# *PRINCIPLES OF GOOD RESEARCH PRACTICE*

Non-regulated research activities (not falling within the scope of Good Laboratory, Good Clinical Laboratory, Good Clinical and Good Manufacturing Practices) must follow defined practices to guarantee the reliability and traceability of data. These principles apply to all researchers involved in internal and external non-regulated research activities for Sanofi and all Countries.

- **General Requirements**

Data from the non-regulated research of new products must be reliable to ensure a solid basis to decide whether to invest in the further development of a product.
Data must be accurately recorded to ensure traceability and recovery of any results, decisions, references, and knowledge that could be used in other studies, submissions, and to support patents and publications.
A quality oversight must be put in place according to specific needs and adapted to the development level of the work. It will be ensured in case of data submission.

- **Personnel**

Personnel must be qualified and trained for the activities performed.
Management must ensure that adequate level of technical skills and practices are in place.
Training records must be available for all individuals conducting non-regulated research activities.

- **Buildings**

The laboratory organisation, together with personnel and material flows must ensure a separation of the different activities to guarantee the execution of each activity.
The environmental conditions must be suitable for use.
Areas must be secured with limited access according to the type of activities performed.

- **Equipment**

All equipment must be suitable for its use.
Key equipment must be calibrated, maintained, and monitored by qualified personnel to ensure accurate and consistent performance.

Any intervention on key equipment and computerized systems, including repairs, routine maintenance, non-routine work, or calibration must be performed and recorded to ensure reliability of data and prevent from loss of data.

- **Information Systems**

The information systems (i.e., software, networks) must acquire, restore, process and store electronic data in a secure and reliable way.

- **Reagents**

Reagents must be managed in a manner to assure identification, use, storage, and disposal.

- **Test Materials**

All test materials (including but not limited to small molecules; biologics; genetic material etc.) and reference items used during non-regulated research activities must be stored, identified, and used to prevent contamination, deterioration or damage ensuring the accuracy of the results derived from their use.
For all research activities using lead candidates, development candidates, compounds in development and marketed materials, analytical data must be available for each batch used.
Biological and chemical risks for human health and environment must be identified, assessed, reported, and managed according to and by the Health, Safety and Environment management.
As soon as data are available, Safety Data Sheets must be used as reference.

- **Test Systems**

The origin, characteristics, arrival date, and conditions upon arrival of test systems (e.g., animals, cell lines, proteins, etc.) must be recorded and archived.

- **Documentation**

All paper or electronic data which is generated must be recorded to ensure traceability, reproducibility and validity of the study or experiment.
Documentation must be done in a manner to ensure that it is of sufficient quality to support decision making during the life cycle of the drug, to protect Sanofi's intellectual property (IP) and to follow regulatory requirements.

Prescriptive documents, including proposals of research topics, protocols or study plans and techniques or procedures must give all instructions for the conduct of a study or experiment and must ensure protection of IP rights and all compliances related to local applicable regulations.
When applicable, approved techniques and procedures or guidelines must be immediately available and understandable to all individuals performing non-regulated research activities.
Descriptive records, including raw data, any derived data, study reports, publications and patents if required, must describe the observations made during a study or experiment.
Data must be recorded promptly, accurately, legibly, indelibly and identified to prevent errors and ensure traceability, reporting, easy recovery, archiving.
Data and records must be authenticated to ensure Intellectual Property rights.

- **Data Submission**

Any study report used to support a regulatory submission must be assessed for compliance with regulatory expectations and with the applicable procedures, standards of Sanofi or those of the Countries.
Availability of raw data and consistency between this raw data and data in the final report must be ensured before submission.
Studies that are used to support a regulatory filing must be handled as evaluation data and may be requested or inspected by Regulatory Authorities.
Wherever needed, compliance with regulatory and local requirements must be regularly assessed through audits and self-inspections.

- **Data Sharing and Publication**

All collected data must be considered as confidential.
All collected data must be protected as part of Intellectual Property.
Non-regulated research personnel publishing results must do it responsibly, being fully aware of the consequences of publishing this information.
Publishing information must be done after consultation with the project team, including the patent attorney, and department Heads, ensuring all departments, including legal, are aware of the publication strategy and are included in the publication review using the Sanofi Publications Review and Approval system, by the principal author submitting the publication.
Direct reports to the Heads of Research and Development must approve all publications coming from their respective departments or establish formal delegation for approval of publications.
Any requested access to raw data must be approved by management or other authorised parties.

- **Storage and Archiving**

The storage system must ensure an easy and rapid retrieval of raw data, intermediate data, results and documents of a study or experiment (protocols and reports of data).
Records must be protected from damage, interference and loss by adequate facilities, electronic systems and processes which ensure controlled access.

- **External Studies**

All studies carried out by a third party must comply with Sanofi Good Research Practices.
Third parties must be assessed with respect to cyber-security prior to the start of a study.