Vsoft Infoware, Inc.

Simplified eClinical Solution from Vsoft Infoware, Inc.



With over 100 years of combined experience of people in different Pharma settings - drugs and device trials. Vsoft has design and developed an **End2End eClinical Solution 'Clinfoware®'** with **Artificial Intelligence**, suitable for **Inexpensive** and **Successful** trial. Clinfoware® has one information repository suitable for adaptive trials and is completely pre-validated with different sets of protocol and therapeutic areas with automation from experimental design to submission stage with provision for more integration. It provides a clean report as you go including SDTM, ADaM and TLGs for submission to regulators.

Vsoft Value Proposition is:

- 15% Reduction in Trial Duration
- 20% Reduction in Enrollment
- 40% Reduction in direct eClinical Costs
- 25% Increase in trial success

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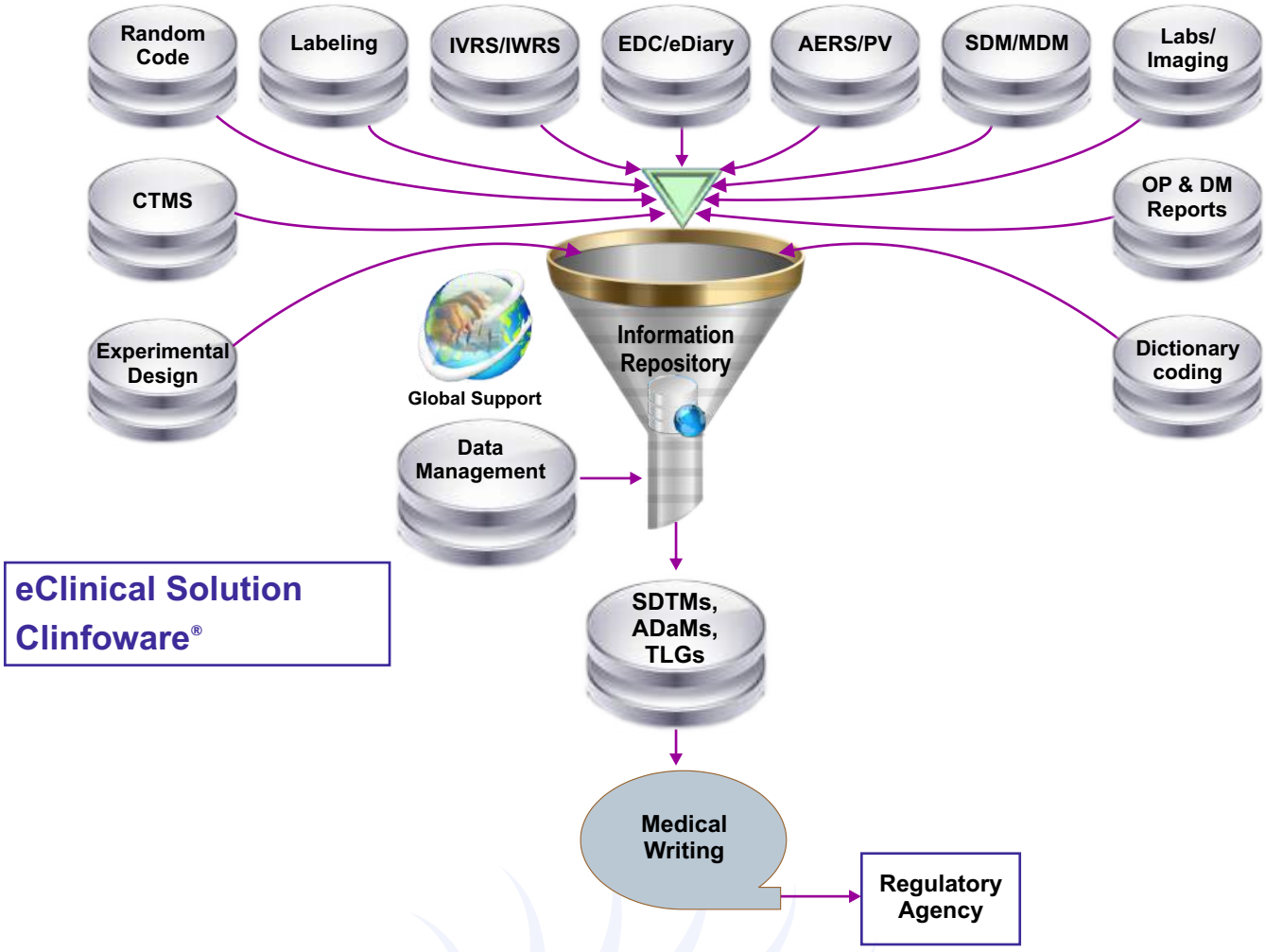

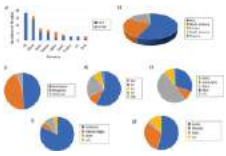

Data Management Services

To reduce start up time and make clinical trials worry-free, Vsoft offers services in Data Management along with its product – Clinfoware® Services include:

- Prepare, Revise, Approve and Monitor DMPs
- Set up database, create eCRFs, place edit checks and dry run
- Load dictionaries – MedDRA and WHO Drug
- Resolve queries, lock database
- Reconcile AEs/SAEs/PV
- Data transfer and batch loading of lab data and normal ranges
- Database backup and recovery
- Prepare pooled data marts
- EDC and AERS Services - training and support in multiple languages

Statistical Programming Services

- Creation of submission Data (SDTM, ADaM)
- Creation of Reports (TLF's)
- Creation of Patient Profile
- Supports In,
    - DMC
    - DSUR
    - Publications
    - Clinical Study Report
    - BLA

Statistical Analysis Services

- Creation of SAP
- Preparing Reports for Submission
- Input to protocols
- Conduct Simulation
- Sample Size and Random Code

Medical Writing and Administrative Services

- Prepare Protocol documents and templates
- Define and maintain consistency in documents
- PV/SAEs/AEs reconciliation and guidelines
- Prepare site monitoring plans and project plans
- Prepare Investigator's Brochure
- Identify and create SOPs and SWPs
- Write narratives
- Assist in site monitoring
- Assist in patient recruitment from approved third party
- Dictionary Coding and QC of controlled terminologies
- Prepare Enrollment Charts and Trial Details report
- Prepare Gantt charts and Single/Multi-year Finance charts
- Create and monitor Service Level Agreements