SECURE EXPORT OF RESULT AND AUDIT DATA





In GLP-regulated environments, data generated by **Comet Assay IV** is often saved to an Oracle database in order to ensure security and integrity of study data. The **Data Extractor** is a powerful tool to view, search and filter this data. The **Data Extractor** also gives authorised users the power to approve and reject data, archive studies and export result and audit data.

- Easy browsing, sorting and filtering of all your result and audit information
- Approve or reject your data with the Data Extractor's electronic signature system
- Securely archive your data In accordance with OECD guidelines
- View images of every scored cell alongside measurement data and audit trails
- A range of secure export formats
 Including Excel, XML and encrypted file types
- Works with System Access Manager for GLP and FDA 21 CFR Part 11 compliance
- Comprehensively tested and validated in accordance with our Quality Management System which is approved to ISO 9001:2008 incorporating ISO 90003

PERCEPTIVE INSTRUMENTS



ACTOY for

Comet Assay

Filter, sort and search your data to quickly locate data for a specific study

The **Data Extractor** for Comet Assay IV allows authorised users and auditors to easily browse and export result and audit data from a secure Oracle database. The Data Extractor makes it easy to locate any past data for review or statistical analysis.

Data can be sorted and grouped quickly by clicking on column headings, and the **Filter builder** offers powerful data filtering capabilities allowing the creation of complex search criteria for selecting data in any conceivable way. Filters can also be saved for future use.

Sign and archive your data in accordance with OECD guidelines

The **Data Extractor** is essential for those wishing to archive their data in line with OECD guidelines, providing a sophisticated electronic signature and archiving system. Authorised users can quickly locate data to be signed or archived using the filtering system.

In order to maintain the integrity and accessibility of your data, the **Data Extractor** marks data as archived within the database. This not only helps ensure the integrity of your data by avoiding any potentially dangerous export and purge operations, but also means you can still view the study and reconstruct reports for auditing and verification.

Comet Assay IV Data Extractor v2.0: James Wa				
File Databa	se Security	Help		
Comet Assay result and audit data Data Extractor audit trail				F
2 sessions were successfully archived.				
Drag a column header here to group data by that column				
Signed	Archived	Signature Entry	System Id	
Yes	No	Approved	20299	
Yes	Yes	Rejected	23491	
No	No		23491	

Batch export of results and images for efficient data processing and auditing

The **Data Extractor** allows results and images of scored cells to be exported in batches. This means you can export all the results for a study in one group. These files can be named automatically using study codes, slide IDs etc. for easy identification.

Exporting images of scored cells can be particularly useful for auditors and study directors. Each cell image is stored with result data and information on exactly how the user scored the cell. These images can be opened in Comet Assay IV and rescored to verify the results attained.

Auditing and user administration helping you meet regulatory requirements

All audit data collected during the use of Comet Assay IV can be viewed by authorised users within the **Data Extractor** and exported. In addition to this, the Data Extractor has a full audit trail of its own, which can also be viewed and exported. Access to both Comet Assay IV and the Data Extractor can be protected using the System Access Manager, allowing for centralised administration of all users. Five access levels are incorporated within the system, each with privileges that can be independently customised. This not only aids the meeting of regulatory requirements, but provides flexibility for your specific demands.

A range of secure export formats for flexible data transfer and reporting

With the **Data Extractor**, users can browse, group and filter data within the database and export it for use with the **Spreadsheet Generator** macro or any other data processing and reporting tools. Users can export study data to Excel, XML and encrypted formats. This allows for ultimate portability, integration into existing data management systems and security of data.

PERCEPTIVE INSTRUMENTS