Data integriteit met OpenLAB

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Produkt Specialist

Lab Informatics

Agilent Technologies

Topics voor vandaag

OpenLAB ECM

    Introductie

    Wat is het precies

    Integratie met andere systemen

    Voordelen

OpenLAB CDS

    Wat is het

    Hoe ziet het er uit

    Hoe is integriteit gewaarborgd

    Integratie met andere systemen
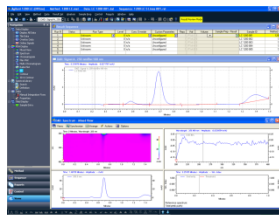
OpenLAB ELN

    Wat is nou een echt ELN????

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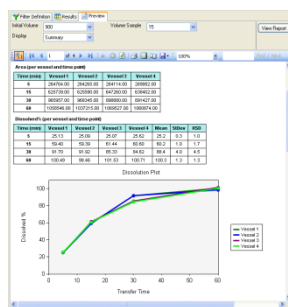# OpenLAB - *The Operating System for the Laboratory*
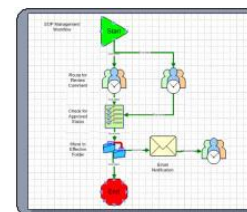
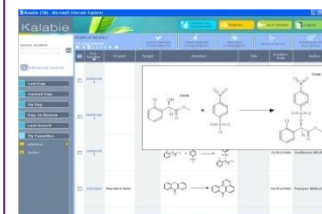| Agilent Solutions for the Lab Informatics	Enterprise Content Management (ECM)	Multi-vendor Instrument Control Manager (OL CDS)	Intelligent Reporter	Business Process Management (BPM)	Electronic Lab Notebook (ELN)

OpenLAB is a fully integrated laboratory system that links people, processes and data, providing all information needed for accelerated decision making.

Integrating framework for other applications and techniques
Web-based, n-tier architecture scalable from small lab to global implementation

OpenLAB manages instruments, people/process and content!

OpenLAB ECM
Data security and authenticity

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Challenges

Laboratories are diverse environments

- Analytical raw data from all kind of instruments, often stand-alone
- Reports often to paper
- Lot of data control in place
- Many procedures to follow
- Lots of regulations (GxP, 21 CFR Part 11, etc.)
- Users need to be able to search and quickly find and retrieve the data, regardless of their storage location (online or in offline archive)

In order to get valuable information out of the data on these multiple systems:

- Data need to be stored on one central system
- Data need to be comparable and available for review in one common form.

Regulations and enforcements
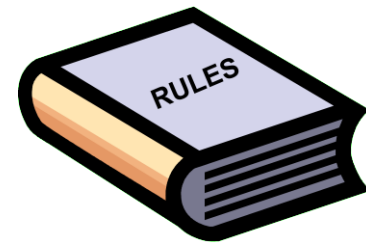
Annex 11
- European Pharma Industry

Renewed 21 CFR Part 11
- FDA Pharma Industry

ISO 17025
- General for laboratories!

Data Integrity and authenticity

Common principles for all regulations apply

- Data security by central storage and controlled access
- Data authenticity by check sum controls
- Audit trail on activities done by users

Accountability

- Management responsible for implementing the new regulations
- Employees need to be trained accordingly
- Checks and balances need to be in place

This can all be supported by a technical solution.

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Compliance by Design

Pressure is moving from customer to supplier

- Technical solution for compliance
  - Software build with compliance in mind, "Start with the end in mind"
- Facilitate audits for
  - Reviewing quality documentation
  - Life cycle approach
- Supplier should/must be aware of compliance regulations
  - Àgilent has dedicated compliance officer in LI
- Support customer from cradle to cradle
  - That means provide customer a safe way of moving to the next version
- Documentation documentation documentation!

Key functionalities OpenLAB ECM is offering *designed with data integrity in mind*

- Advanced Data Archiving and Management
  - Secured storage
- Record Retention Policies
  - Automated and documented record management
- Scientific Data Management
  - Store *ANY* file from any source
- Document Management
  - Plug-in Office at no costs
- Workflow Management with BPM
  - Audited workflow inside ECM.

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Agilent Systems with direct interface
achieving compliance with central control

Masshunter ICP/MS

GC/MS Masshunter

LC/MS ChemStation

UV/Vis ChemStation

Dissolution OpenLAB ChemStation

OpenLAB EZChrom and ChemStation

All share a central repository and security.

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Masshunter integration

Secured storage for large volumes of files

Central login and security

Central audit trail

Behaves just like a normal hard drive

Easy to learn for users

Benefits

- No more manual back-ups
- No more data loss
- No more manual sharing
- Reprocessing made easy!
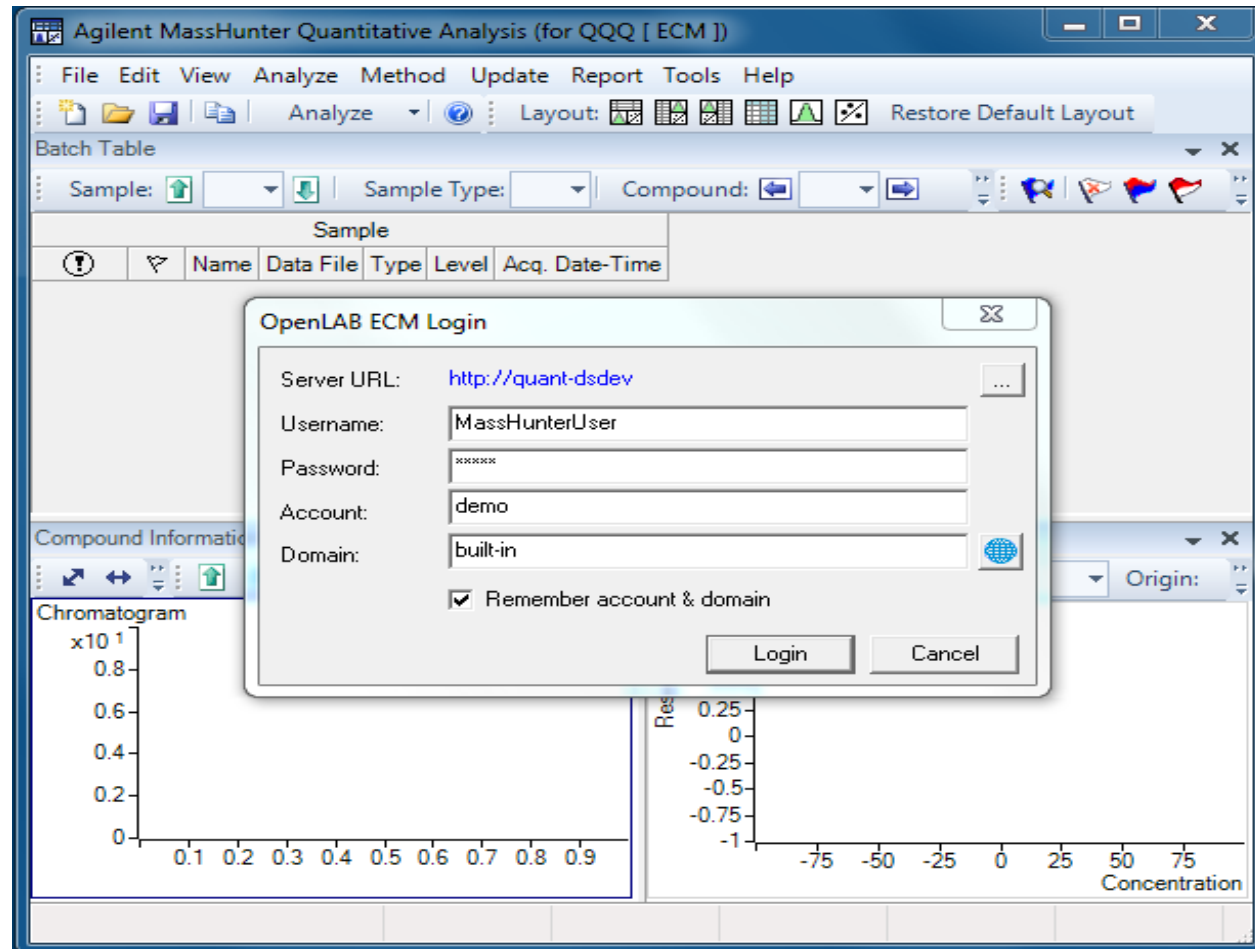
Agilent OpenLAB – linking data across the lab & beyond

Processes

Instruments

Content

SOP Management

Instrument Maintenance

Content Uniformity

OpenLAB

GC/MS

GC

UV-vis

LC

LC/MS

CE

ICP-MS

Lab-on-a Chip

MS Office

Legacy Data

Images

PDF

ELN

LIMS

Drawings

Research

Company Network

Company WAN

Agilent Technologies
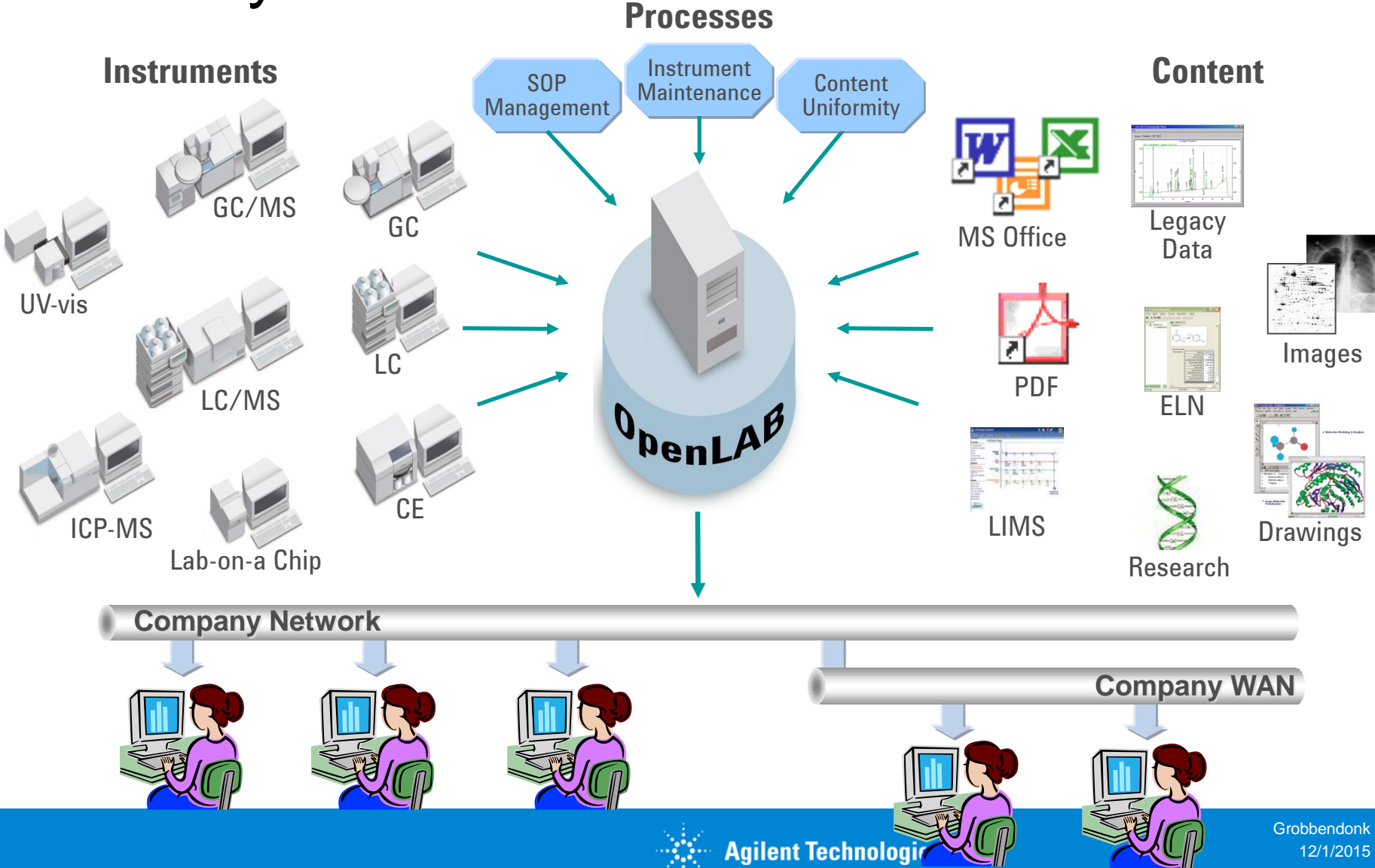
There are multiple ways of uploading data into Agilent OpenLAB
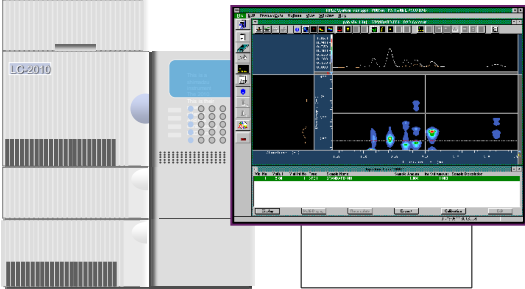
Automatic using the Scheduler
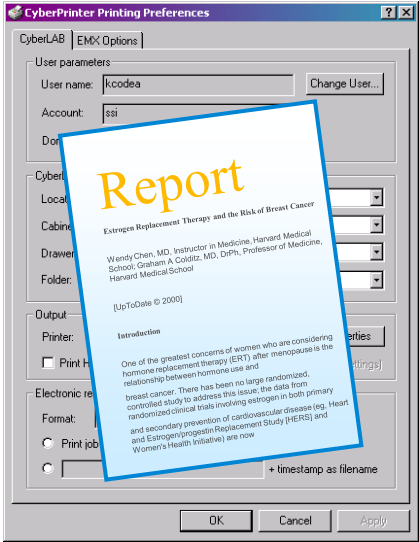
Or printing from Instruments and PC's

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Automatic meta-data capturing at the source
better safe than sorry!

Meta-data is information extracted from records and stored in the database

- Automatic
- Manual

Uniquely identify each record to safe guard it

- Check-sums for protection

Search routines

- Track and trace activities

PACA

- Pro-Active Corrective Actions based on audit trails and meta-data.

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Attribute Extraction Services

✳ Agilent OpenLAB provides over 40 Attribute Extraction Services for different file and document types.

✳ To apply an AES to a set of files, simply select the keys and apply them e.g. to a Cabinet in the LCDF hierarchy.

✳ All files entered into the Cabinet are automatically indexed with the selected keys.

✳ Modify the selection of keys at any time and re-index the files/ documents.
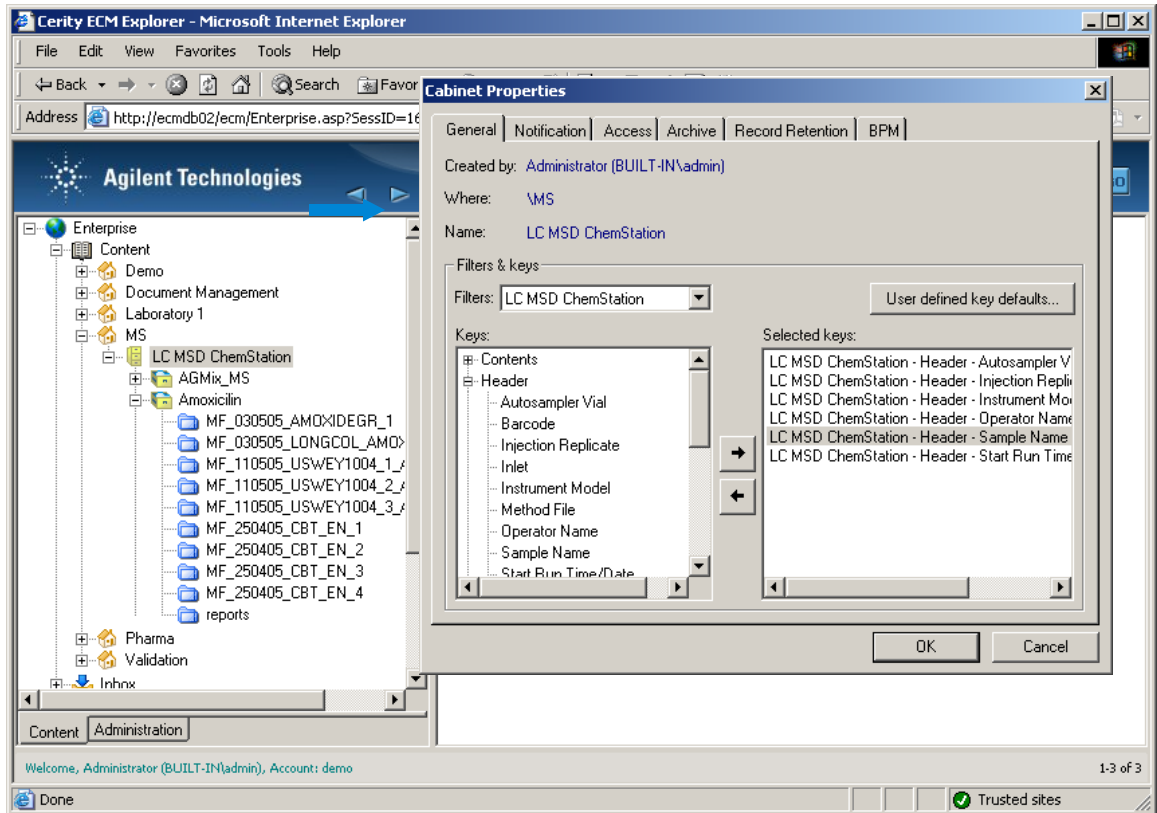
PDF Templates make reports searchable

* Reports can be printed to Agilent OpenLAB ECM in a PDF format using ECM Printer.

* PDF Extraction Templates allow the extraction of metadata (text, graphics, or tables) from the PDF reports.

Agilent OpenLAB: Powerful searches save hours

Find exactly what you need – *fast!!*

- Quick searches

- Smart searches

- Advanced searches with multiple criteria
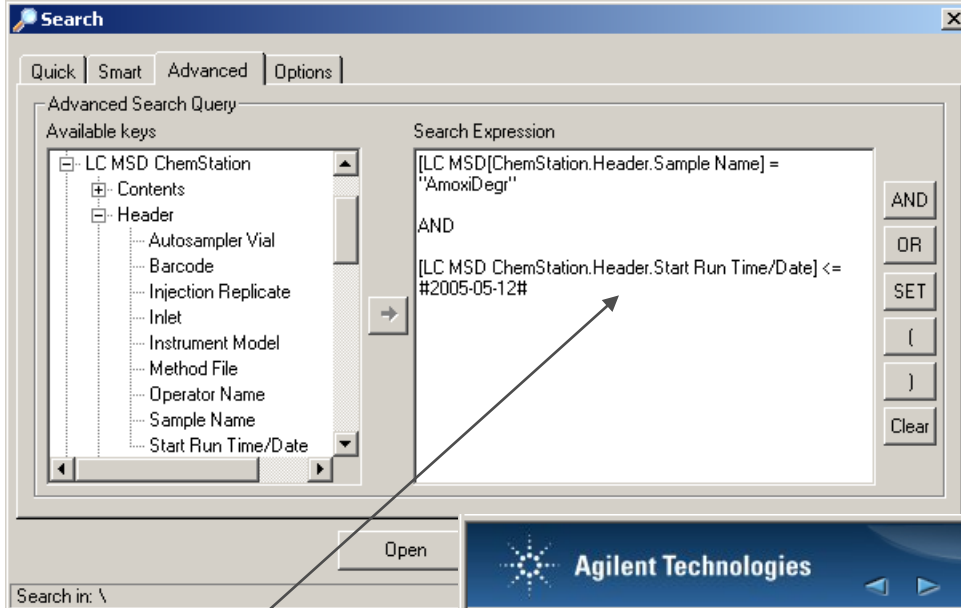
Example: Search for LC/MSD ChemStation data files with the sample name "AmoxiDegr" acquired on or before 5-12-2005.
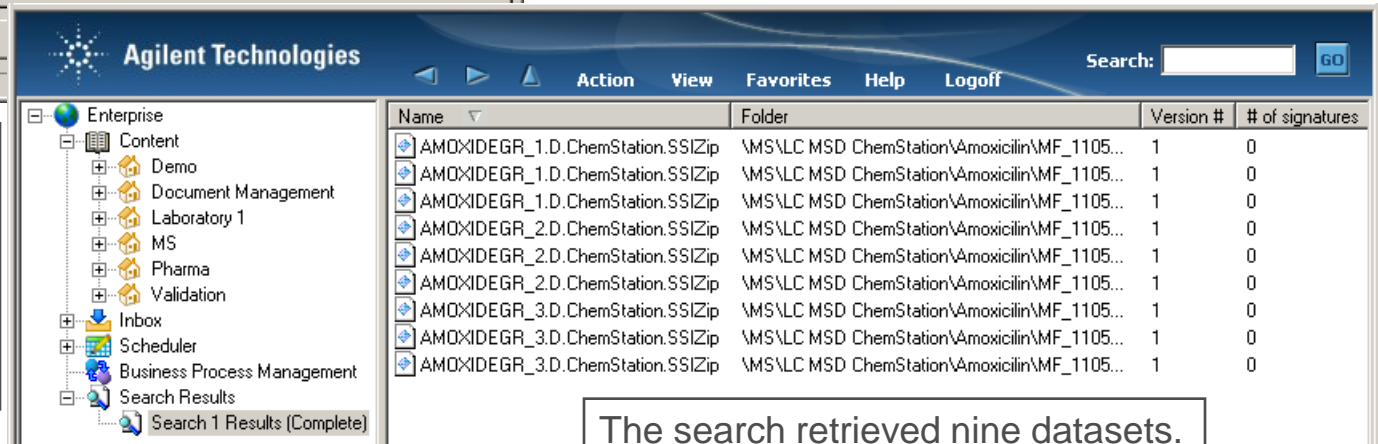
The search retrieved nine datasets.

OL ECM Business Process Management
Workflow Automation of report review and approvals

A BPM review process automates document and report review and approval.
This speeds up review and approval by:

⇨ Automated email notification for new review activities

⇨ Automated or manual delegation of activities
- ⇨ Based on timeout
- ⇨ Manual transfer of approval ownership

⇨ Setup delegates for absent reviewers

⇨ Link of approval request and related document - No more searching for the data required for an approval.

⇨ Full traceability of review progress at any time
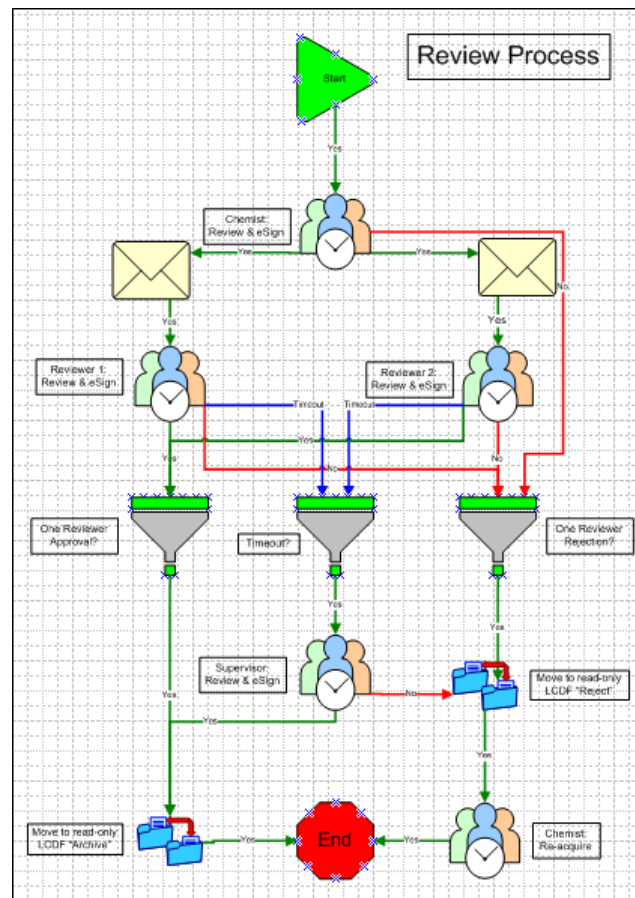
Result: Streamlined process completed in days - not weeks

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Wrap-up

Agilent OpenLAB ECM

- Build with compliance in mind!

Your benefits

- Easy hands-off storage and archiving
- Scalable from 1 to n instruments and users
- Based on standard Microsoft components, no more discussions with IT!
- Used by 100dreds of customers worldwide, guaranteed development
- Paperless activities fully supported
- PACA on audit trail for pro-active management
- Stream lined processes with BPM!

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OpenLAB CDS 2

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Product Specialist

Agilent Technologies

Next Evolution of OpenLAB CDS

"OpenLAB CDS 2.0 - One data system for chromatography and mass spectrometry – Agilent GC, LC, core MS along with third-party instruments."

OpenLAB CDS 2.0 Workstation
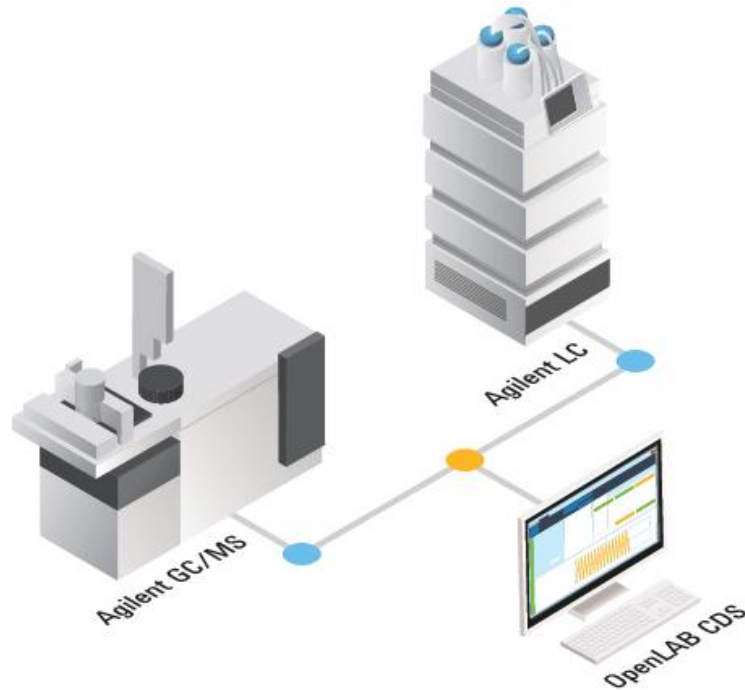
M8410AA Werkstation en komt met 2 instrument licenties

4 * GC / LC or
2 * MS or
2 * 3D LC

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Client/Server Architecture
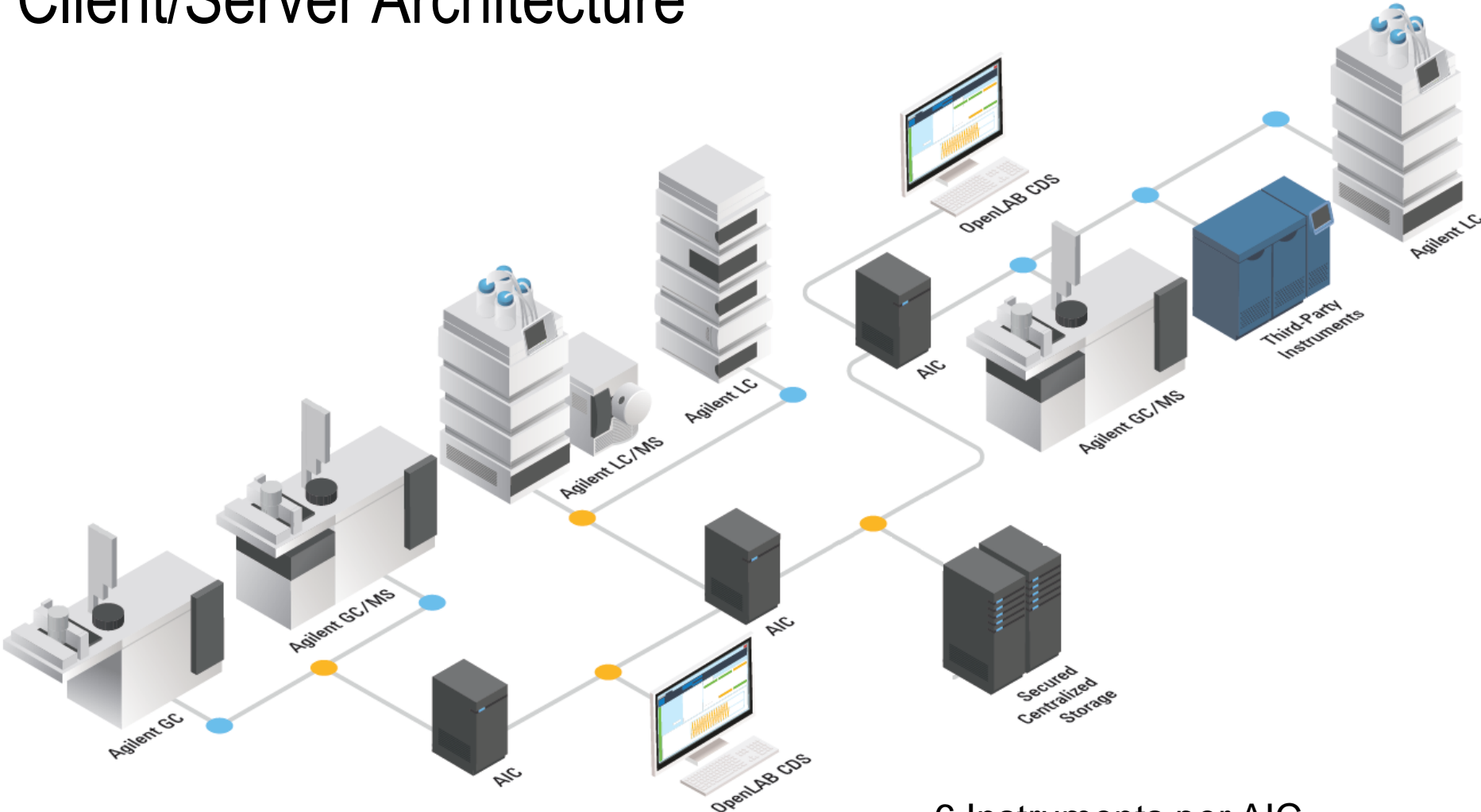
6 Instruments per AIC
200+ instruments supported

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See only what you need when you need it

View your entire lab at a glance

Central point for

- Instrument management
- Administration
- Launching instruments
- License management
- Access to log files
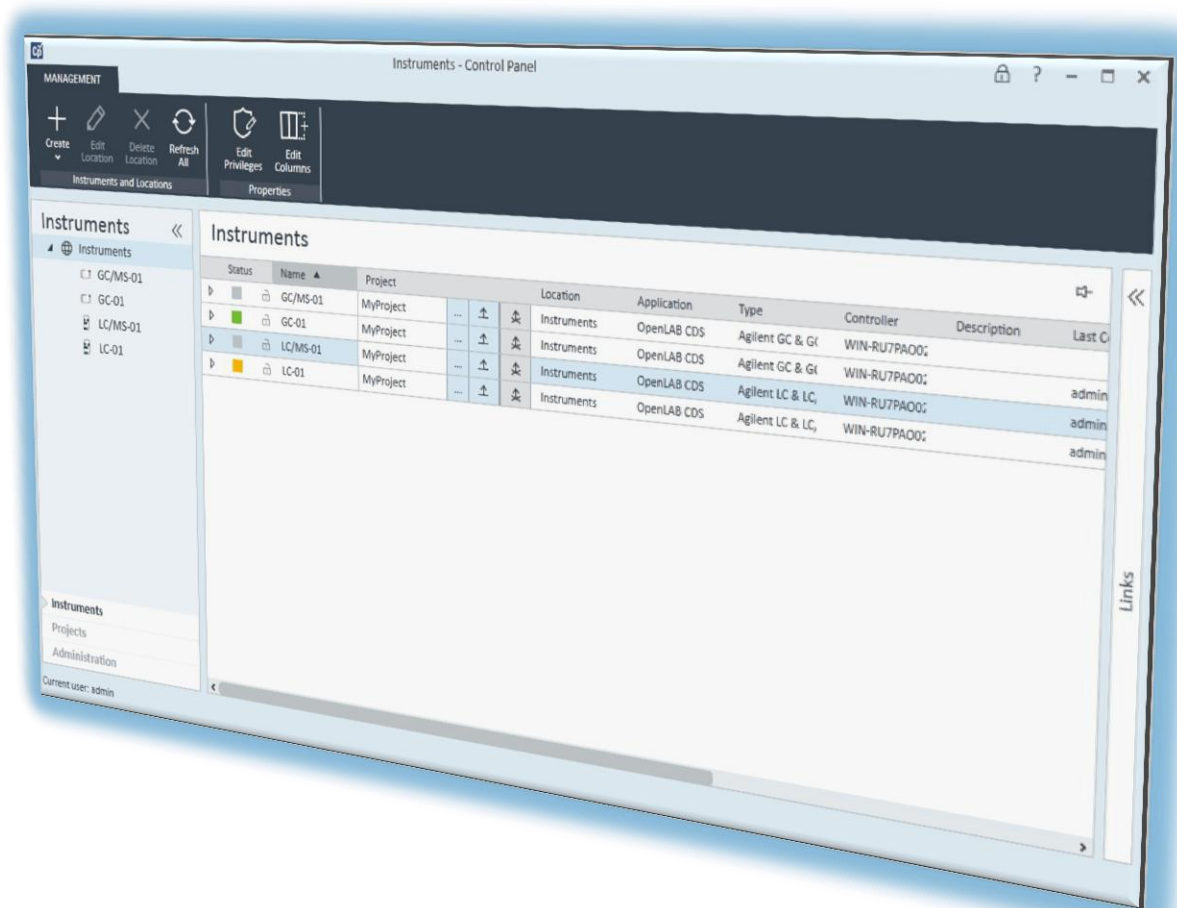
Data and Methods – Some Aspects

Projects

- Organize data context
- Reflect organizational structure
- Specific access rights and settings
- Custom fields on sample
  and compound level

Methods

- Dedicated acquisition and processing methods
- Copy of the methods is stored with the result set
  - Allows adaption of the method in the context of the result container
  - Master method can be updated from local method (requires privilege)

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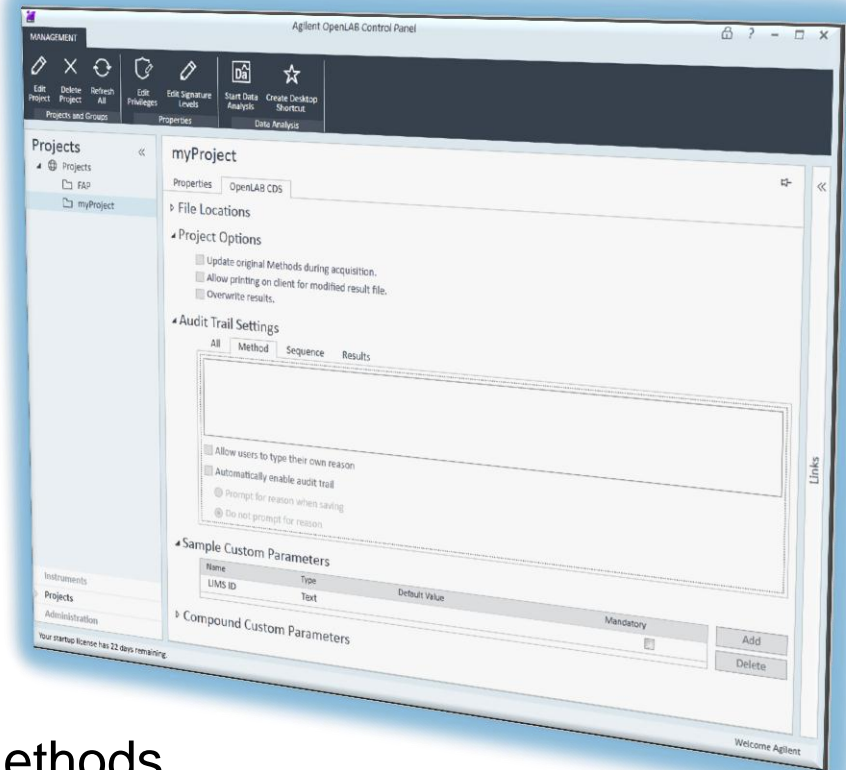
MS Support in OpenLAB CDS 2.0

Support of Agilent LC/MSD and GC/MSD instruments

MS Tuning and Calibration

MS based Quantitation with reference spectra confirmation

GC/MS NIST library searches

Compound Confirmation and Estimation of Sample Purity (LC/MS)

Extracting spectra at specific time or peak based

Reporting of MS data

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OpenLAB CDS 2.0 – Data Analysis

- One tool for LC/GC/3D UV/MS data analysis

- UI adapts to selected data type

- High processing performance

- One-click manual integration

- Fast data review with Peak Explorer

- Advanced Audit Trail Review

- Custom Calculation Designer

- eSignature
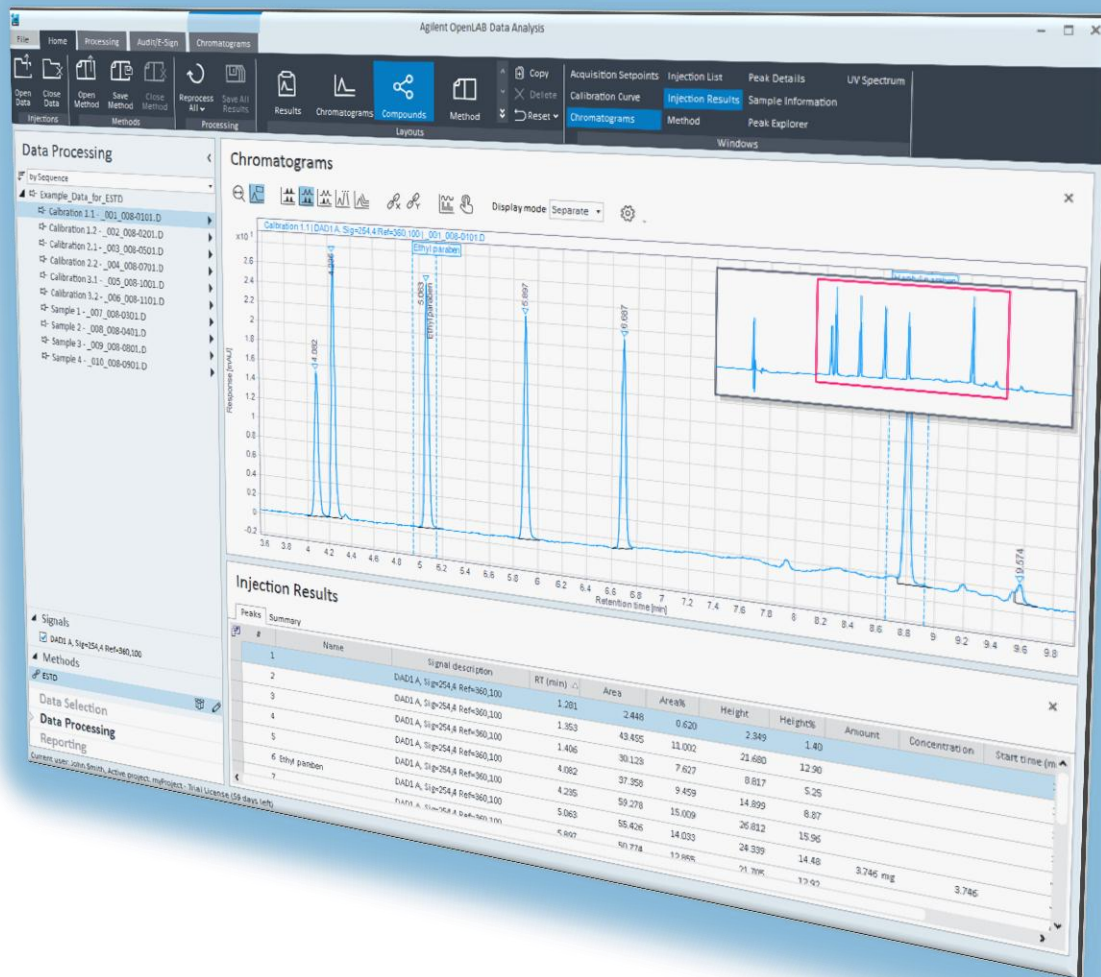
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One-Click Manual Integration
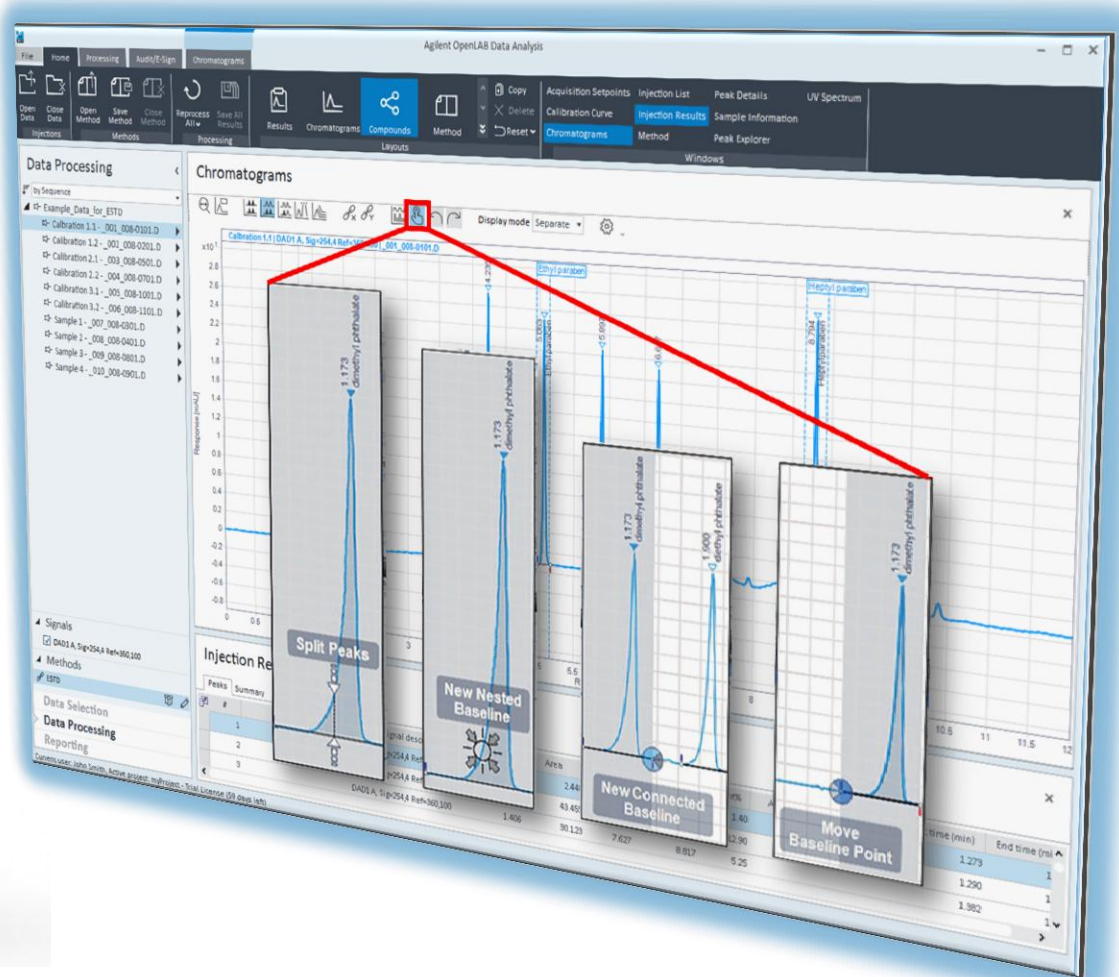
Get new insights into your data
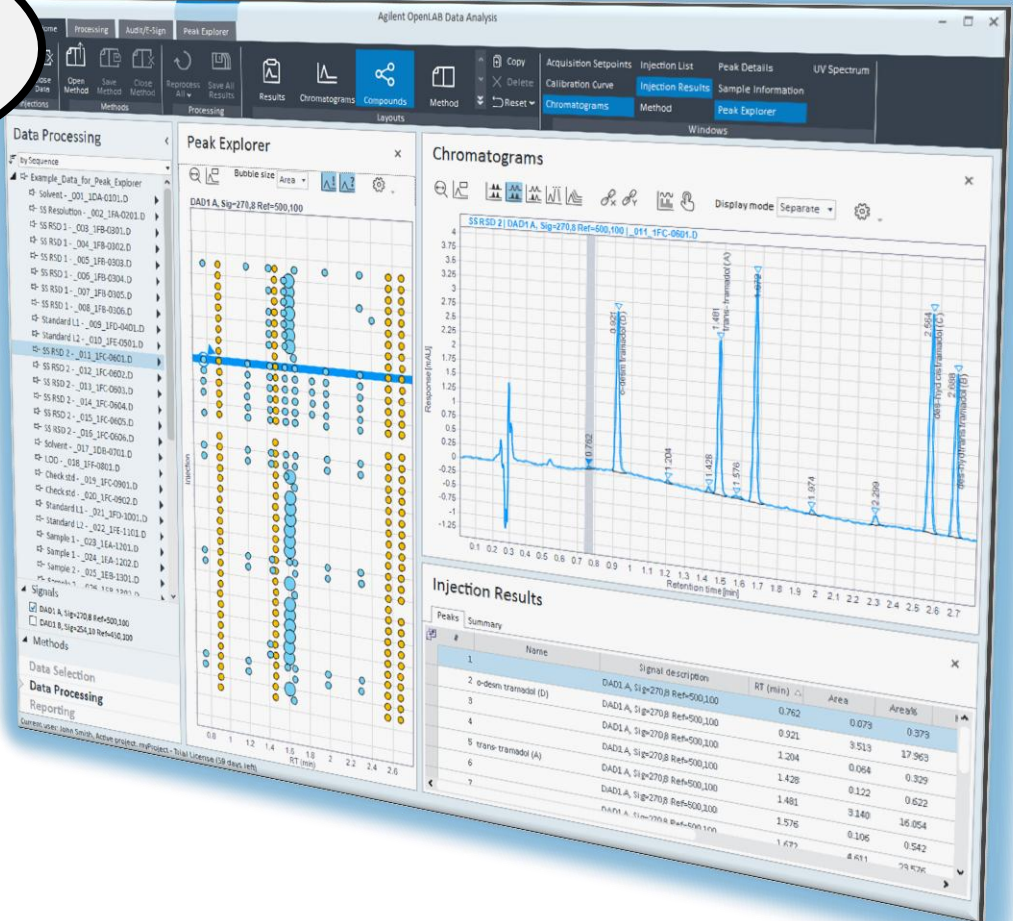
E-Signatures

In Data Analysis

Up to 5 levels

Reportable
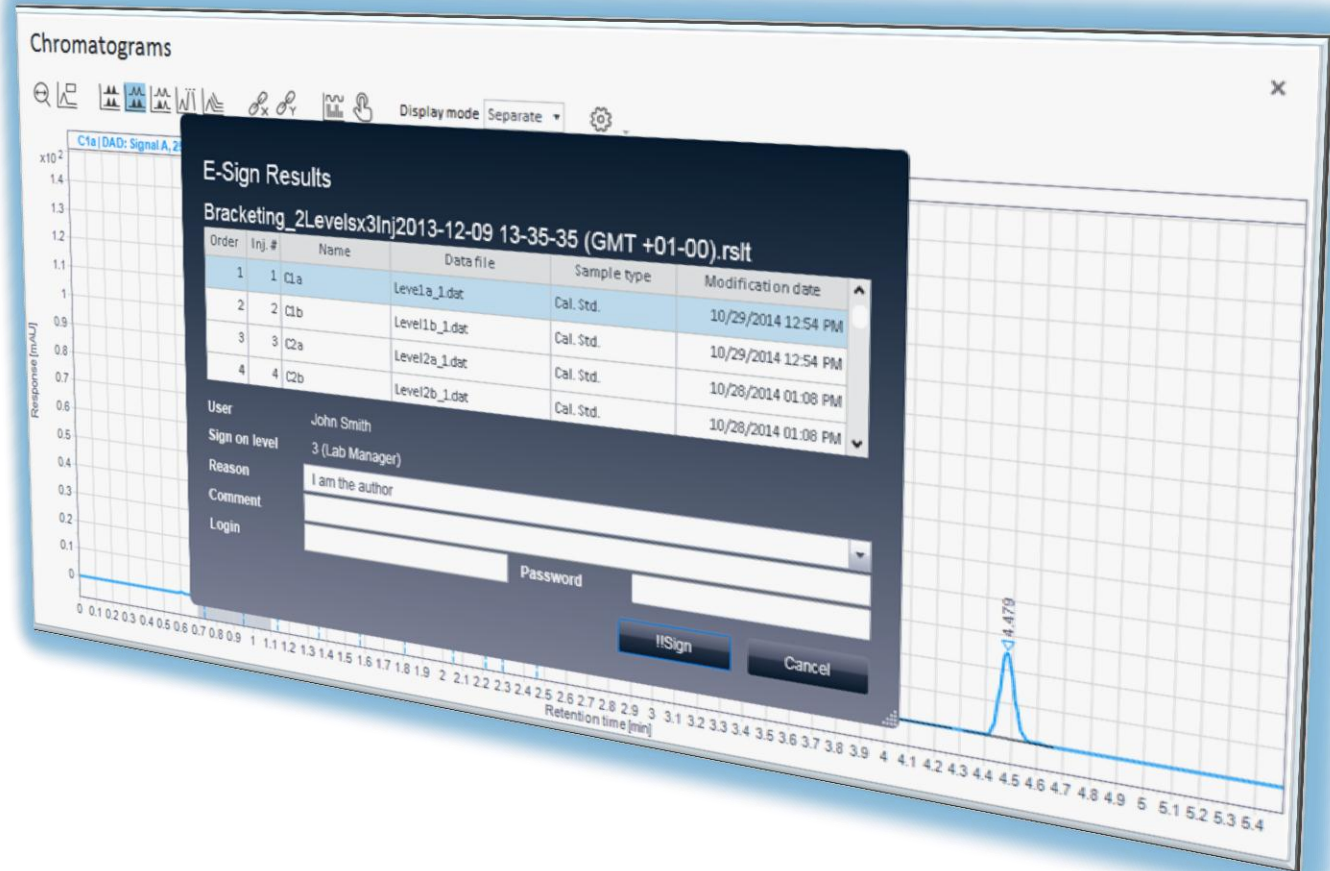
Advanced Audit Trail Review

Documented review

Audit categories

Full text searchable
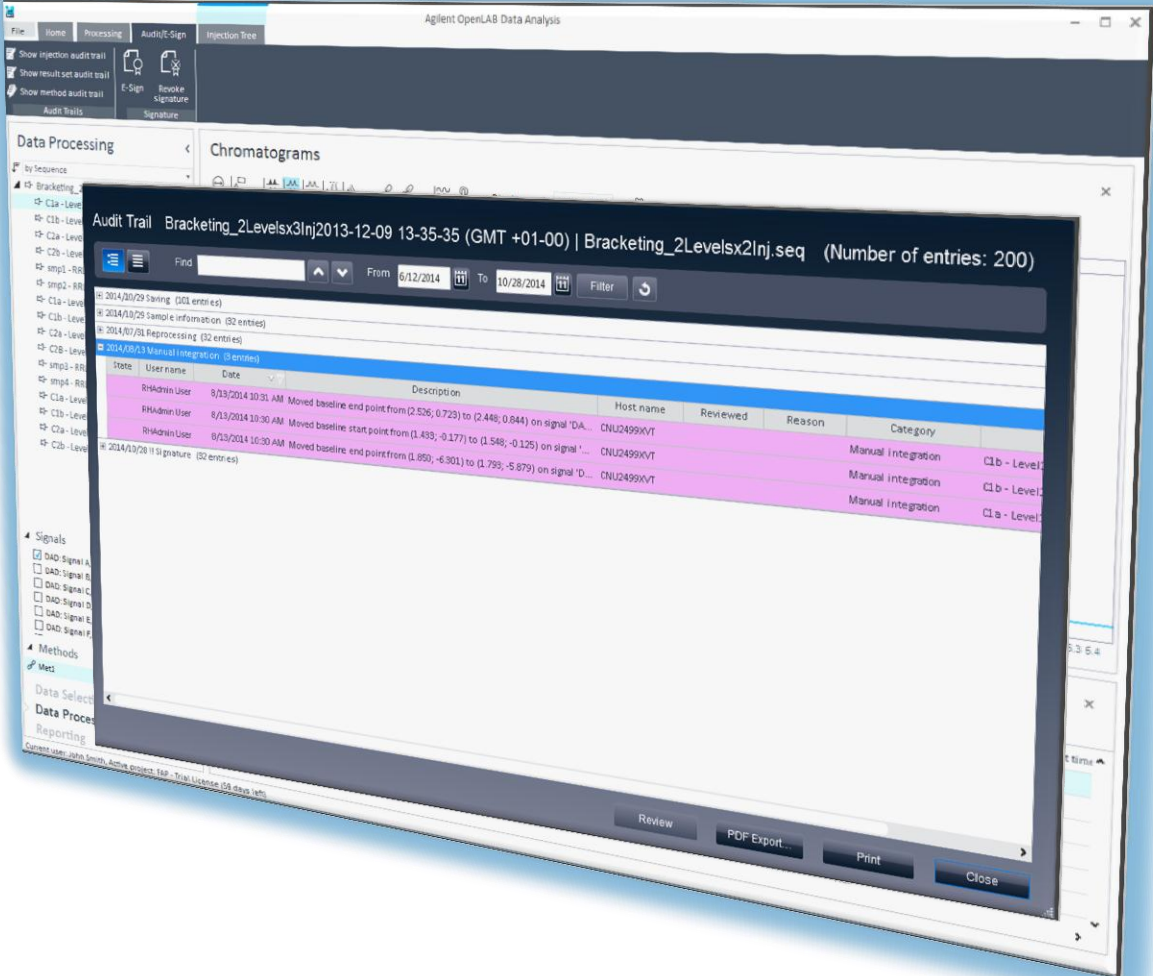
Sample Scheduler for OpenLAB

Configurable out-of-the-box LIMS interface

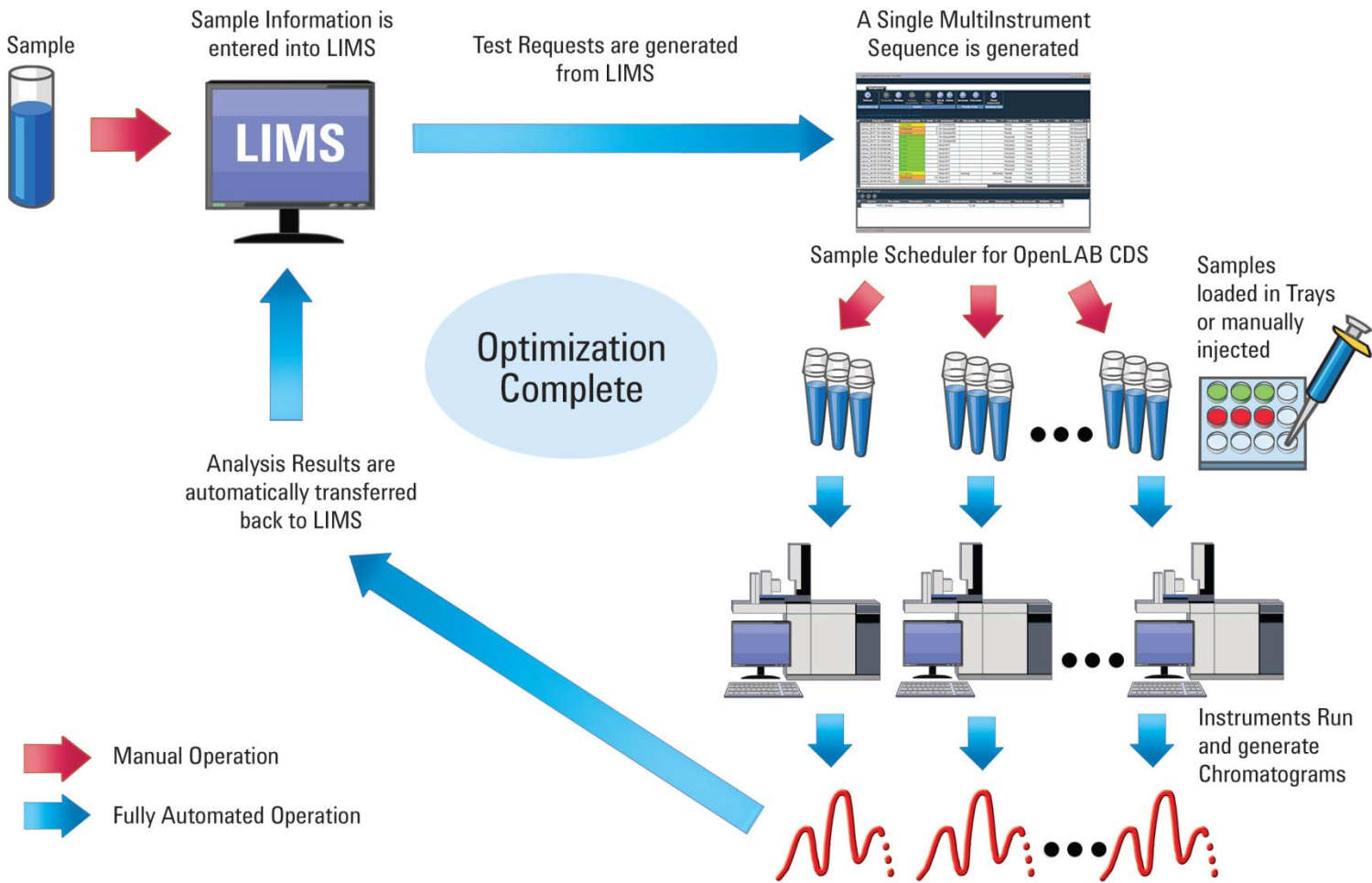Single UI for routing samples to any instrument
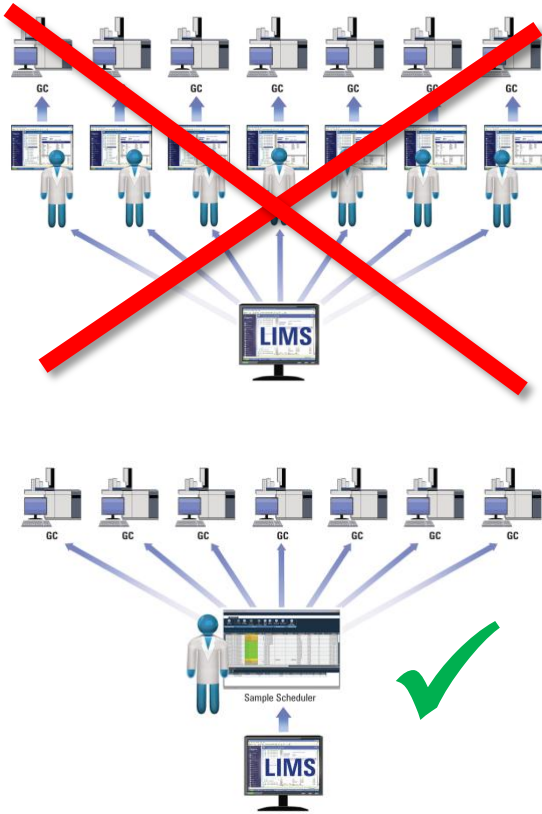
Walk-up interface for ad-hoc samples

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Want a short cut to more reliable results?
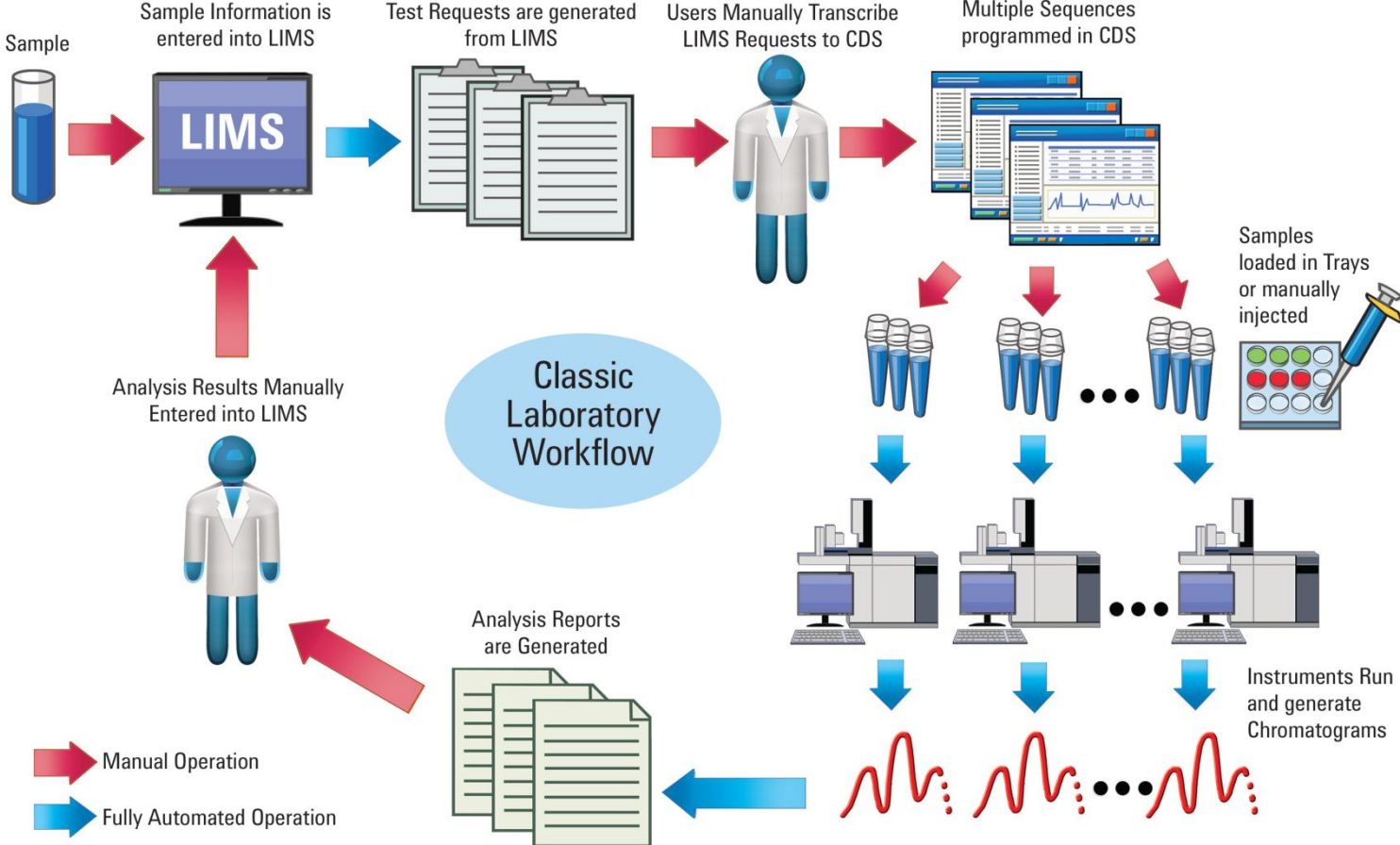
Close the gap between the LIMS and instruments

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Lab wide sequencing across instruments

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Intelligent Reporting - Complex Reporting Made Easy
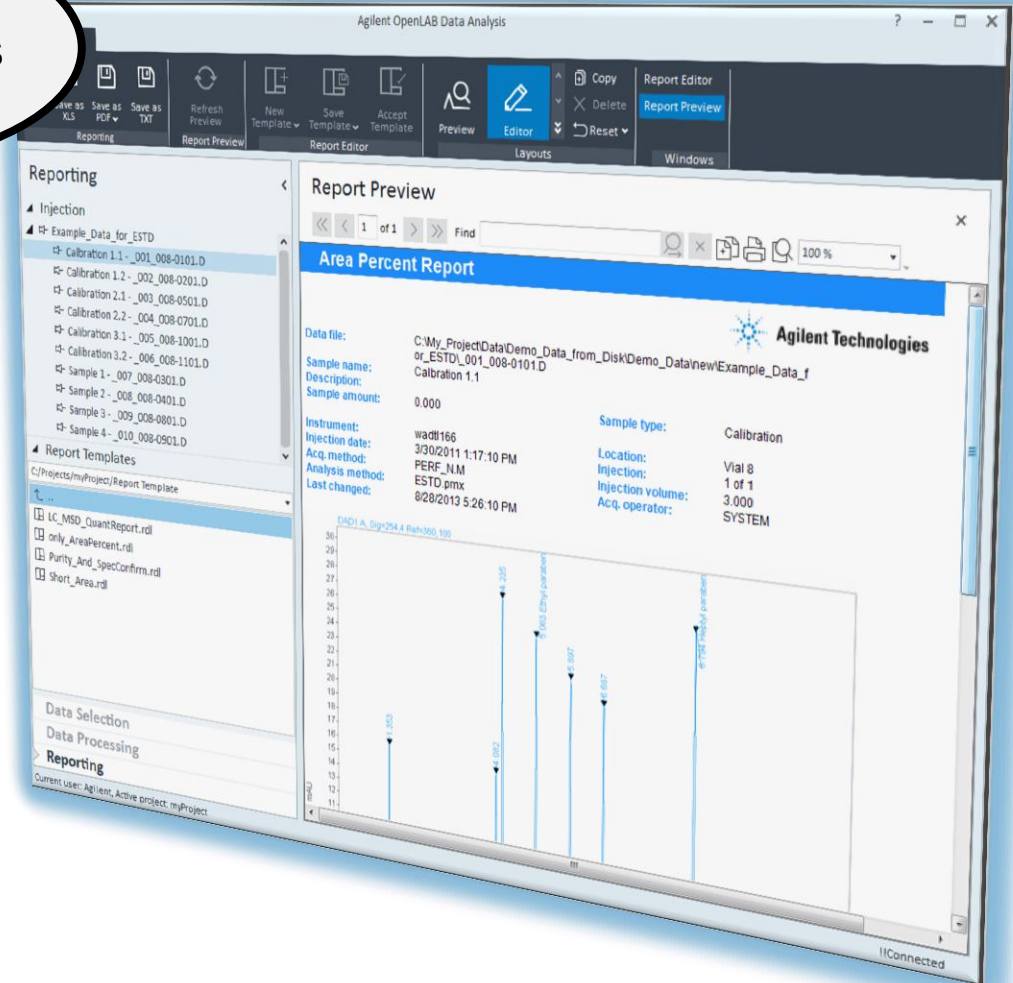
OpenLAB ELN

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Product Specialist

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What is OpenLAB ELN?

Central Hub between Lab Manager + Lab Employees

Delegate experiments

Upload results

Standardize protocols

Prioritize experiments

Plan next steps

View results

Track progress

Search past results

Share latest results

What is OpenLAB ELN?
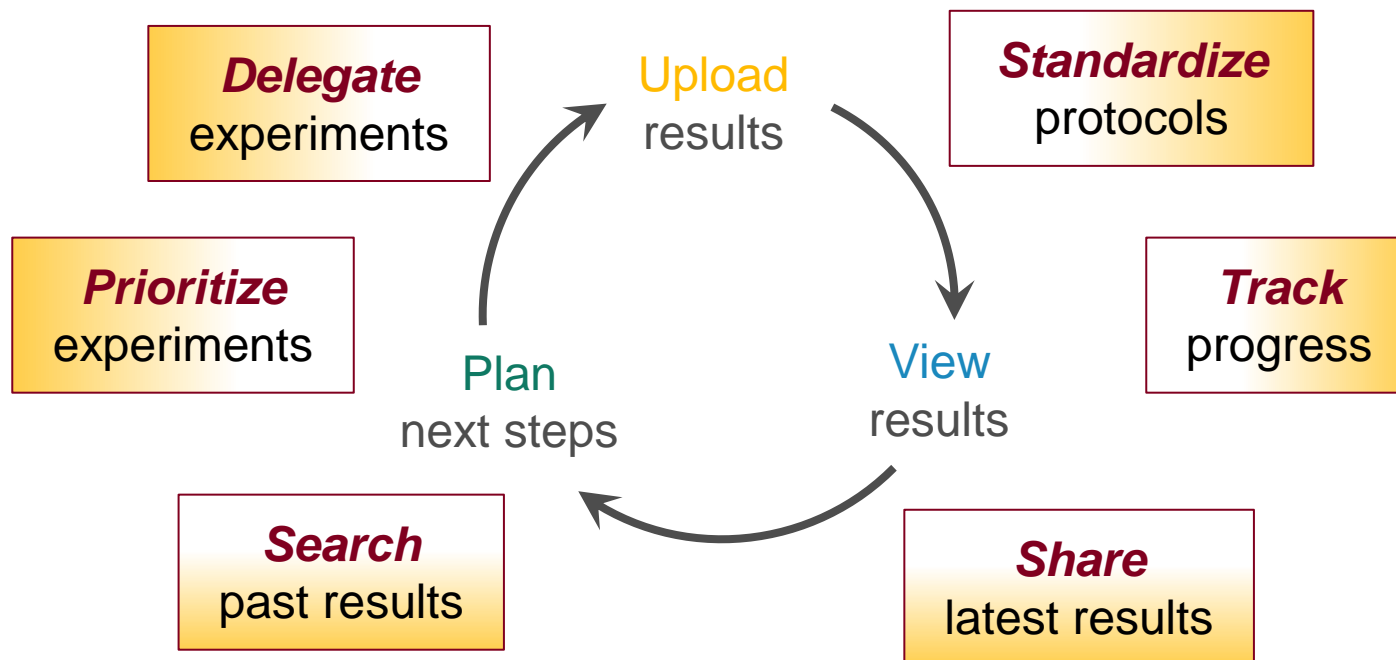
Capture your **complete experiment** (protocol, analysis, results) – all in one place.

- OpenLAB ELN helps you build connections between disparate data files – by bringing all your files together onto one single notebook page

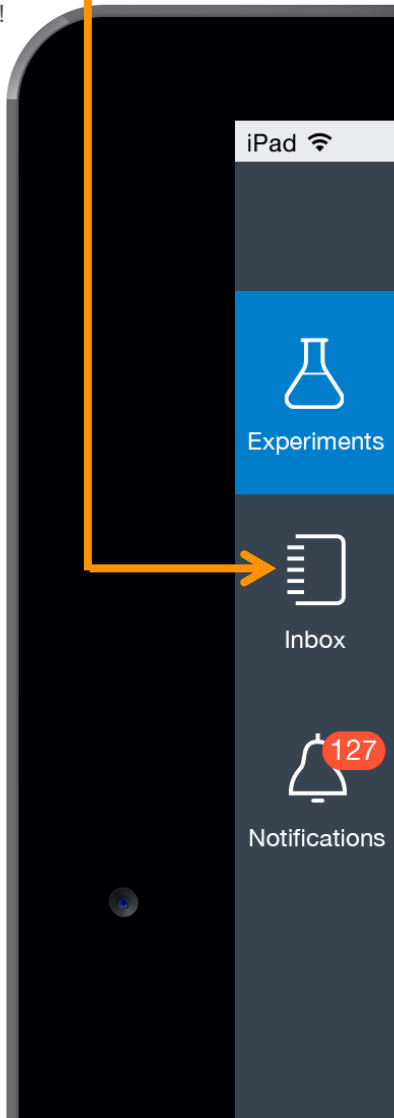- Simply drag-drop your files directly onto the page

Agilent Technologies
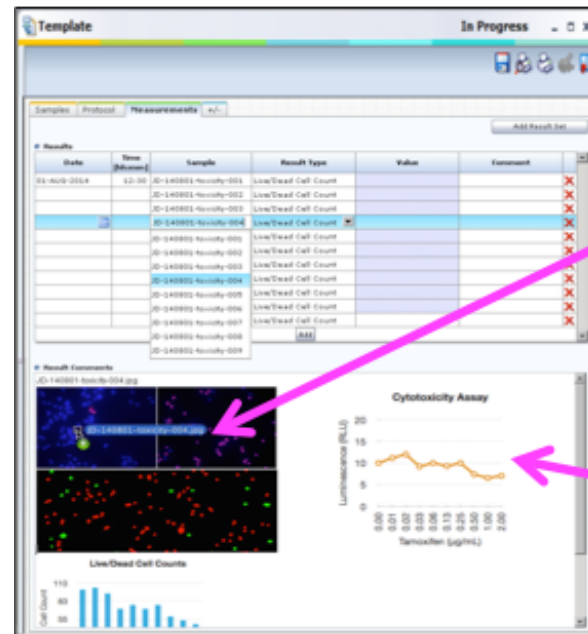
Access OpenLAB ELN – anytime, anywhere

Everywhere

At your desk

In a meeting

Agilent Technologies
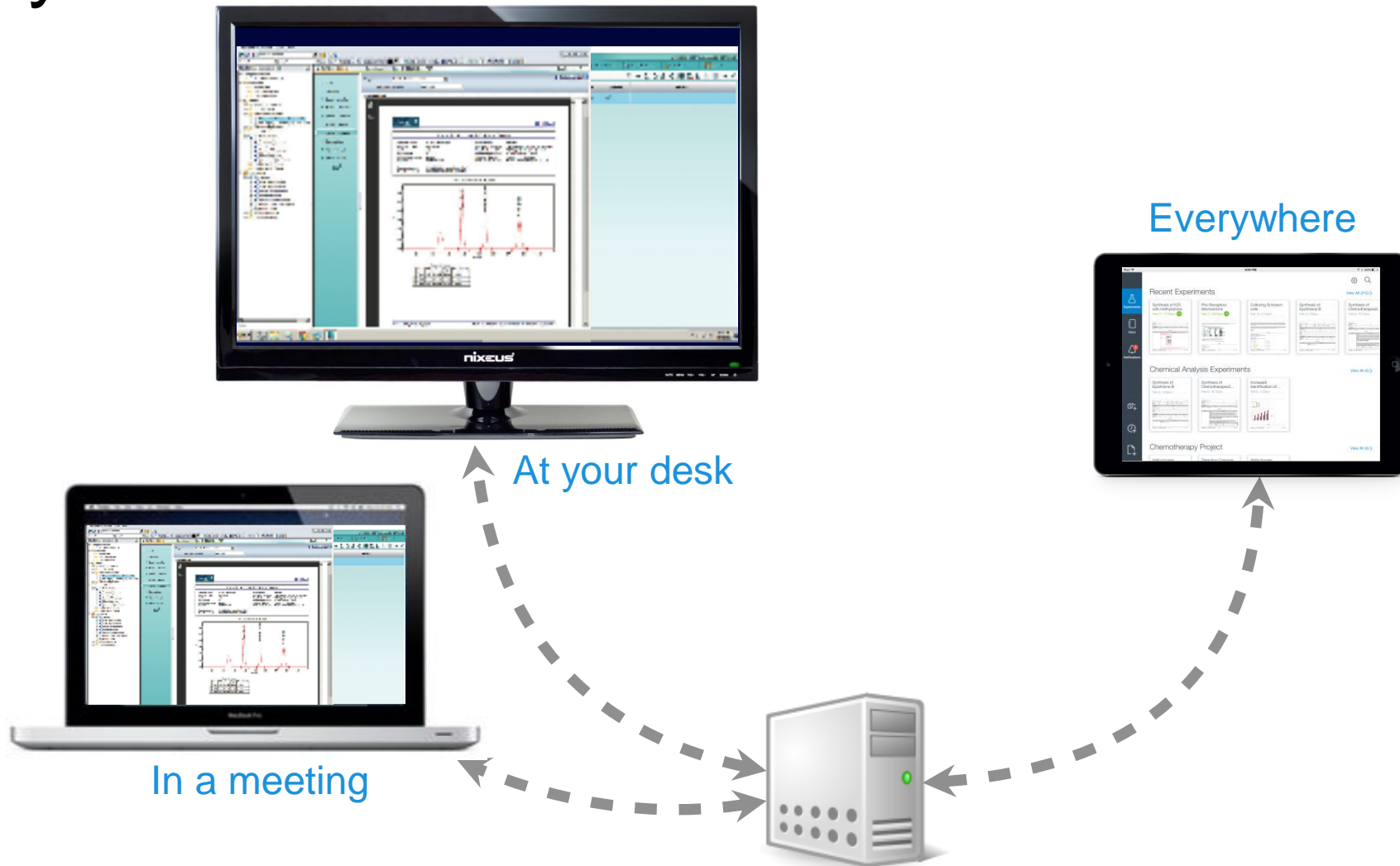
Meet OpenLAB ELN **Mobile.**

ELN Inbox
Send & receive photos, videos, PDFs, Microsoft Office files, and more!

Author ID Badges
Quickly see *who* last made changes

Color Indicators
Quickly see *if* there are new changes

iPad 📶   4:21 PM

Experiments

Inbox

127
Notifications

Recent Experiments

Impact of Temperature on...
Sept 14, 2:12 PM SD

Effect of Trypan Blue on Cells
Sept 14, 2:12 PM

Impact of Temperature on.
Sept 14, 2:12 PM

Biology Experiments

Parallel Synthesis Experiment
Sept 14, 3:45 PM SJ

Effect of Benzene on Cells
Sept 14, 2:12 PM SJ

Effects of Insulin on the Potency...
Sept 14, 2:12 PM

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Why Agilent OpenLAB ELN?

1 | **USER ADOPTION**
No programming required.
| OpenLAB ELN doesn't require any programming skills to capture data. Simply drag-drop Microsoft Excel files onto a page, or build forms that can include checkboxes, drop-down lists, tables, calendars, and more.

2 | **SMART IMPORT**
Making data capture simpler, faster, and more accurate.
| Automatically import data from OpenLAB CDS, other vendors' data systems, or any XML data source. Users can be confident that their data are free of transcription errors and instantly accessible within their experiments.

3 | **REQUEST MANAGER**
Speed up your lab's turn-around time.
| OpenLAB ELN streamlines communication by facilitating task delegation and instant, transparent access to completed results. What's more, it increases your lab's productivity by eliminating bottlenecks and track status/results in real time.

4 | **DYNAMIC FORMS**
Flexible, on-demand design.
| Dynamic Forms automate repetitive tasks, improve data quality, and simplify scientists' work. You can also minimize human error and structure your workflows (using fields such as text, numbers, tables, DNA sequences, molecules, and more).

5 | **OPEN ARCHITECTURE**
Scalability made simple.
| N-tier architecture makes scaling straightforward and easy—whether you're running on-premise or in the cloud. Plus, you can lower your total cost of ownership through minimal upgrade costs, and easy integration with the tools and apps you already use—including LIMS, SDMS, and ERPs.

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