



Statistical Computing Environment

White paper

A statistical computing environment (SCE) is essential for clinical trial reporting.

In order for analytic solutions to truly meet end-user's requirements it is important to put forward requirements for an ideal SCE gathered from pharma companies themselves. This paper brought together the subject matter experts from top global pharma companies to steer those requirements. The recommended and aligned requirements will provide business leads and tech business partners a high-level summary of the requirements to support the development of a future SCE which are comprehensible for all interested parties and are free of any ambiguities.

One possible use for these user requirements would be for the pharma industry to work together to define and develop a common set of SCE tools that could be open source and available for adoption by any organization. Another use would be by a third-party supplier to develop enterprise products by leveraging the comprehensive pharma requirements. Benefits of these uses would be reduced costs for adopting organizations and standardization across industry. The standardization could increase mobility among industry professionals and facilitate partnering among sponsor companies and between sponsor companies and CROs which would enhance scalability and flexibility. It may also ease the integration need giving the dynamic change of the industry when there is merge or acquisition.

Ultimately one could envision a single platform which could be shared with regulatory agencies to facilitate submissions and reviews. By leveling the technical environment across the board, sponsor focus on the science, data and interpretation, and reduce the time and effort to explain to authorities what they did and why their systems and processes are reliable.

You can download the white paper [here](#).

Authors: Mark Bynens (JnJ), Sheetal Patel (GSK), Olivier Leconte (JnJ), Delyth Jones (GSK), Sam Warden (GSK), Sascha Ahrweiler (Bayer), Oliver Richter (Boehringer Ingelheim), Jorine Putter (GSK), Joseph Rowley (Novartis), Marie-Claude Laramée (Novartis), Des Burke (GSK), Holger Dach (Bayer), Mario Lozina (Boehringer Ingelheim), Jon-Paul Mewes (Roche), Paul Fioole (JnJ), Eunice Ndungu (Merck), Mary Kuklinski (BMS), Timothy Kelly (BMS), Timothy Stuart Pearce (Pfizer) and Gary Chen (Pfizer).