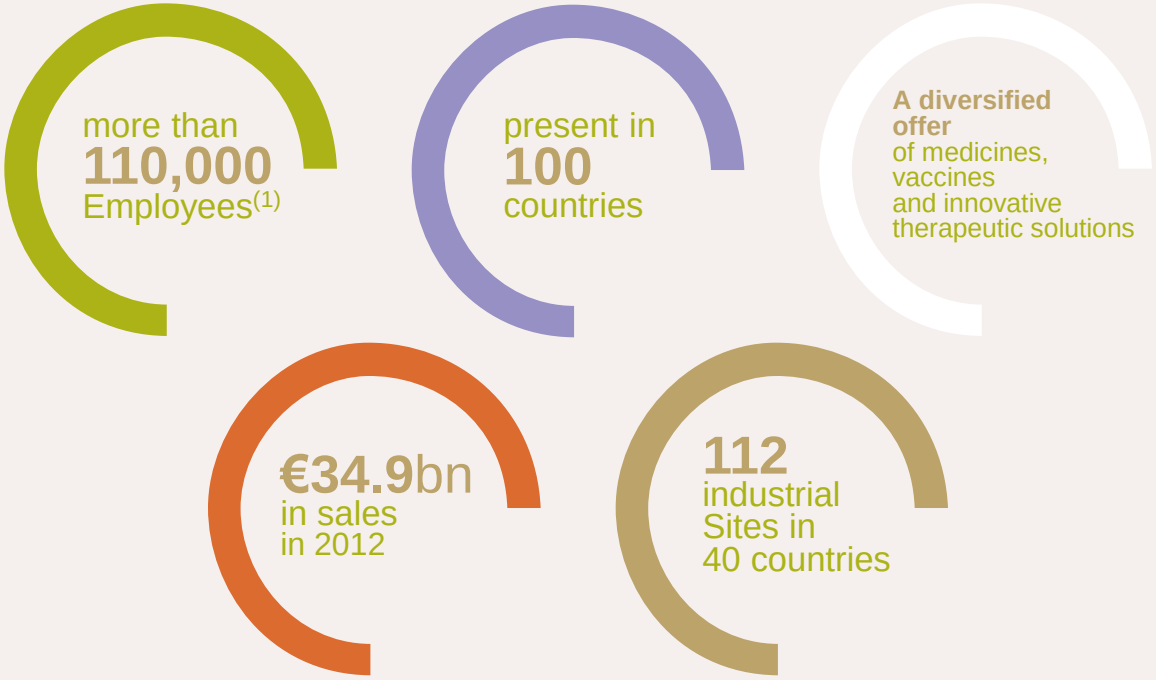
A perpective from the Pharmaceutical Industry

François Bompart, MD
Access to Medicines, Sanofi

Global Health Working Group, EFPIA
(European Federation of Pharmaceutical Industries and Associations)

SANOFI

SANOFI AT A GLANCE



- We are a **global integrated healthcare** company engaged in the research, development, manufacturing and marketing of healthcare products.

- Medicines, vaccines, animal health

(1) As of December 31, 2012

Ethical issues

CORPORATE SOCIAL RESPONSIBILITY

- “Business ethics” (finance, economic intelligence, information ethics…)
- Organizational ethics
- Marketing
- Production
- Conflicts of interest
- Property rights
- International issues
- Bioethics
- Environment
- Animal welfare
- Medical ethics
- Etc.

CORPORATE SOCIAL RESPONSIBILITY

Ethics in clinical trials

Bioethics Committee

CORPORATE SOCIAL RESPONSIBILITY

January 2012: Biotethics Committee creates an "Ethics in clinical trials" sub-committee

Mandate: help ensure that Sanofi

1. **Continues to follow the highest ethical standards for clinical trials everywhere in the world,**

2. **Is positioned as an actor of change and progress, through specific initiatives in the field of ethics.**

3. **Has processes to ensure that new issues and developments in the field are addressed**

Sanofi Bioethics Committee
Informed Consent Process Initiative - Rationale

CORPORATE SOCIAL RESPONSIBILITY

- **Everywhere in the world, informed consent is a complex process**

- **It touches on multiple issues, many of which are related with participants' vulnerability, e.g.**
  - Ability to freely decide on participation
  - Understanding risks and benefits of trial
  - Incentives for participation
  - Post-trial access to medicine / vaccine
  - Indemnification of adverse events
  - Management of intercurrently diagnosed illnesses
  - Etc.

Sanofi Bioethics Committee - Informed Consent Process Initiative: 5 Key Principles

CORPORATE SOCIAL RESPONSIBILITY

1. The study participant must be at the center of the informed consent process

2. Provide selected information that is relevant to the participant's decision to participate or not in the study

3. Information must be provided both orally and in writing.

4. Information materials must be designed to ensure that all information provided is understandable by the participant.

5. Once informed, the participant must be free to decide on his/her participation in a study without incurring any prejudice

Sanofi Bioethics Committee - Informed Consent Process Initiative: 11 Key Elements

Potential participants must be explicitly informed on the following elements:

1. **Purpose and methodology of the study**
2. **Difference between participation in a study and medical care**
3. **Study-specific constraints**
4. **Potential risks and benefits related to participation in the study**
5. **Alternative to participation in the study**
6. **Compensation for expenses during the study**
7. **Indemnification of adverse events**
8. **Participant's post-study access to tested medicine / vaccine**
9. **Study interruption and consent withdrawal**
10. **Access to information**
11. **Participant's privacy and confidentiality of individual data**

Sanofi Bioethics Committee - Informed Consent Process Initiative: Key Elements

Potential participants must be explicitly informed on the following elements:

1. **Purpose and methodology of the study**
2. **Difference between participation in a study and medical care** NEW
3. **Study-specific constraints**
4. **Potential risks and benefits related to participation in the study**
5. **Alternative to participation in the study** NEW
6. **Compensation for expenses during the study**
7. **Indemnification of adverse events**
8. **Participant's post-study access to tested medicine / vaccine** NEW
9. **Study interruption and consent withdrawal**
10. **Access to information**
11. **Participant's privacy and confidentiality of individual data** NEW

Informed Consent Process Initiative: Participant's privacy and confidentiality of individual data

- *DATA : inform participants on*
  - Data privacy
  - Data re-use
  - Transfers to third-parties
  - Incidental findings
  - Etc.

Is « broad consent » permissible?
Is « A la carte » informed consent possible ??

WORK IN PROGRESS

- *BIOLOGICAL SAMPLES : inform participants on*
  - Protection of their privacy
  - Genetic analyses
  - Unplanned re-use of samples
  - Disposal of samples
  - Etc.

EFPIA 2013
Data sharing principles

efpia
European Federation of Pharmaceutical

Companies will provide access to patient-level data and other clinical trial information consistent with the principle of safeguarding patient privacy; patients' informed consent provided in relation to their participation in the clinical trial will be respected. Any patient-level data that is shared will be anonymized to protect personally identifiable information. Companies will not be required to provide access to patient-level data, if there is a reasonable likelihood that individual patients could be re-identified.

A changing environment (1)

- **EU Parliament's proposed amendments to European Commission's proposal for Data Protection Regulation**
  - Emphasis on consent for "specific and similar researches" to authorize re-use of personal data
- **Industry supports call by the European Data in Health Research Alliance**
  - Balance between promoting privacy and research
  - Provide exemption from specific consent for re-use of research data, subject to appropriate and proportional safeguards (e.g. approval by an ethics committee)

A changing environment (2)

US Federal Policy for the Protection of Human Subjects - Proposed changes to the "Common Rule"

- **Applies to clinical trials performed in the US, and conducted by an institution that receives support from a Federal department or agency for human subjects research**
- ***Comments by Dec 5, 2015***

- Informed consent required for secondary research with "biospecimen and identifiable private information"
- Proposed **"broad" consent** form in which a person would give consent to future unspecified research uses
- Would not apply to existing collections

"The Secretary will publish guidance at a later time to explain how consent forms can be written in order to comply with the requirements of this policy"

Ongoing work

- **IMI 2 “Big data for better outcomes” Programme**
  - **Joint EFPIA – European Commission funding**
  - **Objectives :**

    Define standards for personal data protection collection analysis and management

    Single EU informed consent provisions for data protection
  - **Industry / Academic collaboration. Academics wanted !**

  - **Key dates**
    - Publication date: 6 October2015
    - Stage 1 submission start date: 6 October 2015
    - **Stage 1 submission deadline: 12 January 2016**

CORPORATE SOCIAL RESPONSIBILITY

CONCLUSION

Ethics and Corporate Social Responsibility (CSR)

CSR European Commission 2011 definition*:

"The responsibility of enterprises for their impacts on society".

"To fully meet their social responsibility, enterprises should have in place a process to **integrate social, environmental, ethical, human rights and consumer concerns** into their business operations and core strategy in close collaboration with their stakeholders."

- **A renewed EU strategy 2011-14 for Corporate Social Responsibility. Brussels, 25.10.2011 COM(2011) 681 final**

« Four prevailing justifications for Corporate Social Responsibility »

Harvard Business Review

- **Moral obligation**

  « Do the right things »

- **Sustainability**

  « Achieve commercial success in ways that honor ethical values, and respect people, communities and the natural environment »

- **License to operate**

  « Every company needs tacit or explicit permission from governments, communities and numerous other stakeholders to do business »

- **Reputation**

  « Improve company's image, strengthen its brand, enliven morale and even raise the value of its stock »

Ref: The Link Between Competitive Advantage and Corporate Social Responsibility - Michael E. Porter and Mark R. Kramer, Harvard Business Review, December 2006

SANOFI

Conclusion

CORPORATE SOCIAL RESPONSIBILITY

- **Good ethical standards defined and enforced: a condition for good science and good business**
  - **No double standards**

- **Adherence of all players to similar ethical standards is an absolute necessity**
  - **Incentives**
  - **Monitoring**
  - **Sanctions**

CORPORATE SOCIAL RESPONSIBILITY

Contact : francois.bompart@sanofi.com

SANOFI