



Features

- ✓ Normality test – Shapiro Wilk
- ✓ Log transformation
- ✓ Outlier elimination
- ✓ Variance determination
- ✓ Determination of cut point based on similarity of mean and variance among datasets
- ✓ Cut point calculation using mean or median approach

An Integrated Bioanalytical Method Validation Software for PK, ADA, Biomarker, and Biosimilar Assays

Aegyris software is designed to enable bioanalytical scientists to perform method validation and statistical analysis in a streamlined and regulatory compliant manner.

The Aegyris software is being developed as a web-based application. The web front end of the software provides rich user interface for data analysis and visualization. The backend integrates with a fully functional on demand R statistical analytic engine. The application is massively scalable and supports real time analytics by storing data in a NoSQL database. A built in open interface module allows seamless importing and exporting of data from various third-party laboratory instrument software or LIMS.

Aegyris can save up to 90% of time and costs in method validation support activities when implemented as designed.

The screenshot displays the Aegyris web application interface. On the left, a navigation sidebar shows a 3-level organization structure: Program, Project, and Study, with a 'Study' item highlighted and circled with a '1'. The main content area is titled 'Study' and contains a 'Screening Cutpoint' configuration panel (circled with a '2') and a 'Screening Cutpoint Result' table (circled with a '3').

Create Date	Name	Cutpoint Type	Cutpoint Factor	Comment
Fri Apr 06 2018	DEN cutpoint	Floating	2.794	
Fri Apr 06 2018	DEN non-parametric cutpoint	Non-parametric	0.034	

1 3-level organization structure for easy navigation - Program, Project & Study

2 Study specific parameter (e.g. screening cutpoint, confirmatory cutpoint, etc.)

3 Result panel for each study specific params

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