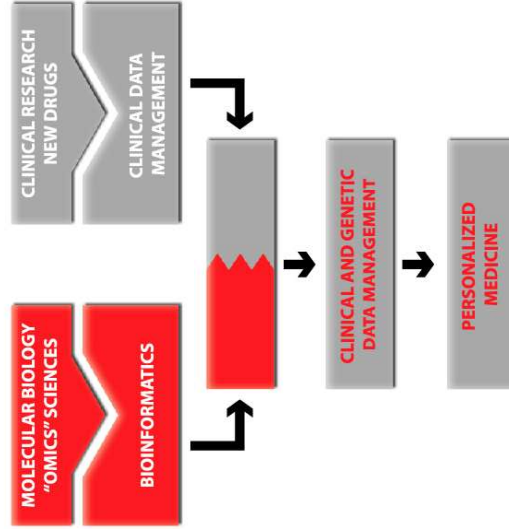




CONSULTING | **BIOINFORMATICS & DATA MANAGEMENT**

Consultancy in:

- Quality and regulatory requirements in **bioinformatics tools** during all life cycle phases and according its **intended use**.
- Implementation and follow-up of **Good Clinical Data Management Practices** and regulatory compliance in clinical research.
- Treatment of **clinical and genetic information** and its impact in data management processes.



1 Bioinformatics

The introduction of **bioinformatics tools** in the **regulated industry** for treatment and analysis of genomic, proteomic,... information, implies the need of compliance in some of **regulatory requirements** and with **good software development practices**.

- SVS offers:**
- Regulatory compliance
 - Implementation of plans and procedures for software development
 - Design documentation
 - Risk management and risk analysis
 - Configuration Control
 - Defect and Change Management
 - V&V Plans
 - Test Summary Reports
 - Bioinformatics Suppliers Audits

2 Data Management

Clinical Data Management is a key point in **clinical research**, due to validity of statistical results depends on **quality** of clinical data.

- SVS offers:**
- Data Management **Suppliers Audits** (CRO)
 - **EDC strategies**
 - **Data Management Plan** (FDA compliant)
 - **Outsourcing strategies**
 - Collection and treatment of **common data** in all clinical trials
 - **Standards:**
 - CDISC,
 - HL7,
 - Quality assurance ICH E6
 - **Validation:**
 - Data Management System
 - Each study/protocol
 - **Reconciliation** with safety database
 - **Coding** (MedDRA, WHO-DRUG,...)

3 Bioinformatics & Data Management

- How should we treat **clinical and genetic information** in clinical research?
 - How should we assure subjects **privacy**?
 - How should we collect data and which **standards** should be used?

- SVS offers:**
- Collection of clinical and genetic information during a clinical trial: Impact in Data Management
 - Information treatment in pharmacogenomics studies
 - Implementation Plan for new guidances and regulatory recommendations

