



European Directorate for the Quality of Medicines & HealthCare

Council of Europe

edqm
European Directorate
for the Quality
of Medicines
& HealthCare | Direction européenne
de la qualité
du médicament
& soins de santé

COUNCIL OF EUROPE

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CombiStats online

Training module 1



Introduction to the online application

Content

★ Introduction

★ Workspace

★ File and folder management

★ Data entry, analysis options & audit trail

★ Batch creating .epax files

The CombiStats Software

Statistical analysis of data of dilution assays in accordance with Ph. Eur. Chapter 5.3

5.3. STATISTICAL ANALYSIS OF RESULTS OF BIOLOGICAL ASSAYS AND TESTS

1. INTRODUCTION

This chapter provides guidance for the design of bioassays prescribed in the European Pharmacopoeia (Ph. Eur.) and for analysis of their results. It is intended for use by those whose primary training and responsibilities are not in statistics, but who have responsibility for analysis or interpretation of the results of these assays, often without the help and advice of a statistician. The methods of calculation described in this annex are not mandatory for the bioassays which themselves constitute a mandatory part of the Ph. Eur. Alternative methods can be used and may be accepted by the competent authorities, provided that they are supported by relevant data and justified during the assay validation process. A wide range of computer software is available and may be useful depending on the facilities available to, and the expertise of, the analyst.

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 - 3.2. the parallel-line model
 - 3.3. the slope-ratio model
 - 3.4. extended sigmoid dose-response curves
4. assays depending upon **quantal responses**
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 - 4.5. the median effective dose
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 - 6.2. combination of independent assay results
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7. beyond this annex
8. tables and generating procedures
9. glossary of symbols
10. literature

Some figures

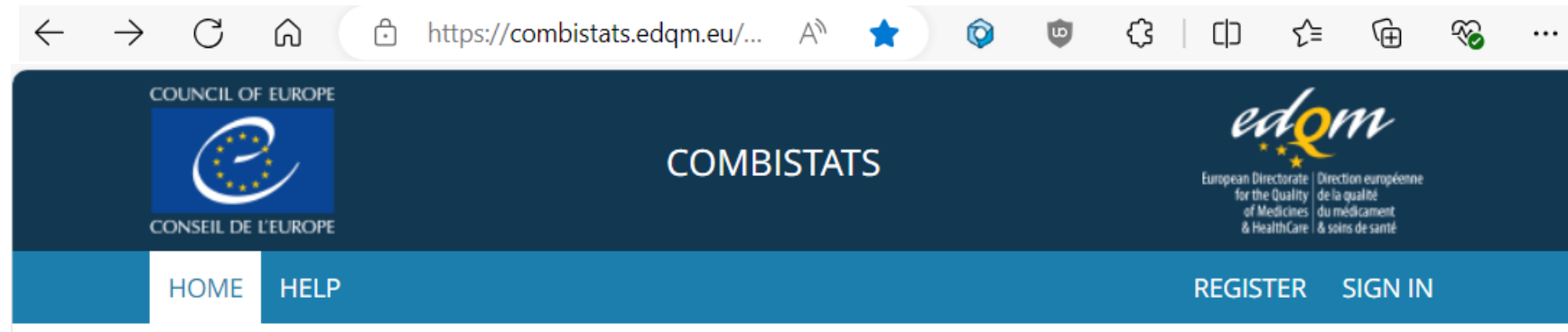
★ Desktop version release in 1999 to OMCLs, in 2005 to non-OMCLs

★ **CS-online release in 2024**

★ Users' expectations (top 3)

- ★ User identification (individual login/password)
- ★ More interactivity (e.g. information/error messages)
- ★ Audit trail

Notes for guidance in free access <https://combistats.edqm.eu/home/>



How to

- Create my account

Notices

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- Security Notice

Notes for guidance

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- EN15 Potency Estimates
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- EN18 Spearman-Kaerber Approach
- EN19 Single-dose Assay
- EN20 Multiple-dose Assay (Standard Only)
- EN21 Template & Protection
- EN22 Audit Trail
- EN23 Information & Error Messages
- EN24 Structure of epax & epx files

Technical requirements

- Computer with access to the Internet, Chrome or Edge browsers
- Acrobat Reader for viewing PDF reports, MS Excel for viewing extra analysis results

Sustainable tool using a modern programming language

★ Flexible licence management system

- ★ EDQM Store: 1 licence = n users/seats
- ★ Possibility to assign and revoke users

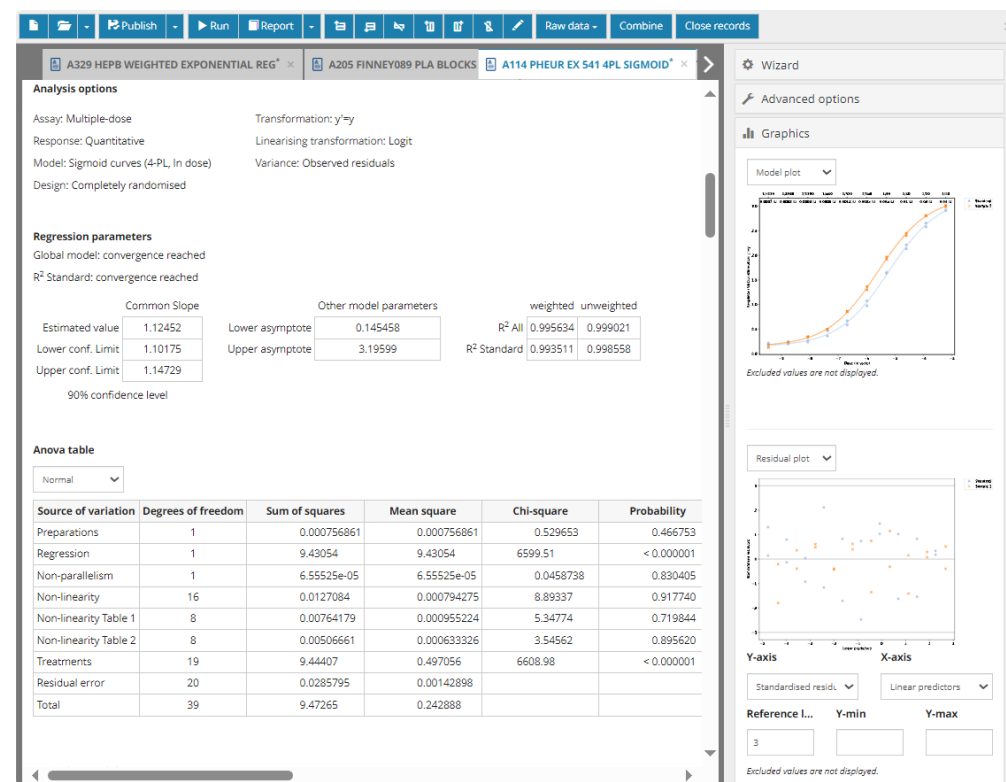
Dedicated workspace for your organisation

- ★ Access by login/password
- ★ Folders & files creation, management, sharing
- ★ Import of CombiStats Desktop 5.0 to 7.0 files

Modern & interactive interface

- ★ Better flow of analysis options
- ★ Enhanced graphical views
- ★ Information and error messages
- ★ Template, file protection
- ★ PDF report, audit trail

☐	Type	Name	Created	Created by	Last modified	Last modified by	Owner	
☐		A_folder01	31 May 2024	User U	today	User U	User U	Shared ...
☐		A_folder02	25 Jun 2024	User U	today	User U	USER 1 T	...



Content

★ Introduction

★ **Workspace**

★ File and folder management

★ Data entry, analysis options & audit trail

★ Batch creating .epax files

User account creation



COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

COMBISTATS



European Directorate
for the Quality
of Medicines
& HealthCare

Direction européenne
de la qualité
du médicament
& soins de santé

[HOME](#) [HELP](#) [REGISTER](#) [SIGN IN](#)

Registration

E-mail ID*

my_email@address.com

Please enter the e-mail address that will serve as login

Captcha*

 ZPR

Back

Next

Registration

First name*

My first name

Last name*

My last name

Professional organisation*

My professional organisation

Country (of organisation)*

France

Back

Register

Your account has been created. You will shortly receive an e-mail with a link to define your password in order to finalise your registration.

You already have an EDQM account. Your access to this application has been granted. Please use your EDQM credentials to login.

User account activation

1. Click the link received by email

[EDQM-Account] Creating your account - Please define your password -- [Compte EDQM] Création de votre compte - Veuillez définir votre mot de passe 



From noreply-qual@edqm.eu on 2024-06-28 10:12

 Details  Headers  Plain text

Version française plus bas

*** This is an automatically generated e-mail, please do not reply ***

Dear My first name My las,

Welcome to the EDQM environment.

In order to activate your account, you will need to set your password. To do so, please follow the link below:

<http://sign-qual.edqm.eu/validation/MzExOA/6mb-fc6404052bcf121c90cc/?>

[lang=en&redirect=aHR0cHM6Ly9jb21iaXN0YXRzLXF1YWwuZWRxbSSldS9hY2NvdW50cy9sb2dpbg](http://sign-qual.edqm.eu/validation/MzExOA/6mb-fc6404052bcf121c90cc/?lang=en&redirect=aHR0cHM6Ly9jb21iaXN0YXRzLXF1YWwuZWRxbSSldS9hY2NvdW50cy9sb2dpbg)

Do not forward this link to other users, as it contains a token that is only valid for your e-mail address for 1 day.

Please be informed that your account will be deactivated if you do not set up your password and log in within 5 days.

For your information, your login is your e-mail address.

Permissions will be granted to your account, when necessary, for applications you need to access to. In this case, you will receive an automatic e-mail from the so-called applications.

2. Create a password

Enter your password

Please enter your password twice so we can verify you typed it in correctly.

New password*

- Your password must contain at least 10 characters.
- Your password must contain at least 1 uppercase character.
- Your password must contain at least 1 digit.
- Your password must contain at least 1 special character among !@#\$\$%^&*(){}[]-+.
- Your new password can not be identical to any of the 10 previously entered.
- Your password can't be a commonly used password.
- Your password can't be entirely numeric.
- Your password can't be too similar to your other personal information.

New password confirmation*

3. Sign in to activate your account

One last step

Password set. In order to finalise the activation of your account, you now need to log in.

Sign In

How many seats users (seats) for your organisation?

★ EDQM webshop: <https://store.edqm.eu/index.html>

▼ Products
☒ EUROPEAN PHARMACOPOEIA 11th EDITION
☐ BIOLOGICAL STANDARDISATION PROGRAMME
☐ BLOOD TRANSFUSION
☐ COSMETICS
☐ COUNTERFEIT MEDICINES AND SIMILAR CRIMES
☐ FOOD CONTACT
☐ ORGANS, TISSUES AND CELLS
☐ PHARMACEUTICAL CARE
☐ QUALITY MANAGEMENT FOR BLOOD ESTABLISHMENTS
☐ TATTOOS AND PERMANENT MAKE-UP
☒ CombiStats

DESCRIPTION

CombiStats is a calculation program for the statistical analysis of data from biological dilution assays according to Ph. Eur. general chapter 5.3.

You can find out more about CombiStats [on the dedicated webpage](#) and [FAQs](#) on the EDQM website.

Languages: English

Ordering: The following discounts are available for orders for multiple users:

- 5% for 2 to 4 users;
- 10% for 5 to 10 users;
- 20% for 11 to 20 users;
- 30% for 21 or more users.

These discounts will be applied after validation of your order/quotation.

Technical requirements :

CombiStats runs on recent versions of all modern web browsers including Chrome and Edge. Reports are exportable in PDF format and results in an Excel-compatible format. For more information on the technical requirements, please see the [EDQM FAQs](#).

Name	Price	Quantity	
Combistats licence	600.00 EUR	1 PCE	
Combistats licence - Extension	600.00 EUR	1 PCE	

**Enter the number
of seats (users)
here.**

Example

- First order: a licence for 2 seats (users)

Name	Price	Quantity	
Combistats licence	600.00 EUR	2 PCE	
Combistats licence - Seat Extension	600.00 EUR	0 PCE	



CSID code to activate the workspace



Validity: 1 year from licence activation date (anniversary date)

- Second order: 3 additional seats (same workspace)

Name	Price	Quantity	
Combistats licence	600.00 EUR	0 PCE	
Combistats licence - Seat Extension	600.00 EUR	3 PCE	

CSID code to extend the workspace

Validity: anniversary date of first order



- Licence for 3 seats in another workspace

Name	Price	Quantity	
Combistats licence	600.00 EUR	3 PCE	
Combistats licence - Seat Extension	600.00 EUR	0 PCE	

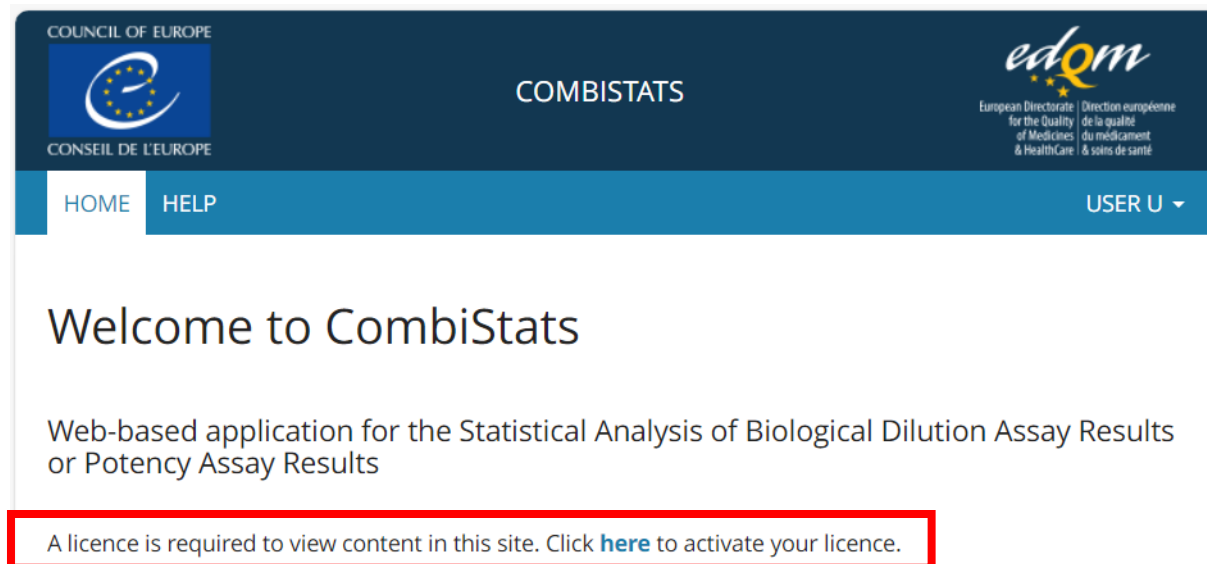
CSID code to activate the workspace

Validity: 1 year from licence activation date



Workspaces do not communicate between each other

Workspace activation



The screenshot shows the top navigation bar of the CombiStats website. It includes the Council of Europe logo and name on the left, the 'COMBISTATS' title in the center, and the EDQM logo with its full name on the right. Below this is a secondary bar with 'HOME' and 'HELP' links on the left, and a 'USER U' dropdown menu on the right. The main content area displays a 'Welcome to CombiStats' message, followed by a description of the application as a 'Web-based application for the Statistical Analysis of Biological Dilution Assay Results or Potency Assay Results'. A red rectangular box highlights a message at the bottom: 'A licence is required to view content in this site. Click [here](#) to activate your licence.'

From: Sales@edqm.eu <Sales@edqm.eu>
Sent: Wednesday, October 30, 2024 5:00:00 PM (UTC+01:00) Brussels, Copenhagen, Madrid, Paris
Your CombiStats licence - Your order 0123456789 - Our order confirmation 543210
DO NOT REPLY TO THIS MESSAGE
Dear Customer,
Thank you for your order. Please find your licence activation key below:
Combistats licence - Access for N user(s)
CSID-///// -//////// -///// -//// ➔ Activation code = licence key = CSID
The procedure for activating the licence key and registering users can be found [here](#).
If applicable, please forward this message to the person responsible for managing
CombiStats licences within your organisation.
If you experience any problems, do not hesitate to contact us via the [EDQM HelpDesk](#).

Licence Activation

If you have a licence key, activate it here to create your workspace.

Otherwise, contact the licence manager within your organisation.

Licence key (CSID)*:

Once activated, your licence key will be valid for a year.

Activate

Each organisation can manage access to the workspace

LICENCE

Workspace ID: 5BNDLNKJ
Number of access: 4 assigned - 3 available
Expiration date: 01 July, 2025

This page is accessible to licence managers only

NEW LICENCE ACTIVATION

CSID code*:

Activate

In case of renewal, your licence key will be valid for a year. In case of extension of the number of seats, the expiration date remains unchanged.

Licence key	Access count	Subscription	Activated on	Activated by
CSID-5D0QG-XV5YK16Q4C-TPB57-H8P0	7	until 2025-07-01	01/07/2024	bao lalala

ASSIGNEES

E-mail*

Assign user (one-at-a-time)

☐ Can manage

Assign single

Choose file*

Assign multiple users (at once)

Assign multiple

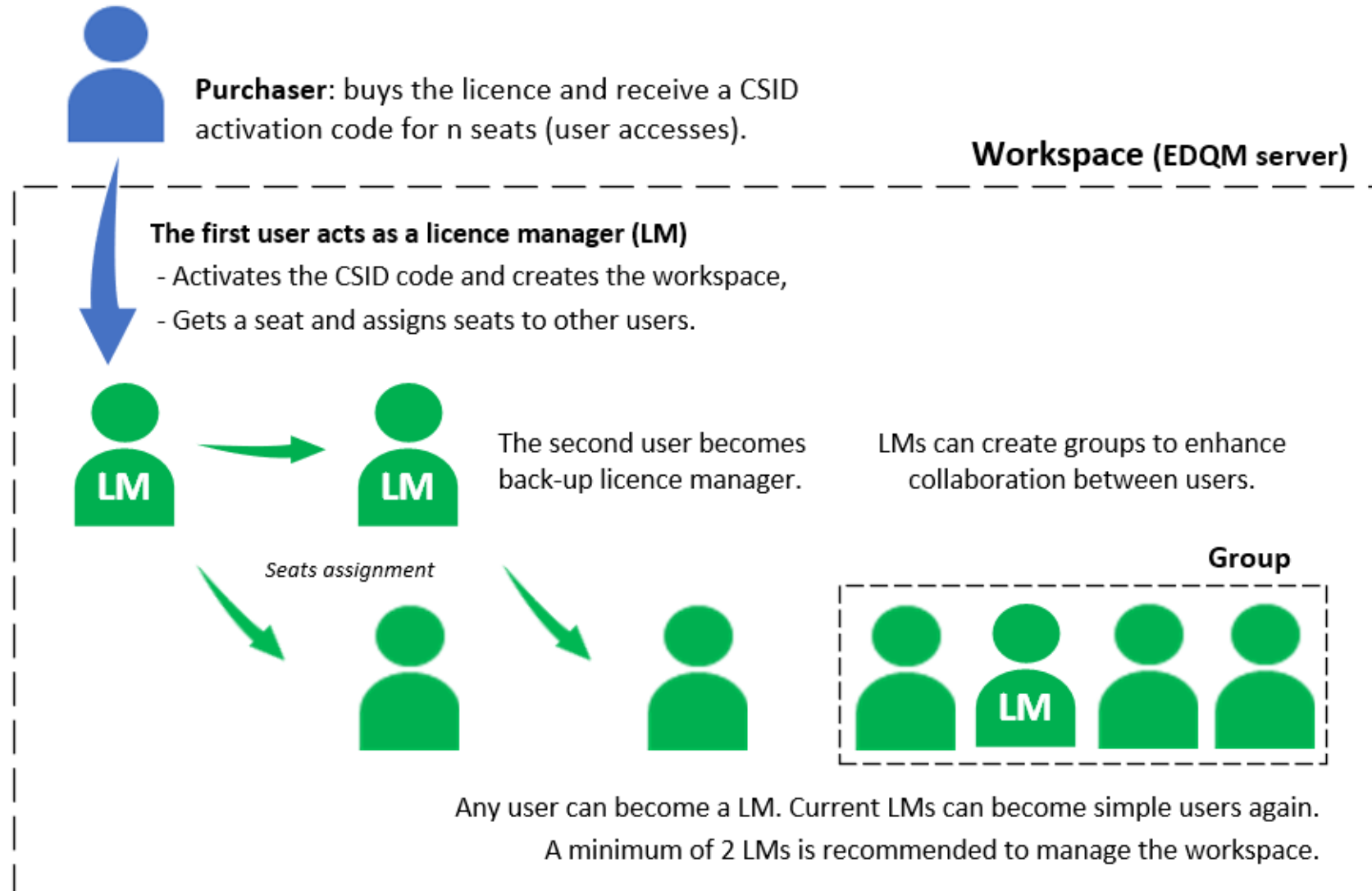


	A
1	user1@CS.org
2	user2@CS.org
3	user3@CS.org
4	...

You can download a template to fill in here

E-mail	Assignee	Can manage workspace	
baothanh.nguyenvan@edqm.eu	bao lalala	☒	Revoke

Workspace: secure & collaborative working environment



Licence manager (LM role)

A user who can:

- ★ Enter CSID codes to activate/renew the workspace
- ★ Assign users to the workspace, give LM roles
- ★ Revoke users from the workspace, revoke LM roles (including him/herself)
- ★ Create, edit, delete user groups
- ★ Manage files and folders

Note. Revoke a user...

E-mail	Assignee	Can manage works	
combistats@edqm.eu	Test User	☒	Revoke

The user can give read/write access to their folders before being revoked. Alternatively, a LM can do it.

Remarks

- ★ You cannot access CS-online unless your account has been assigned to a seat. Assignment to a seat is managed by a licence manager (see previous slide)
- ★ A same email address cannot be used with several workspaces
- ★ Licence renewal: place an order (webshop or email)

E-mail	Assignee	Can manage workspace	
david.le-taltec@edqm.eu	> DLT	☒	<button>Revoke</button>

<https://www.edqm.eu/en/lp-combistats>



- ★ E-mail notifications to licence manager(s) 1 month and 2 weeks **before expiry**

- Renewal: enter the new CSID code
- No renewal: workspace locked

NEW LICENCE ACTIVATION

CSID code*:

Activate

In case of renewal, your licence key will be valid for a year. In case of extension of the number of seats, the expiration date remains unchanged.

Homepage: Your licence has expired. Please renew it in order to access your workspace.
Renewal after expiry still possible

RENEW ACCESS

Licence key (CSID)*:

Renew

If you know that you will stop using CS-online for a long period, export files locally (files are automatically deleted 3 years after their date of creation).

Remarks

★ In case where the workspace has only one seat (user is necessarily licence manager)

Licence key	Access count
CSID-AAAAA-BBBBBBBBBB-CCCCC-DDDD	1

TRANSFER LICENCE

E-mail*

Transfer

If changing positions, this user should **transfer** the licence ownership to his/her replacement

The new licence manager will have full access to folders & files

★ Notices

- [Privacy Notice](#)
- [Security Notice](#)

The EDQM processes your data based on the Council of Europe Regulations on the Protection of Personal Data (**CERPPD**).

Registration

First name*

Last name*

Professional organisation*

Country (of organisation)*

- [Privacy Notice](#)
- [Security Notice](#)



Data is processed by a server of the EDQM located in France.

1. **General aspects:** e.g. governance, development policy, risk & incident management
2. **Data protection:** e.g. user access, data encryption, data retention
3. **Infrastructure:** e.g. security, availability & resilience, recovery

Remarks

★ Should I transfer all my epa files (CS-desktop) to the workspace? **NO**

After reviewing the user manual, I noticed that it only allows importing files one at a time. Given that we have over 15 years' worth of work in .epa format, this process would be quite time-consuming for us.

★ Files are deleted 3 years after their creation (the EDQM server is not meant to become a database)

Option:

- Store legacy files (epa, epc) locally in case where you would need to import them to CS-online for reanalysis
- Export files (epax, epcx) on a regular basis unless PDF reports (raw data, analysis options, calculated results, audit trail) are enough

Validation

Release notes

CombiStats has been successfully tested using the Chrome and Edge web browsers. The calculation modules previously available in the desktop version have been reproduced using more up-to-date language and terminology. Although the EDQM has not published any documentation pertaining to the validation of CombiStats Online, since the application is not certified, the examples from Ph. Eur. general chapter 5.3 and Appendix A of the desktop version user manual, as well as the majority of the examples provided in *Statistical Method in Biological Assay* by David J. Finney (3d ed., 1978, ISBN 0852642520), were tested and the results were successfully compared with those generated by the desktop version.

<https://combistats.edqm.eu/faq/link/87/>

Content

★ Introduction

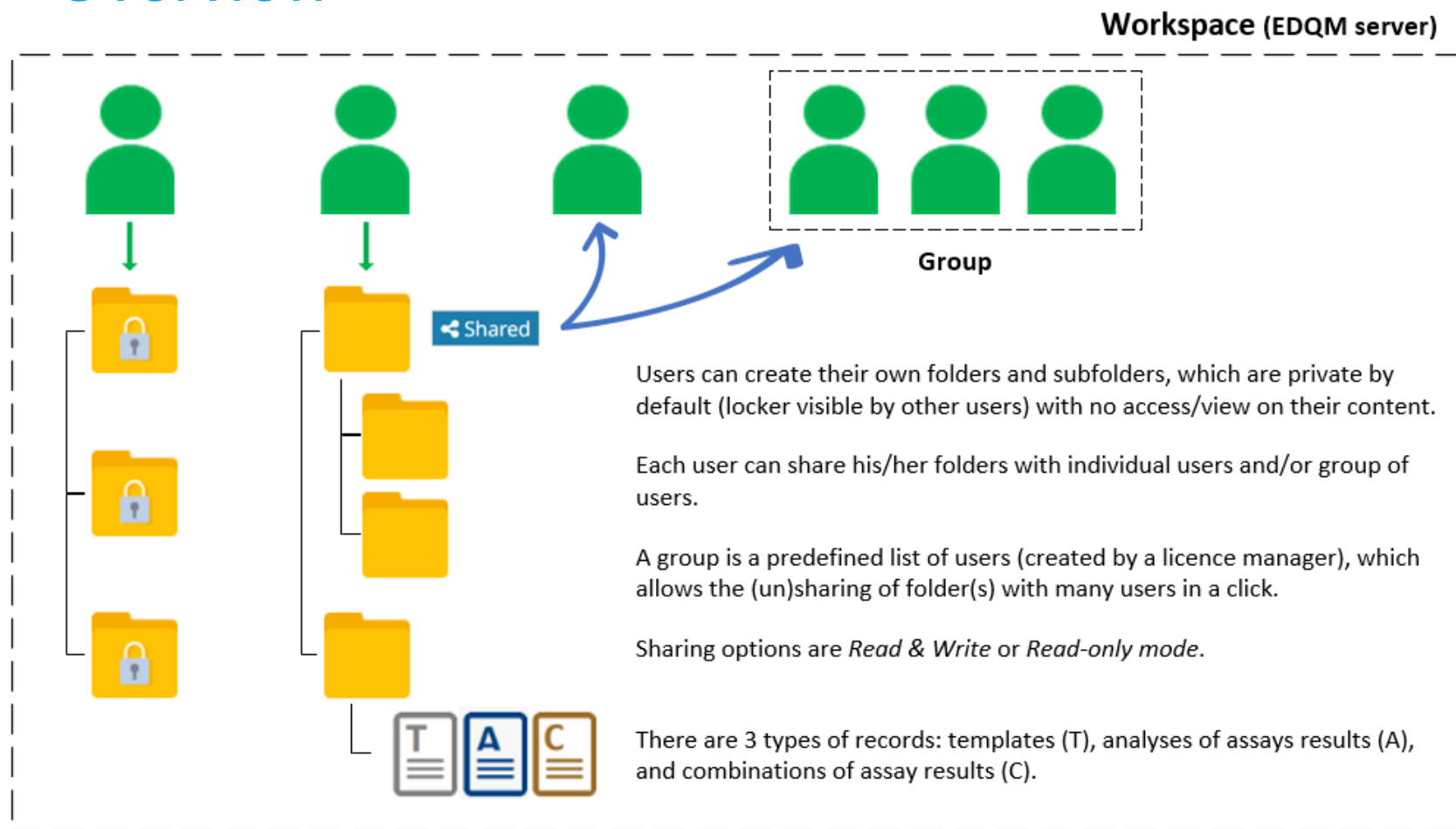
★ Workspace

★ File and folder management

★ Data entry, analysis options & audit trail

★ Batch creating .epax files

Overview



Actions

- Import CS-desktop files
- Create folders, files
- Search, rename
- Copy, move to
- Export (zip file) / import
- Add to my Favourites
- Share (read-only or read-write)

Trash: items remain 30 days in the trash after deletion. Can be restored or deleted permanently

Outside the workspace, exports of files



User group

How to share a folder with several users (in bulk):

- ★ create a user group
- ★ share the folder with the group

E-mail	Assignee
combistats@edqm.eu	Test User
david.le-tallec@edqm.eu	User U
elena.regourd@edqm.eu	ELENA REGOURD

Licence assignee history

GROUPS

Add

New group

Display name*

My_group

☒ Is active

MEMBERS

Name

User U

Add another

Cancel

Save

Display name

Is active

My_group

✓



Share folder "User_1"

GENERAL

Owner

User U

SHARE TO

Name

My_group

Add another

Access

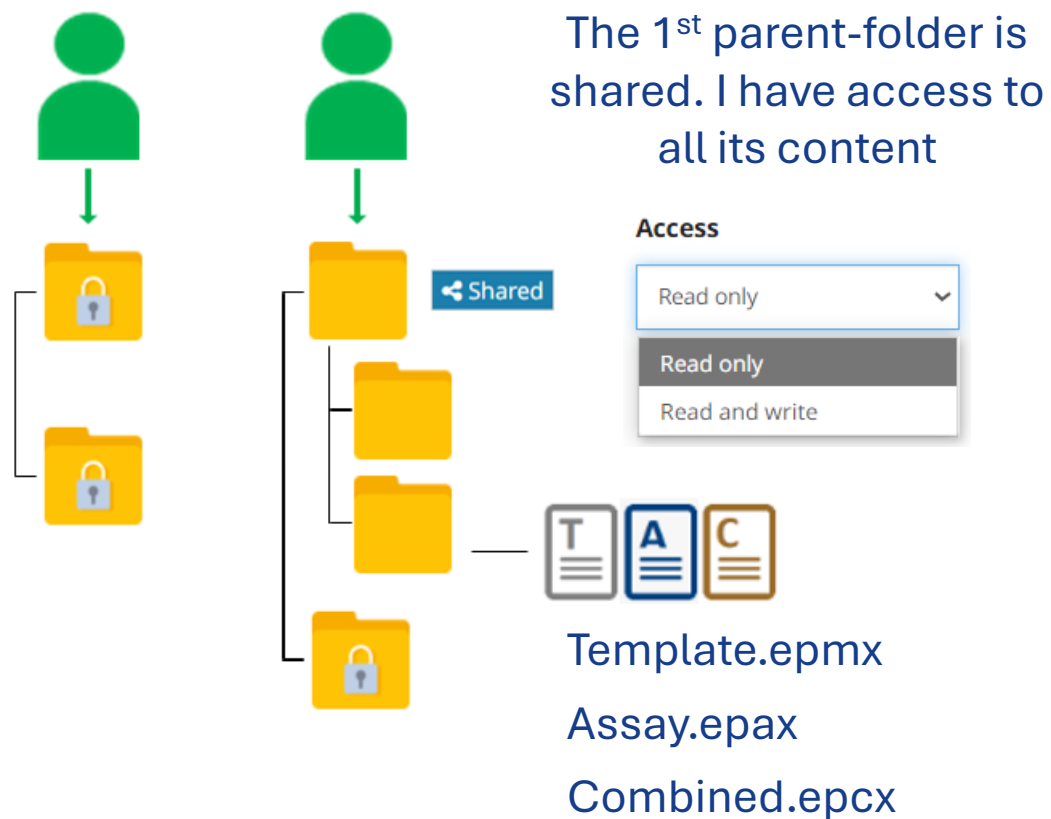
Read only

Read only

Read and write

Remarks

★ **Permissions** are set at the level of parent-folders



★ **Templates (.epmx)**

Protection level

No protection

No protection

L1: Wizard and advanced options are protected

L2: L1 + number and dimension of tables are protected

L3: L2 + non-empty cells are protected

Only .epax files created from a template can inherit the protection level of the template

An .epax file created from scratch cannot be protected

However, at any time, a file can be published in 'read-only' mode

Content

★ Introduction

★ Workspace

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★ Data entry, analysis options & audit trail

★ Batch creating .epax files

Features

Data tables	Quantal/quantitative response	Graphics
Preparations, labels, info.	Model	Average plot
Potency value/pre-dilutions	Parallel lines, Slope ratio	Regression plot (linearised)
Number of doses, replicates	3-parameter exponential curves	Residual plot (incl. studentised)
Descriptive stat/dose	4- & 5-parameter sigmoid curves	Potency estimates
Orientation of tables	Single-dose assay	precision, relative to assigned value
Doses vertical/horizontal	Transformation	Prediction
Doses entry	Dropdown list/user-defined	Effective doses, inverse prediction
Manual/automatic	Variance	Confidence level
Statistical design	Dropdown list/user-defined	From 80% to 99%
Completely randomised	Fixed parameters	Weight function
Randomised block	Slope, addition, multiplication	Dropdown list/user-defined
Latin square > show design	ANOVA	Combination of assay results
Show design	No ANOVA to Complete ANOVA	Homogeneity of potency estimates
Plate layout, block structure	Equivalence of slopes/intercepts	weighted, semi-weighted, unweighted
Table of blank results	Parallel-line analysis	Template & protection
Descriptive stat (mean, sd, rsd)	Subset analysis (dose selection)	Statistical report & audit trail

Confidence levels, correlation/determination coefficients

Results	Desktop	Online application
	(fixed)	(range)
Common slope or intercept	90%	95% (80%-99%)
Potency estimates	95%	95% (80%-99%)
Effective doses, predictions	95%	95% (80%-99%)
Equivalence - individual slopes or intercepts	95%	95% (80%-99%)
Equivalence - differences or ratios	90%	90% (fixed)
Combination of results	95%	95% (80%-99%)

Desktop version (90% conf. level)

Common slope(factor): $b = -111.255$ (-115.612 to -106.898)
Correlation | r |: 0.991424

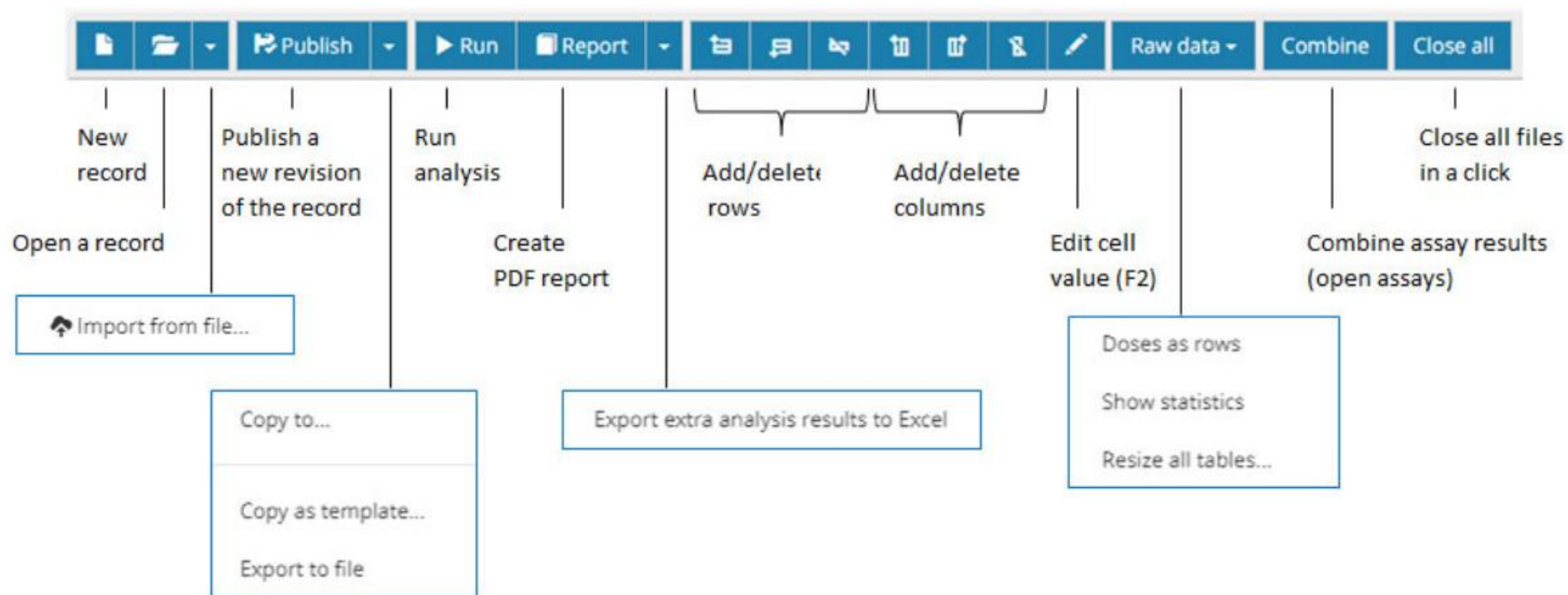
Online application (95% conf. level)

Common Slope	
Estimated value	-111.255
Lower conf. Limit	-116.501
Upper conf. Limit	-106.009

95% confidence level

R^2 All	0.982922
R^2 Standard	0.977164

Taskbar and analysis options



Wizard

Assay

Multiple-dose

Type of design

Completely randomised

Response variable

Quantitative

Model

Sigmoid curves (4-PL, ln dose)

Transformation

No transformation: $y=y$

Linearising transformation

Logit

Variance

Observed residuals

Dose entry

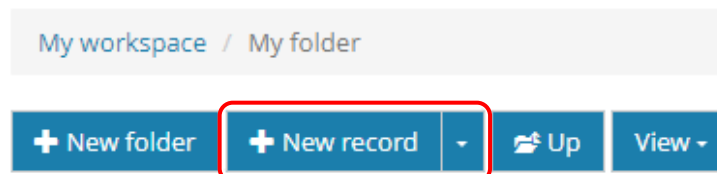
Manual

Show design

Yes

Create a new record

1. Create a new record



Taskbar in editor



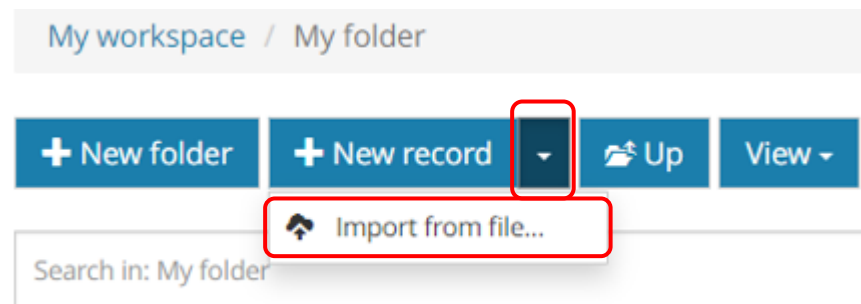
2. Enter the record type and name, select destination folder and assay set-up

New record

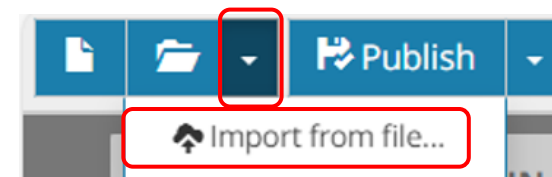
Type Assay	Assay Multiple-dose	Type of design Completely randomised	Response variable Quantitative	Model Sigmoid curves (4-PL, In dose)
Name Assay1_4PL	Preparations 2	Max doses 5	Max replicates 3	
To folder David Elena My folder	Cancel	Create		

Import a record

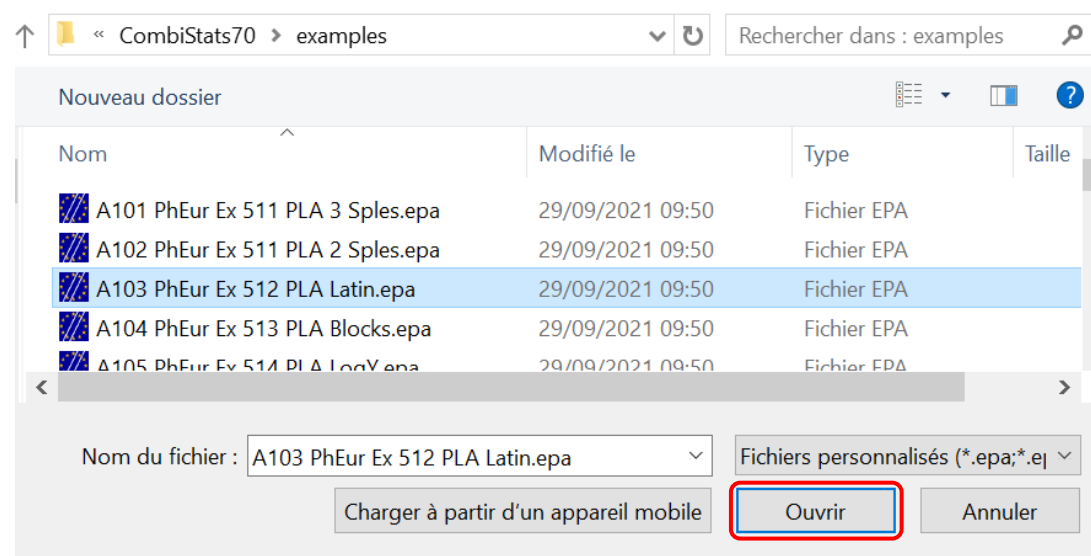
1. Import from file...



Taskbar in editor



2. Browse to and select the file you wish to import, then click on Open.



Data entry

<https://combistats.edqm.eu/help/>

Preparations

		Information		Potency		Pre-dilution	
Table	Preparation	ID	Long label	Potency	Value	Reconstitution	Stock solution
1	Standard ▾	S	standard	Assigned	100 IU/amp.	1 amp./mL	1 mL/10 mL
2	Sample 1 ▾	T	test sample	Assumed ▾	80 IU/vial	1 vial/0.5 mL	0.5 mL/5 mL
3	Sample 2 ▾	C1	Control 1	Assumed ▾	25 IU/mL		
4	Sample 3 ▾	C2	Control 2	Assumed ▾	120 IU/mL		

Observ.	c1	c2	c3	c4	c5	c6	c7	c8	c9	c10	c11	c12
r1												
r2	0.031	0.044	0.027	0.032	0.028	0.051	0.117	0.097	0.104	0.093	0.112	0.047
r3	0.046	2.912	2.579	2.130	1.651	1.073	0.585	0.463	0.266	0.228	0.176	0.031
r4	0.024	2.917	2.654	2.212	1.638	0.973	0.666	0.356	0.234	0.197	0.215	0.050
r5	0.030	3.017	2.801	2.401	1.918	1.364	0.861	0.497	0.340	0.242	0.178	0.035
r6	0.045	2.987	2.808	2.450	1.963	1.299	0.854	0.496	0.344	0.217	0.125	0.024
r7	0.051	2.105	2.074	2.162	1.948	2.037	1.974	1.925	2.017	2.106	1.938	0.038
r8												

Blank results

0.031	0.046	0.024	0.030	0.045	0.051
0.047	0.031	0.050	0.035	0.024	0.038

Mean SD RSD%
0.038 0.010 26.2

Table 1					
Preparation	Standard				
ID	S				
Long label	standard				
Potency	Assigned				
Potency value	100 IU/amp.				
Reconstitution	1 amp./mL				
Stock solution	1 mL/10 mL				
Dose	Rep.1	Rep.2	Mean	SD	RSD%
1/1	2.912	2.917	2.914	0.004	0.1
1/2	2.579	2.654	2.617	0.053	2.0
1/4	2.130	2.212	2.171	0.058	2.7
1/8	1.651	1.638	1.644	0.009	0.6
1/16	1.073	0.973	1.023	0.071	6.9
1/32	0.585	0.666	0.626	0.057	9.2
1/64	0.463	0.356	0.410	0.076	18.5
1/128	0.266	0.234	0.250	0.023	9.1
1/256	0.228	0.197	0.213	0.022	10.3
1/512	0.176	0.215	0.196	0.028	14.1

EN01 Information And Remarks
EN02 Taskbar
EN05 Preparations Table
EN06 Rawdata Tables
EN07 Show Design
EN08 Table of Blank Results

Data entry options

Wizard

Dose entry

Manual

Manual

Automatic

Show design

No

No

Yes

Show blank results

No

No

Yes

Taskbar

Show blank results

Yes

Number of rows

2

Number of columns

5

Blank results

Blank results

0.031	0.046	0.024	0.030	0.045	0.051
0.047	0.031	0.050	0.035	0.024	0.038

Raw data

Doses as rows

Show statistics

Resize all tables...

Mean	SD	RSD%
0.038	0.010	26.2

Dose entry

Automatic

Highest dose

Last dose

Dilution step

1.5

Dose

1/1

1/1.5¹

1/1.5²

Dose entry

Automatic

Highest dose

Last dose

Zero dose

☒

Dose

2/2

1/2

0

Dose

0

1/2

2/2

Show design

Yes

Number of rows

8

Number of columns

12

Rawdata reference

Table|Dose|Rep

Corresponding response

Design	c1	c2	c3	c4	c5	c6
r1	Pos	1 1 1	2 1 1			Neg
r2	Pos	1 2 1	2 2 1			Neg

Observ.	c1	c2	c3	c4	c5	c6
r1	2.222	2.879	3.025			0.125
r2		2.854	2.998			

edqm

European Directorate for the Quality of Medicines & HealthCare

Direction européenne de la qualité du médicament & soins de santé

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Data analysis options

The list of the available Wizard and Advanced options depend on the Assay, Response variable and Model

For more details refer to

<https://combistats.edqm.eu/help/>

EN03 Wizard Options

EN04 Advanced Options

Wizard

Assay

Multiple-dose ▼

Type of design

Completely randomised ▼

Response variable

Quantitative ▼

Model

Sigmoid curves (4-PL, In dos ▼

Transformation

No transformation: $y'=y$ ▼

Linearising transformation

Logit ▼

Variance

Observed residuals ▼

Advanced options

FIXED PARAMETER

Slope

Addition

Multiplication

CONFIDENCE LEVELS

Slope / intercept

90 %

Potency / Effective dose / Inverse...

95 %

PREDICTED VALUES

Effective dose

50 %

Reported as

Container / Effective Dose ▼

Y values

You can specify up to 6 response values, separated by semicolons.

REGRESSION TYPE

Weighting

Unweighted regression ▼

Maximum number of iterations

Summary statistics

Regression parameters

Global model: convergence reached

R² Standard: convergence reached

Common Slope	
Estimated value	1.12452
Lower conf. Limit	1.08725
Upper conf. Limit	1.16179

95% confidence level

	weighted	unweighted
R ² All	0.991457	0.998112
R ² Standard	0.993511	0.998558

Other model parameters	
Lower asymptote	0.145458
Upper asymptote	3.19599

Equivalence of slopes

Preparation	Slope	Difference with Standard	Ratio with Standard
Standard: S	1.12755 (1.07426, 1.18084)	0.000000	1.00000
Sample 1: T	1.12162 (1.06949, 1.17375)	-0.00593102 (-0.0684964, 0.0566344)	0.994740 (0.940903, 1.05171)

Slopes: confidence limits (in brackets) calculated for a 95% confidence level (advanced options).

Differences and ratios of slopes: confidence limits (in brackets) calculated for a 90% confidence level.

Anova table

Normal

Source of variation	Degrees of freedom	Sum of squares	Mean square	Chi-square	Probability	Level of significance
Preparations	3	0.813672	0.271224	301.79	< 0.000001	***
Regression	1	9.43054	9.43054	3497.77	< 0.000001	***
Non-parallelism	1	6.55525e-05	6.55525e-05	0.0243133	0.876090	
Non-linearity	16	0.0127084	0.000794275	4.71353	0.997004	
Non-linearity Table 1	8	0.00764179	0.000955224	2.83433	0.944320	
Non-linearity Table 2	8	0.00506661	0.000633326	1.8792	0.984494	
Treatments	21	10.257	0.488428	3804.3	< 0.000001	***
Residual error	28	0.0754923	0.00269615			
Total	49	10.3325	0.210867			

Potency and effective dose values

Potency estimates

		Potency		Relative To Estimate (%)		Relative To Assumed/Assigned (%)	
Preparation	Units	Estimate	(LCL, UCL)	Rel. To Est.	(LCL, UCL)	Rel. To Ass.	(LCL, UCL)
Sample 1: T	IU/vial	72.9429	(68.3897, 77.8023)	100	(93.76, 106.66)	91.18	(85.49, 97.25)
Sample 2: C1	IU/mL	21.5772	(20.0321, 23.2672)	100	(92.84, 107.83)	86.31	(80.13, 93.07)
Sample 3: C2	IU/mL	118.279	(109.978, 127.322)	100	(92.98, 107.65)	98.57	(91.65, 106.10)

Confidence limits (in brackets) calculated for a 95% confidence level (advanced options).

Precision

Recovery

Effective dose estimates

		Effective Dose (ED)		Relative To Estimate (%)	
Preparation	Units	Estimate	(LCL, UCL)	Rel. To Est.	(LCL, UCL)
Standard: S	IU/ED50	1.34768	(1.28756, 1.41071)	100	(95.54, 104.68)
Sample 1: T	IU/ED50	1.47806	(1.41232, 1.54693)	100	(95.55, 104.66)
Sample 2: C1	IU/ED50	1.56146	(1.47123, 1.65552)	100	(94.22, 106.02)
Sample 3: C2	IU/ED50	1.36729	(1.29102, 1.44685)	100	(94.42, 105.82)

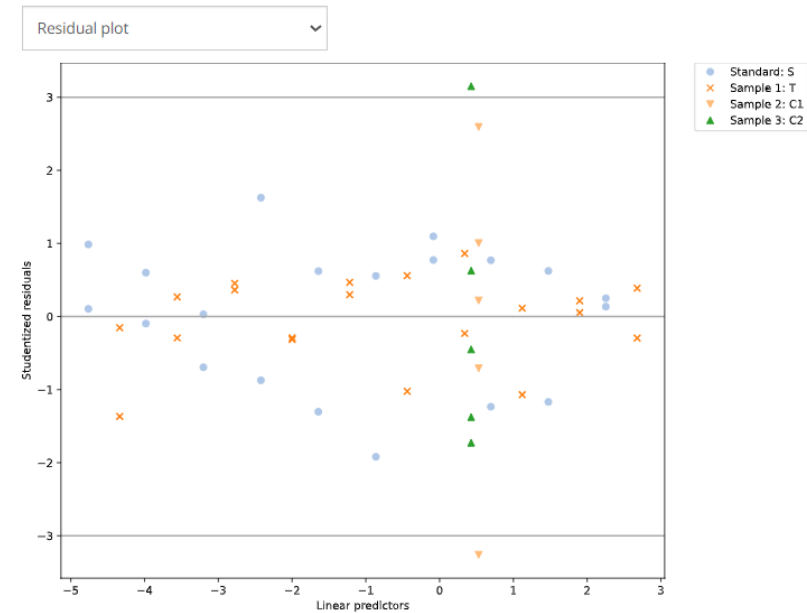
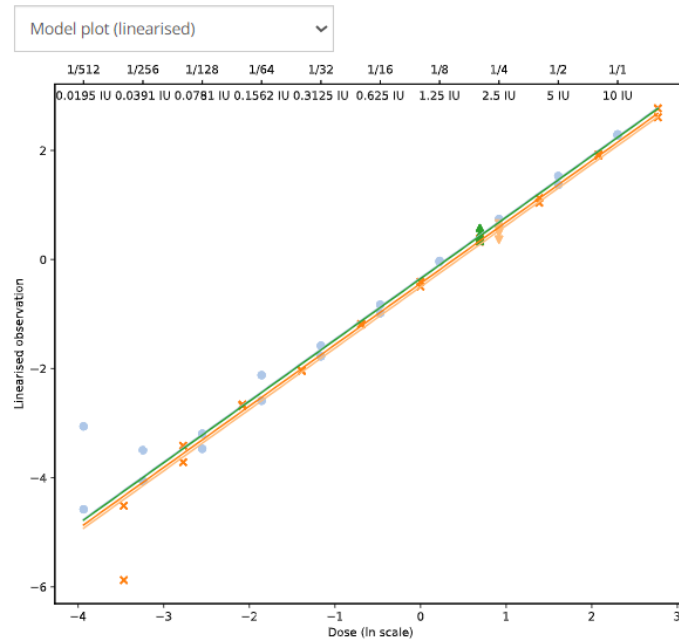
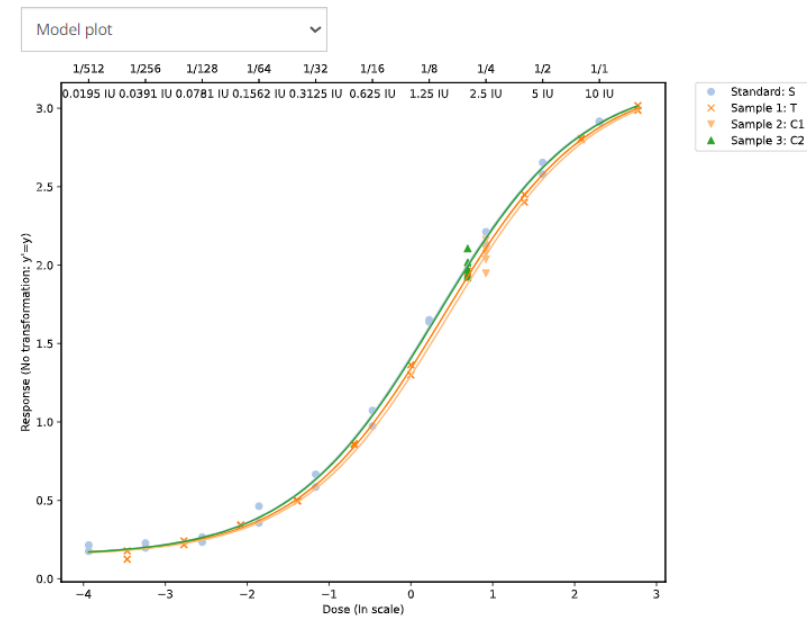
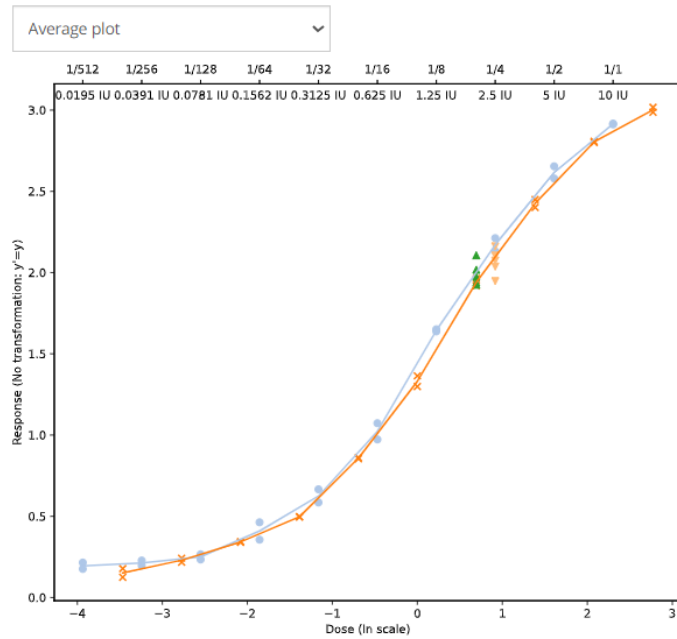
Confidence limits (in brackets) calculated for a 95% confidence level (advanced options).

Inverse predictions

		y-value(s)			
		1		1.5	
Preparation	Units	Estimate	(LCL, UCL)	Estimate	(LCL, UCL)
Standard: S	IU	0.582207	(0.551716, 0.613296)	1.10348	(1.05369, 1.15521)
Sample 1: T	IU	0.638534	(0.604979, 0.672733)	1.21024	(1.15569, 1.26686)
Sample 2: C1	IU	0.674564	(0.627048, 0.723594)	1.27853	(1.20187, 1.35809)
Sample 3: C2	IU	0.590679	(0.550703, 0.631861)	1.11954	(1.05493, 1.18659)

Confidence limits (in brackets) calculated for a 95% confidence level (advanced options).

Graphics



Audit trail

Wizard

Advanced options

Graphics

Revisions

- v6 (Current) - 12/11/2024 at 18:08:59 - ELENA REGOURD**
No description
- v5 - 12/11/2024 at 18:08:49 - ELENA REGOURD**
No description
- v4 - 12/11/2024 at 18:03:40 - ELENA REGOURD**
Copy from "Test2 - v3 - 12/11/2024 17:58:09"
this is a copy
- v3 - 12/11/2024 at 17:58:09 - ELENA REGOURD**
Restored from v1
No description
- v2 - 12/11/2024 at 17:57:34 - ELENA REGOURD**
No description
- v1 - 12/11/2024 at 17:57:05 - ELENA REGOURD**
No description

Each time the assay is published a new version is created and differences to previous published version are recorded

User can add a comment and protect the sheet

Meta-data for each version:
date, GMT time and username

Publish a new version

Comment

this is a copy

☐ Publish in read-only mode, the sheet can no longer be modified.

Publish

Cancel

The modifications and comments for each version

- displayed in the report
- can be accessed by clicking in the version in the revisions section

V.4 (CURRENT) - PUBLISHED ON 12/11/2024 AT 18:03 BY ELENA REGOURD		
Copy from "Test2 - v3 - 12/11/2024 17:58:09" this is a copy		
Field	Old value	New value
Wizard		
Transformation	y'=y	y'=sqrt(y)
Variance	Observed residuals	Deviation from model
Raw-data		
Table 1		
	Dose 1/30	Dose 1/30
	Rep.5 176	Rep.5 400

Content

★ Introduction

★ Workspace

★ File and folder management

★ Data entry, analysis options & audit trail

★ Batch creating .epax files

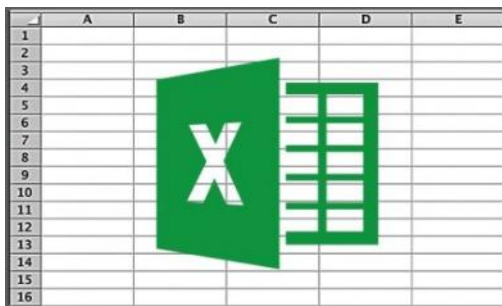
How to automate data entry into .epax files?

E.g.

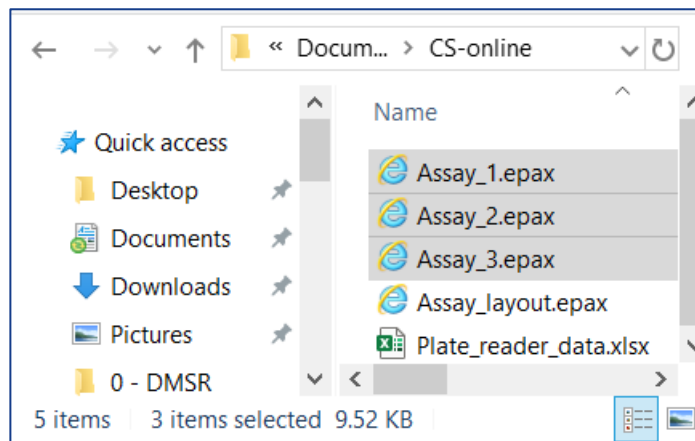
1. Microplate reader



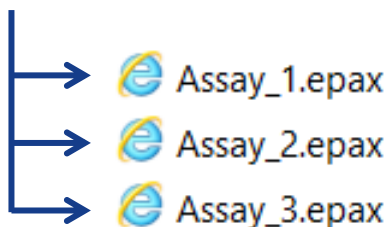
2. Plate_reader_data.xlsx



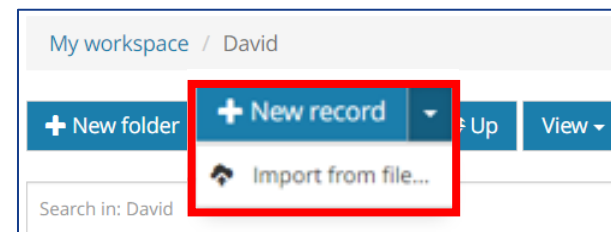
3.



Assay_layout.epax



4.



☐	Type	Name	Created
☐		Assay_1	today
☐		Assay_2	today
☐		Assay_3	today

➔ See demo

Useful links

- ★ Institutional website

<https://www.edqm.eu/en/lp-combistats>

- ★ FAQs, privacy, security notices

<https://combistats.edqm.eu/help/>

- ★ User guide (sign in first)

https://combistats.edqm.eu/user-manuals/combistats_user_guide.pdf/

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