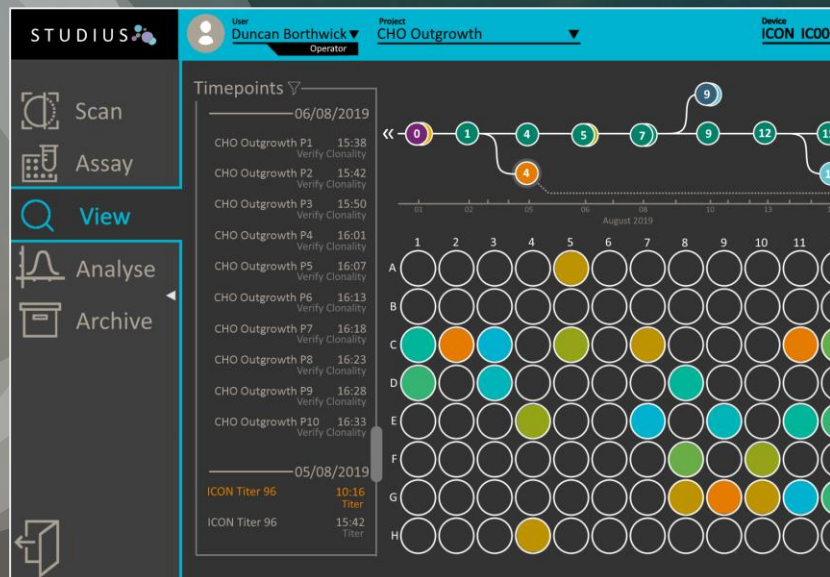


STUDIUS™

The new standard in cell line development

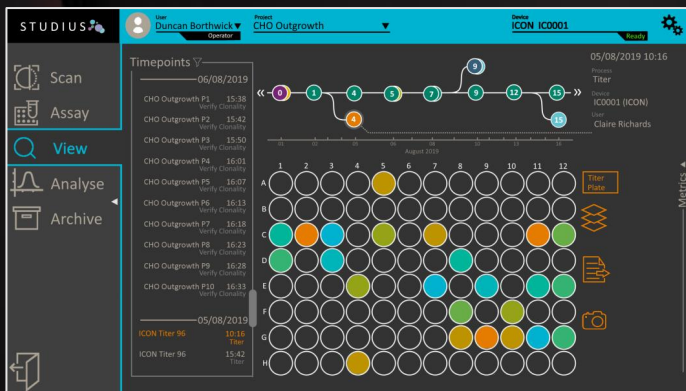
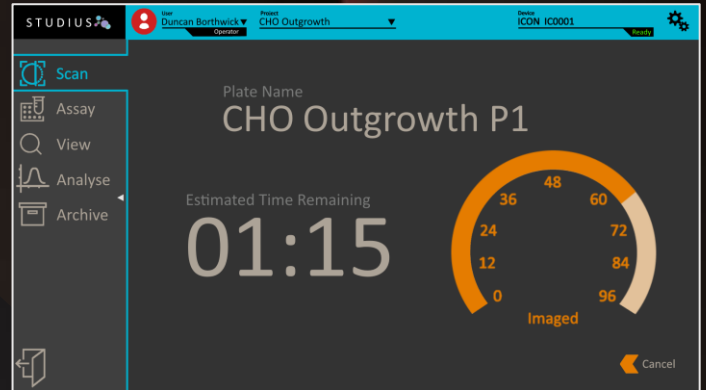
Smarter data driven
decision making in
cell line development.

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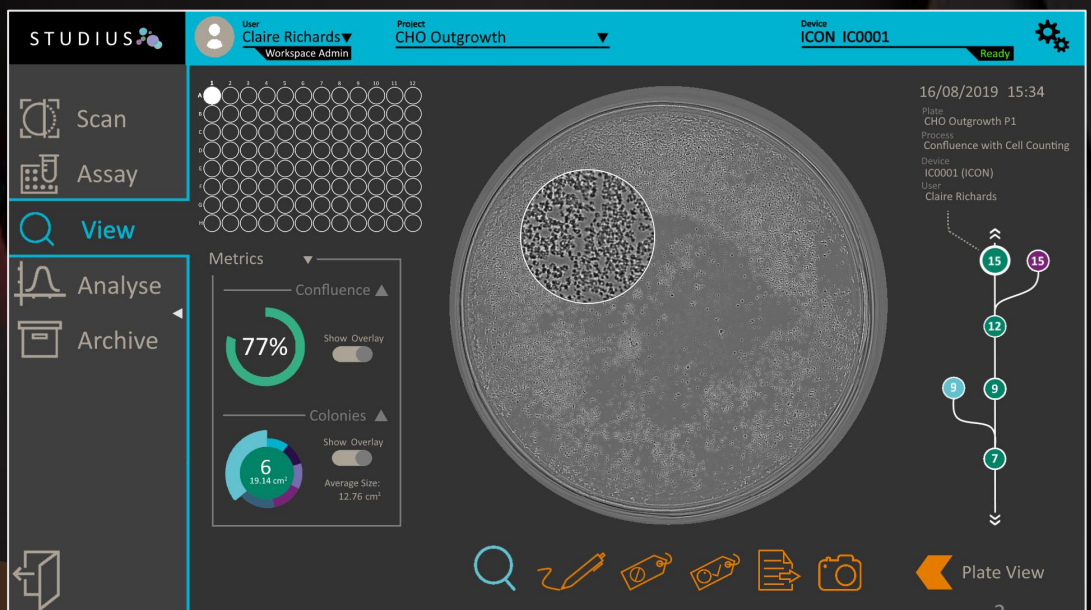


Introducing a new standard for cell line development

Integrated to work with Solentim's technology platforms, **STUDIUS™** manages and reports on cell line development data. Tracking each cell's journey, **STUDIUS** offers dynamic data sorting to streamline the selection of candidate clones with desirable traits.



- **Manage:** User management hierarchy including inbuilt user training course.
- **HISTORYTREE™:** Displays multiple data points from a clone's history along a unique graphical timeline.
- **Sort:** Rapid filtering of per-cell data to characterize lead candidates.
- **Report:** Draws on system and service status within final report as evidence of quality process.
- **Operates** Continuous Audit Mode supporting requirements to achieve 21 CFR part 11 and EU Annex 11 compliance.



Managing quality & user management

Continuous Audit Mode

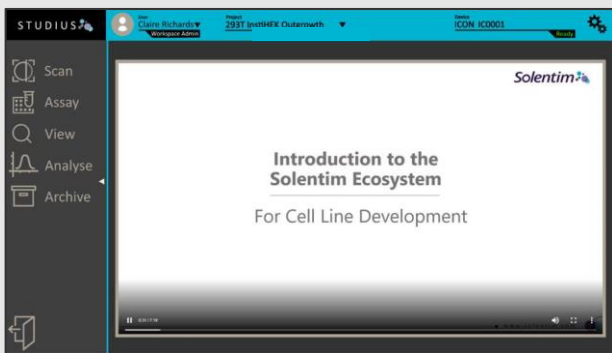
STUDIUS offers Continuous Audit Mode. In this mode, a range of data control related features are activated in line with clients' 'Part 11' needs.

Includes:

- Data stored in a Microsoft SQL Server database. All access security and authentication has been developed using the built in MS SQL Server permission system. This provides accurate and ready retrieval of records following the customer's backup and retention policy.
- Access to the system and database is restricted to users authenticating access with a 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

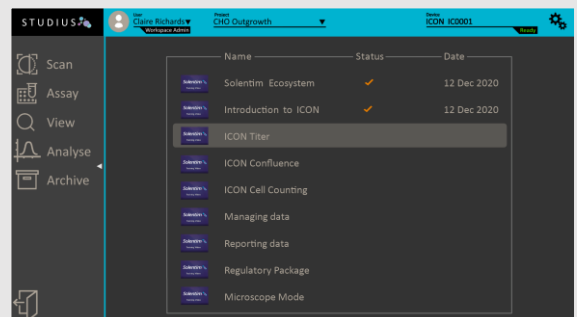
STUDIUS is supplied with a range of training tools to drive best practice and process quality control. These include online training, mandatory for user creation in Continuous Audit Mode, application and software user guides.



User training videos within STUDIUS



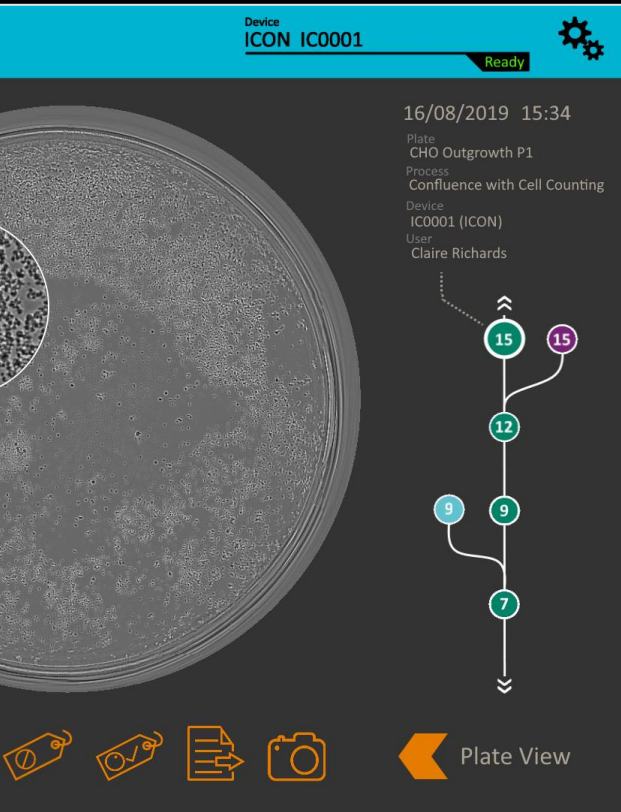
Multi-level access with co-signature requirements support 'Part 11' compliance.



In-built user training facility with the Continuous Audit Mode package.

Supports requirements to achieve
21 CFR part 11 and EU Annex 11 Compliance

A holistic view with HISTORYTREE™



A unique view of cell's journey

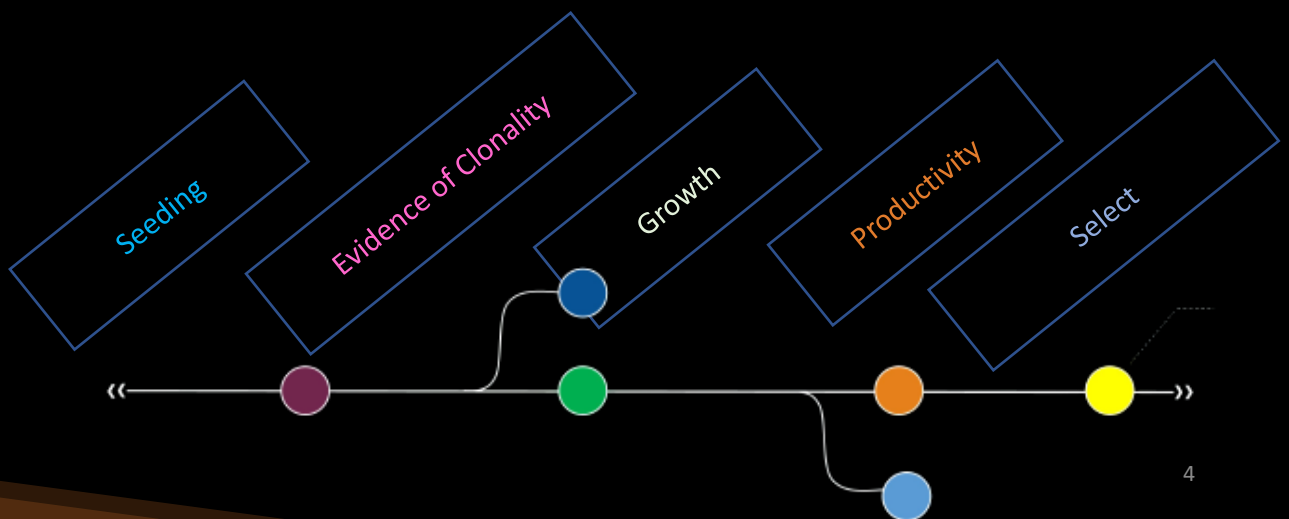
HISTORYTREE™ is a unique graphical representation of a cell's journey through cell line development. From seeding, through sorting, growth and productivity selection each node on the tree represents a time point in the cell's journey offering easy access to critical data.

Furthermore, this cell-centric view establishes 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 plastic plate format so that each cell on its journey is considered as a unique data point.

For the cell line development scientist, this is nothing less than liberation. No more sifting through plate images, just engagement with the same cell at different time points.



HISTORYTREE™ tracks a cell's life story from seeding, evidence of clonality through growth, productivity and selection.

Process control & oversight

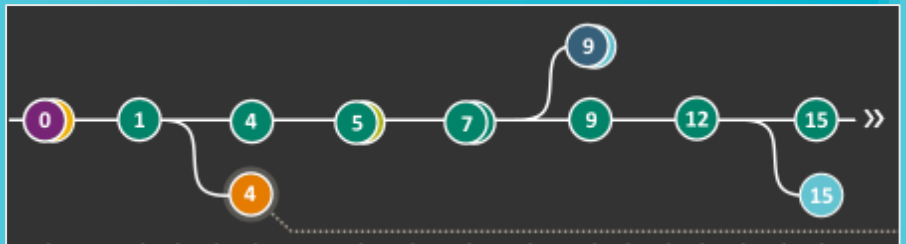
Reviewing key data from cell line development

STUDIUS can import key data from VIPS™, Cell Metric® and ICON™ to enable a single point of oversight from the whole cell line development process.

When used with the office-based STUDIUS Command version, this platform becomes a key tool for process and quality management.

Data includes key factors previously submitted in the laboratory including evidence of clonality, growth and productivity.

STUDIUS imports key data from other Solentim platforms for an integrated approach to decision making and assurance.



VIPS



Cell Metric



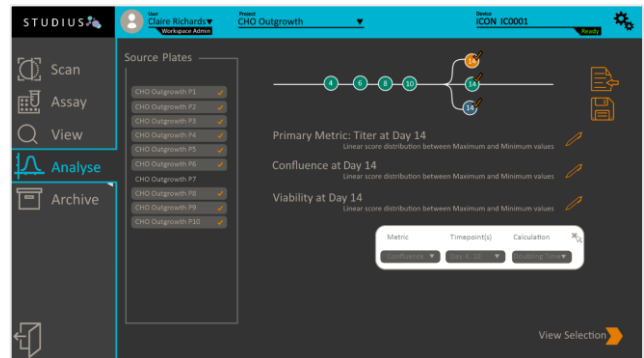
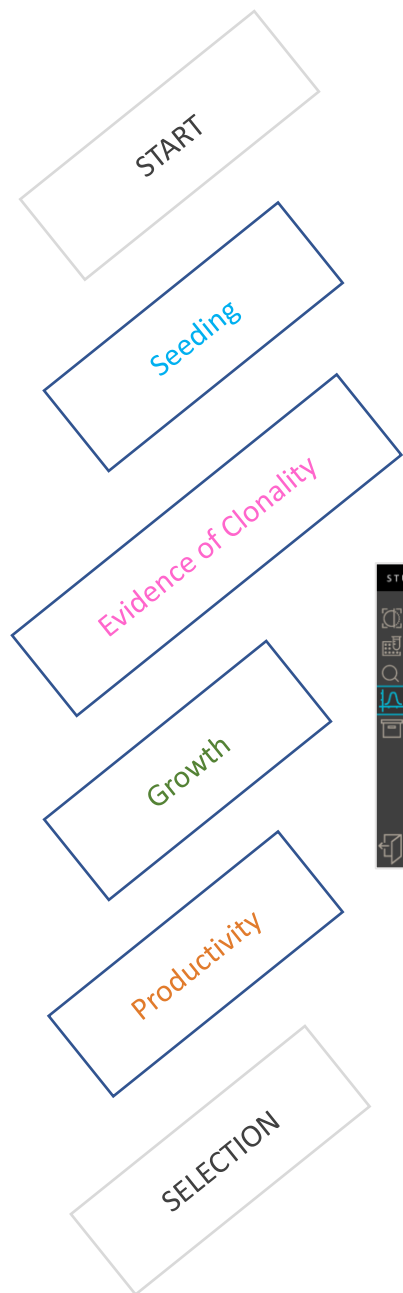
ICON



Dynamic sorting to characterize lead candidates

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

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

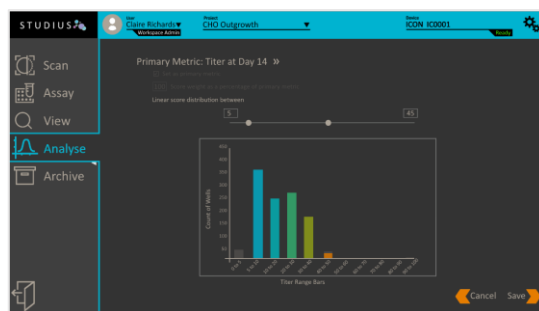


Rapid data filtering based on Boolean logic.

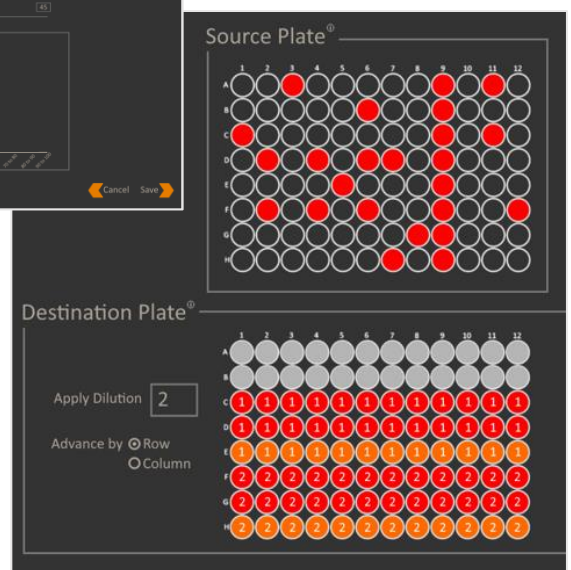
The power to focus on what is important

The ability to sift and sort opens new opportunities in how cell line development operates.

By sorting out clones you don't want and focusing on the attributes you desire, condensed workflows based on priority can be established, slashing timelines and plastic usage.



Gating and weighting critical quality attributes



Selecting wells based on ICON-derived information opens the doors to new streamlined workflows.

Standardized reporting

rich in quality

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

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 experimental data plus information on your instrument's 'health' including service status and operational history.



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

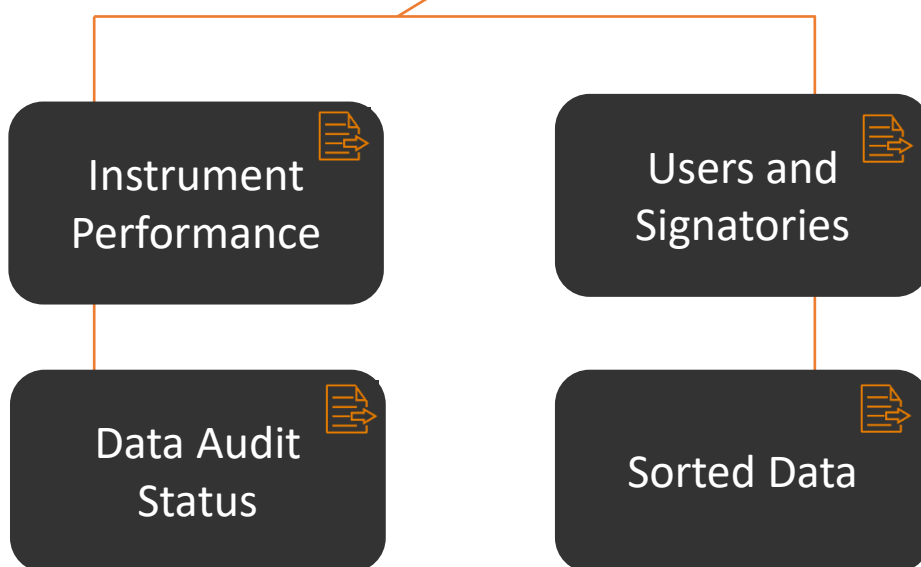


Image grab and assay export

In addition to final reporting, STUDIUS offers convenient individual image and assay exporting ideal for every-day laboratory use.



A new workflow based on early assessment of assurance & productivity

Verified In-Situ Plate Seeding (**VIPS**) is designed for single-cell seeding and image-based clonality assurance for 96-well and 384-well plates.

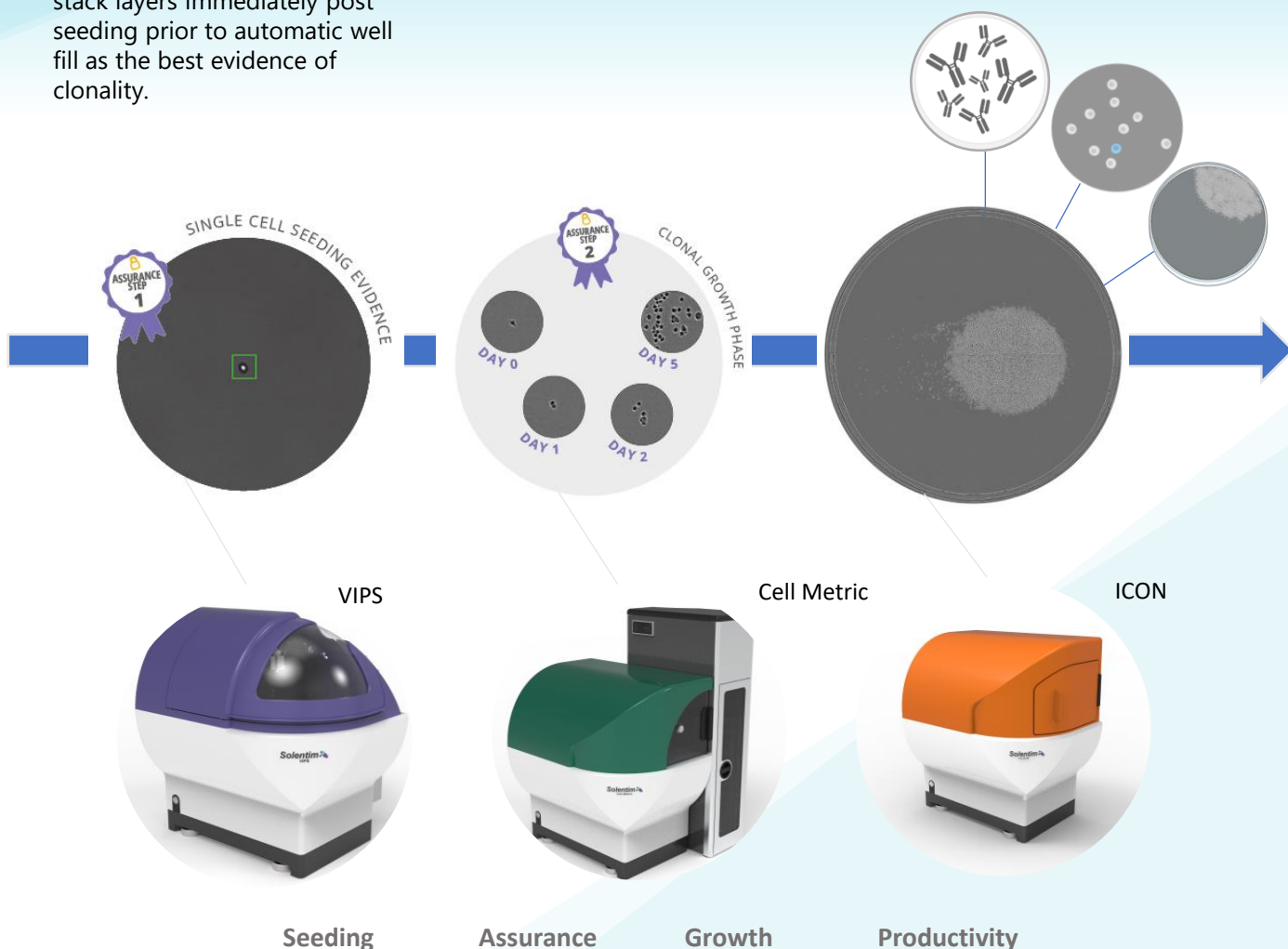
With sterile consumables designed to last your project, VIPS provides high efficiency seeding at very low pressures for high cell viability and outgrowth.

Cells are imaged in multiple z-stack layers immediately post seeding prior to automatic well fill as the best evidence of clonality.

Cell Metric is the industry standard for whole well imaging. From a single cell at day 0 and through early days of cell division, Cell Metric provides unambiguous, time-line based evidence of a single cell's journey through outgrowth to clonally-derived colony.

Through clonal outgrowth, passaging and selection, **ICON** assesses productivity as a function of titer and viable cell number.

STUDIUS compiles information throughout cell line development enabling rapid stratification of top clones.



A Decisive New Cell Line Development Workflow

Three instruments to span cell line development from high efficiency seeding, a double-lock of assurance, accelerated growth and selection based on productivity, all linked through STUDIUS™.

About Solentim

Solentim is the trusted global leader in workflows for antibody and cell-based therapies.

Our assurance rich technologies enable the isolation, growth and characterization of high value cells while our data driven platform enables smarter decision earlier in the process. Together, our customers experience faster workflows, confidently designed for regulatory environments.

FOCUSED ON HIGH VALUE CELLS



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