

Data, errors and headaches: How STUDIUS™ and the Solentim Ecosystem is tackling the crisis in data consolidation and reporting in Cell Line Development

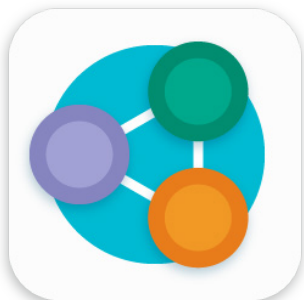


Game Changer

One project, 7 analytical instruments, 7 staff members, 5 data formats. 3 different permutations of plate names 3 months, 13 excel files, containing 46 sheet worth of data. Manual Vlookups. Copy-and-pastes. USB Sticks. This situation is not uncommon.

Operating within the structure of Chemical, Manufacturing and Control (CMC), Cell Line Development (CLD) is a pivotal control strategy within the development of therapeutic antibodies. Risk-based strategies towards quality control are deeply embedded in CLD yet challenged, as are CLD scientists, on a daily basis with the burden and worry of data consolidation.

Methodologies, utilized in CLD, include viable cell counting, confluency measurements, single cell seeding, plate transfer and consolidation, titer assays and microscopy. It is central to this narrative that data from all these aspects are joined together in a single story of a cell's journey through this process.



“Consolidation of data within projects is the biggest headache to us CLD scientists and also presents the greatest potential risk for hidden error.”

However, data consolidation in many labs still relies on methods, difficult to manage within a quality system and time consuming. In a recent case study, consolidation of a single study took one senior scientist 80% of her time over a two week period.

Solentim has worked alongside the Cell Line Development community for more than a decade developing instruments and reagents to enhance the quality of assurance and increase process throughput.

Now with instruments covering seeding+assurance, growth+assurance and selection based on productivity, Solentim has tackled, the little spoken of elephant in the room, that of data management.

With STUDIUS™, a bespoke data management system, Solentim has changed Cell Line Development forever. An integrated view on project data all the way from seeding to selection. An entire project in a single report. A protected ecosystem of data for users and managers alike.

The benefits are instant. Users can view a complete project, on a per well, per plate, per user, per decision basis - STUDIUS harnesses the principles and demands of 21 CFR Part 11 to bring data auditing, user control and security.

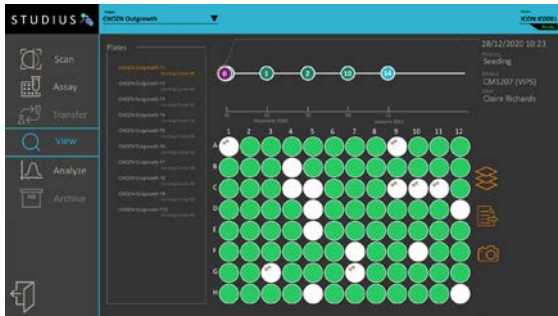


Figure 1. Single cell seeded data on STUDIUS. STUDIUS enables cell line development project visibility on a single platform.

STUDIUS employees HISTORYTREE™, a novel graphical representation of the CLD process where each action is presented as a circular 'node' on a path.

Colors denote seeding, imaging, titer. Removal of samples for external testing is shown on a 'wave' while mathematics, for instance, correct titer, is shown as a data node.

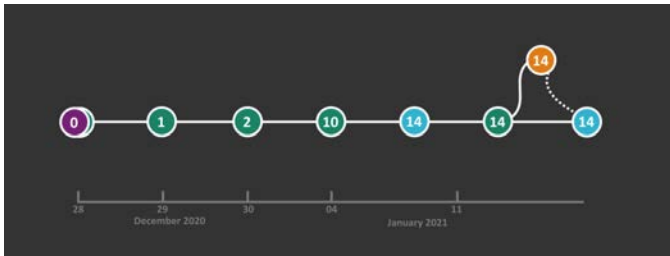


Figure 2. STUDIUS projects are displayed through HISTORYTREE with each node, an event or piece of generated data. The 'wave' and dotted line motif at day 14 describes well imaging, sampling for titer assay then generation of corrected titer data (blue node).

Assays performed on ICON™ are also managed directly using STUDIUS including titer and viable cell density measurements.

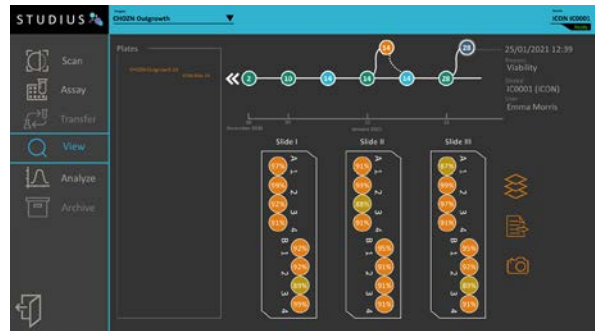


Figure 3. Titer (3) and viable cell density (3b) measurements conducted on ICON via the STUDIUS assay interface.

Having the whole project in a single view, enables manager and supervisors to examine and control consistencies and inconsistencies within the laboratory process, visibility, perhaps for the full time turning STUDIUS into a design-of-experiment asset.

While, the final report, which wraps an entire, quality managed data set in with system performance, becomes a gold-plate asset for either communicating internally, to clients or to the Regulator.