

## Data management challenges in BA BE studies and available informatics solutions

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Bio Analytical workflows differ from the conventional laboratory workflows in many ways. While, Bio Analytical workflows are study centric, the conventional workflows are sample centric. Hence a generic informatics solution cannot be customized or configured to meet the Bio analytical needs. This demands informatics solutions to be created from core, suiting exactly the Bio Analytical needs.

Besides, data and meta data associated with the Bio Analytical samples, subjects are to be tracked with audit trails for Quality Assurance and regulatory requirements. Validation of the system is mandatory for regulatory Bio Analysis. This is difficult when a generic informatics solution is tried for Bio Analytical work.

Along with the processed data, raw data, subject information, clinical data, sample repository and movement are also to be managed for a comprehensive study. So far, LIMS, ELN and SDMS solutions are available which are, interfaced to provide the seamless access of raw data of instrument within LIMS system. However, the clinical data, subject management information, sample preparation steps in the laboratory are still handled either in paper based system or automated systems that are silos. Efforts have been made to make the multiple systems seamlessly interfaced with validation, to provide access to the relevant data from different informatics systems. Two implementations are discussed and the future of real “paper less laboratory” is also briefly discussed which eliminates the need of multiple system management.

### Biography

Sudhakar Kasturi is currently working as a Business Consultant ,Informatics APAC Region with Thermo Fisher Scientific. He has 18 years of experience in analytical instrumentation and informatics solutions for various industries including CROs, Pharmaceutical value chain from Research to Production, Food Safety, Petroleum and Environmental testing. He completed M.Sc Physics ( Electronics & Spectroscopy) from Cochin University of Science & Technology and has worked in Varian India Pvt Ltd, Applitech Solutions India Ltd, Agilent Technologies India Pvt Ltd

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