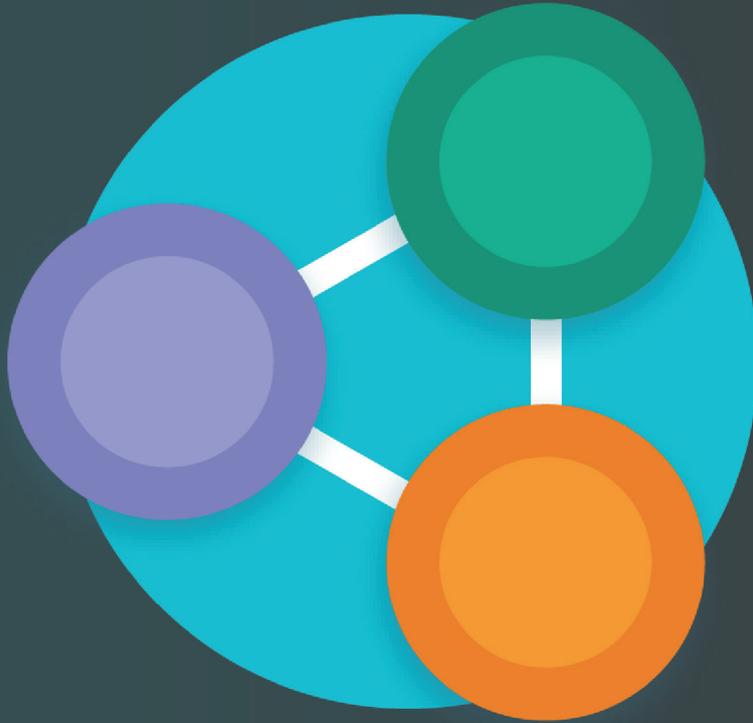


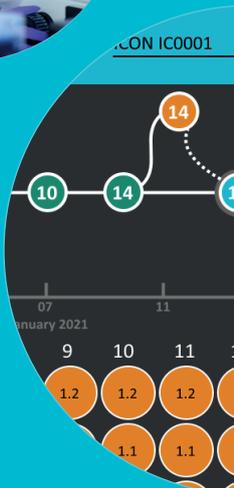
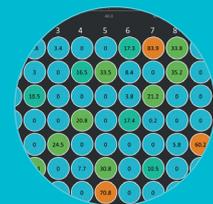
STUDIUS™



The new standard for cell line development



Data Management Solution for Cell Line Development Projects

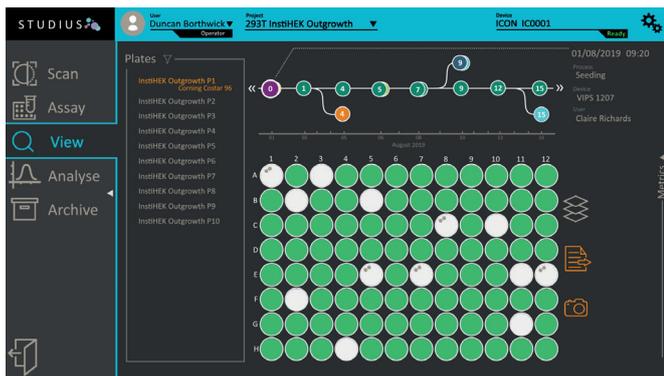
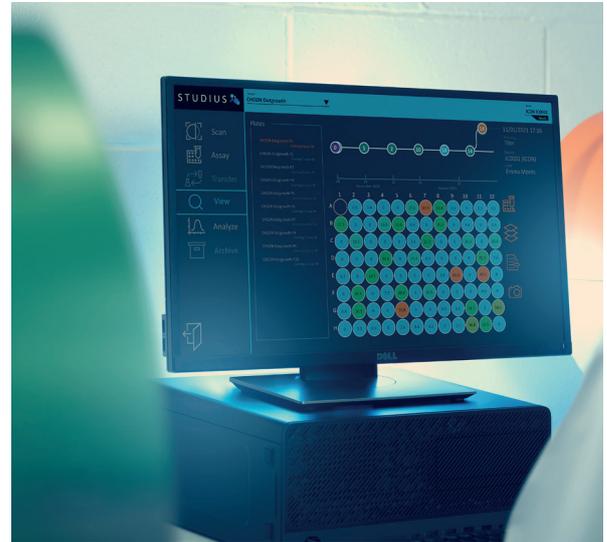


A panoramic view of cell line development

A new standard for cell line development, STUDIUS™. Designed to manage and report on cell line development data and well history, STUDIUS enables scientists to collate and view all the data, from seeding through assurance to selection gathered from Solentim's instrumentation.

STUDIUS offers dynamic data sorting to streamline the selection of candidate clones.

STUDIUS is secure and supports requirements to achieve 21 CFR part 11 and EU Annex 11 compliance.



- **View:** accesses data from Solentim's seeding, imaging and selection instruments.
- **Sort:** Rapid filtering of per-well data to characterise lead candidates.
- **Report:** Draws on system and service status within final report as evidence of quality process.
- Supports requirements to achieve 21 CFR part 11 and EU Annex 11 compliance

STUDIUS Project: **CHOZN Outgrowth** Device: **ICON IC0001** Ready

Navigation: Scan, Assay, Transfer, View, Analyze, Archive

Analysis Nodes | Triage and Rank

Selection Sample Size
Virtual Plate Size: 96 wells
Select Top: 3 plates of samples

Triage
 Exclude non-clonal
 Exclude wells where Titer is below 10
 Exclude wells where Confluence is below 20

Rank
Rank by: D14 Corrected Titer

View Results

Your project data: safe & secure

Continuous Audit Mode

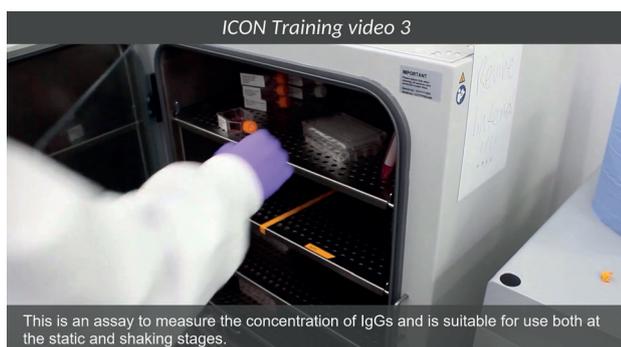
STUDIUS's Continuous Audit Mode enables enhanced control over data security and process control.

Key Features

- Data stored safely within in a Microsoft SQL Server database. All access security and authentication managed by MS SQL Server permission system providing accurate records inline with backup and retention policies.
- User access restricted by valid username and password. Access to functionality and data is based on the role assigned to the authenticated user.
- All user actions that create, modify, or delete records in the software are recorded by the Continuous Audit Module. The audit trail includes the action, who performed it and the date and time it was done. There is no user option to delete audit trail data.

User guides and video-based training

STUDIUS is supplied with a range of training tools to drive best practice and process quality control. These include online training, application and software user guides.



Supports requirements to achieve



21 CFR part 11 and EU Annex 11 Compliance



Single-vendor from seeding through assurance & selection

Standardized formats, quality data, multiple points, STUDIUS marks the end of spreadsheets.

Import data from VIPS™, Cell Metric® and ICON™ to enable a single point of oversight of cell line development process.

STUDIUS unlocks single-vendor status for the core functions of cell line development, a key advantage in quality process design.

Solentim Single-Vendor benefits:

- Over a decade of experience and engagement with the cell line development community.
- Simplification of Risk-assessments through reduction of moving parts and commonality in formats.
- Multiple instruments cross-monitoring of same clones through multiple time points generates consistency and confidence of data.
- Single wrap around Total Project Report including system health, process performance and clone to selection Clonality Report.



HISTORYTREE™

a holistic view on cell line development



Figure 1. HISTORYTREE. A liberating presentation of a cell's journey through cell line development.

A unique view of cell's journey

HISTORYTREE™ is a dynamic navigational tool, a new graphical representation of a cell's journey through Cell Line Development. From seeding, through growth, productivity assays and sorting,

Each colored node on the tree represents a time point in the cell's journey offering easy access to critical data.

Furthermore, this cell-centric view established a clear statement of data continuity, providing confidence ahead of regulatory submission.

Virtual Plates: Beyond the confines of plastic

HISTORYTREE frees cells from the confines of the ubiquitous SBS plate format so that each clone is considered as a unique data point. For the cell line development scientist, this is liberation! No more sifting through plate images, just engagement with the same clone at different time points.

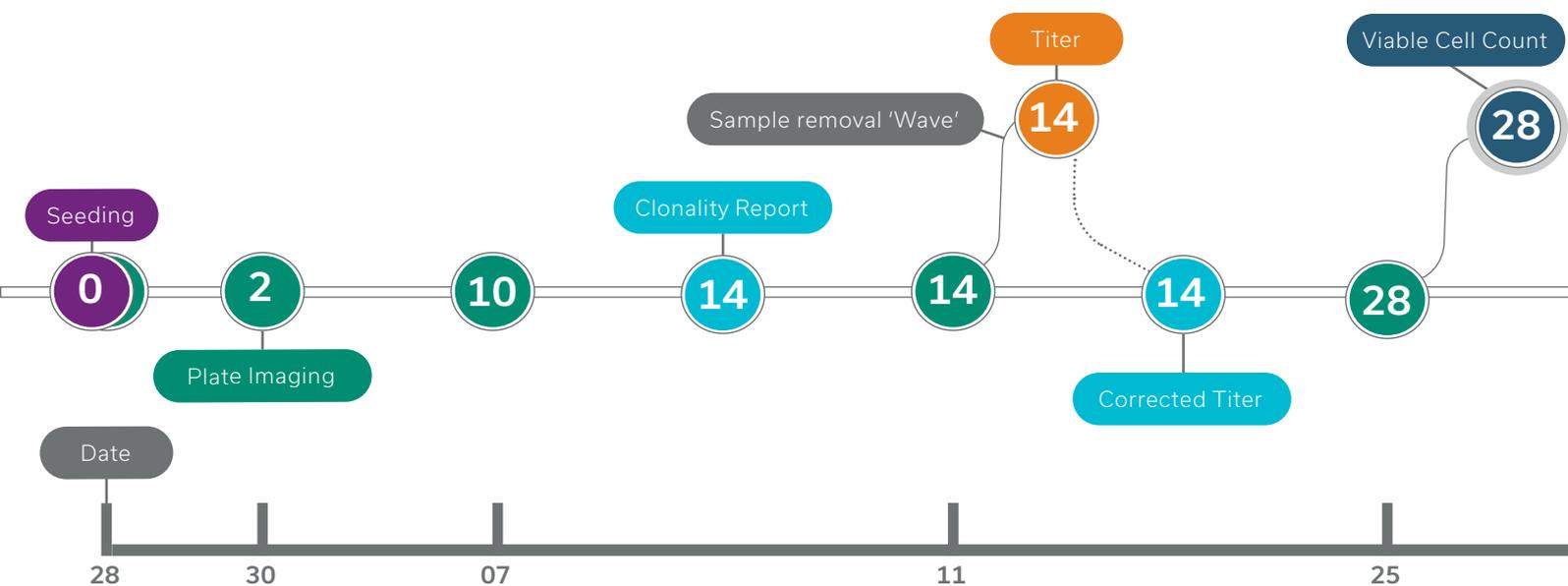


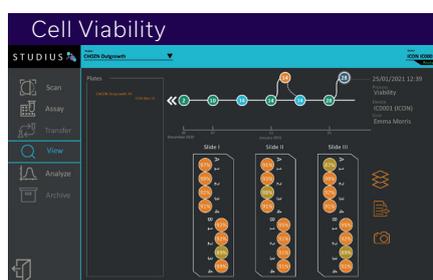
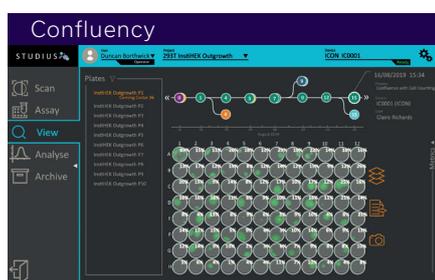
Figure 2. HISTORYTREE Legend

Running critical assays....

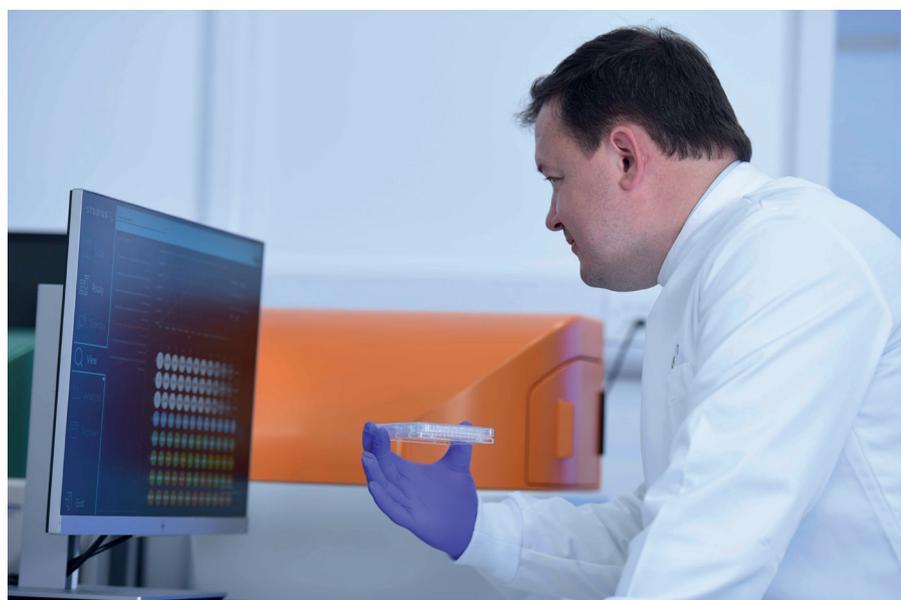
Simple control over your ICON

Run your ICON assays direct from STUDIUS to gather data on confluency, cell number and viability and titer.

Data is presented clearly as a colored heatmap, focussing scientist's attention on the clone rank.



...then picking the winners



The power to focus on what is important

With quality data, comes the power to sort, sift and choose. STUDIUS has powerful dynamic data sorting enabling cell line development scientists sort leading candidate clones based on information gathered by the Solentim products.

Sort by data captured around seeding, evidence of clonality, growth and productivity to quickly focus on a subset of clones.

Standardized Reporting

Rich in quality

STUDIUS reports are rich in quality-based information offering unique features including

Individual Assay Export

Export ICON assay results in standardized formats ready for lab review or communication.

Pick-list Export

Consolidating plates for assays made easy using plate mapping and export tools.

Complete *HISTORYTREE* export

Report on the entire cell line development process, from seeding through to selection.

Virtual Plate formation

With data sorted and filtered, users can escape from the confines of the SBS plate format by constructing virtual plates of information on their top candidates.

Instrument and service status:

To demonstrate the quality focus of your workflow, STUDIUS reports combine both experimental data plus information on your instrument's 'health' including service status and operational history.

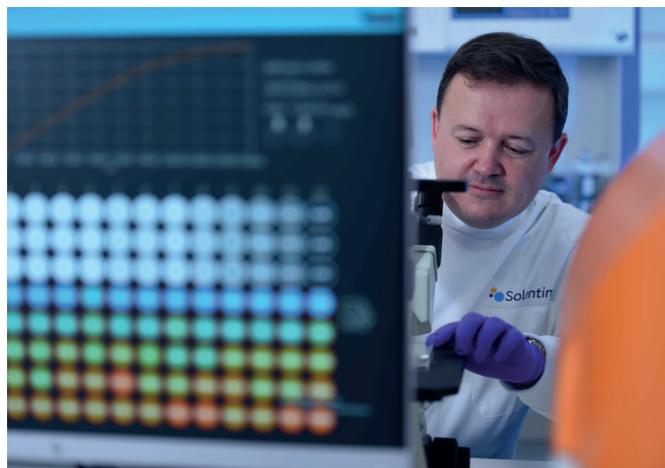
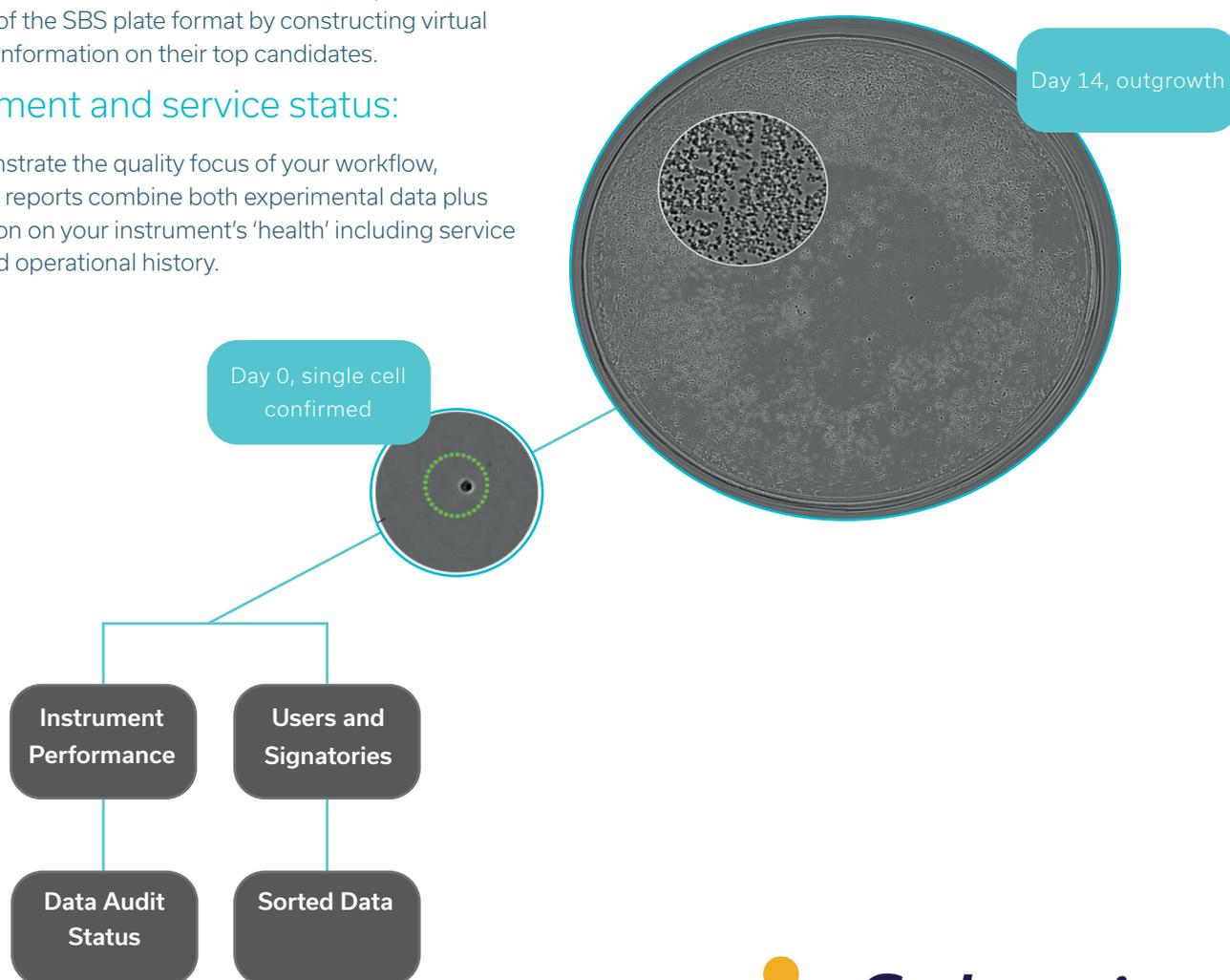


Figure 3. Selection of lead candidates is backed with a solid, quality rich report linking both experiment data and instrument status.



About Solentim

Solentim is the trusted global leader for solutions to create, isolate and characterize the highest value cells for the development of new biological medicines and therapies.

Our portfolio of proven and innovative technologies, combined with our unparalleled experience, ensures our customers achieve accelerated Master Cell Bank development and are confidently prepared for regulatory review.

Solentim, part of Advanced Instruments



Focused on high value cells



www.solentim.com



www.aicompanies.com



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