

# OCS Analysis Studio: A Tool Suite for Exploring Safety Signals and Creating Review-Ready Tables and Figures

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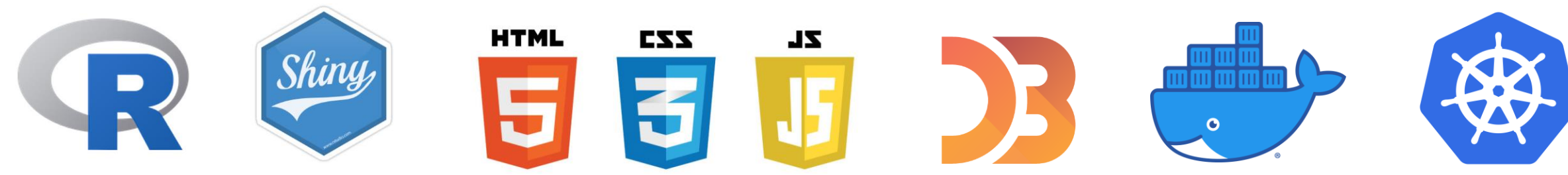


## Introduction

OCS Analysis Studio offers a set of reactive and flexible tools useful for improving the clinical review process. The OCS Analysis Studio application enables creation of tables and figures for review documents, as well as exploratory visualizations. Users are empowered to upload their own clinical trial data, customize the inputs according to their needs, and view resulting outputs in real time.

## Methods

The tools are built and deployed using R, R Shiny, JavaScript, D3.js, and more:

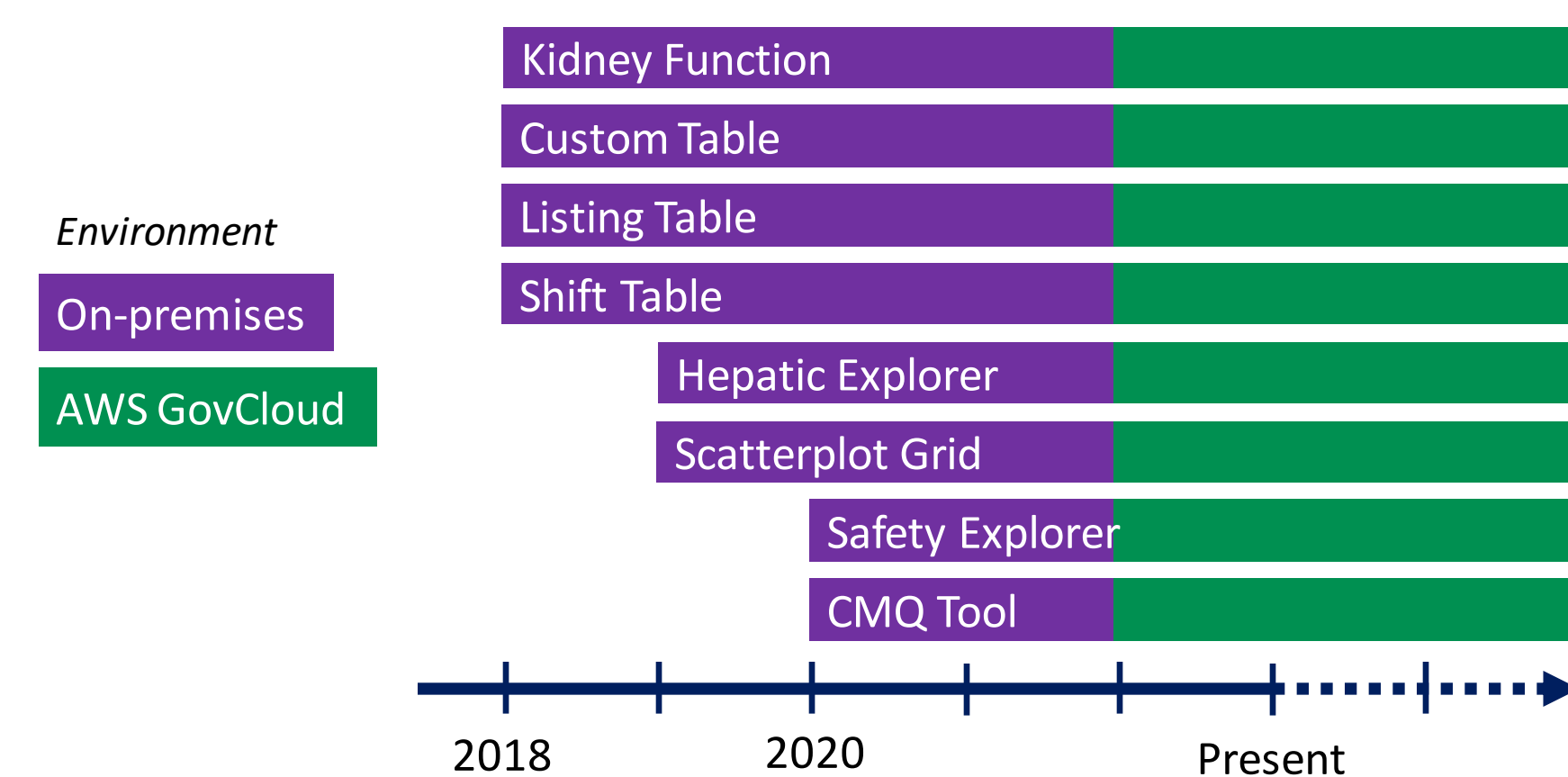


## Features

- Consistent user interface (UI) throughout tool suite
- Ability to download Word and Excel outputs for transfer to review documents
- Analytical details (e.g., data filters) provided in footnotes for auditability and output reproducibility
- Built-in demo data allows users to explore tool functionality

## Rollout Timeline

OCS Analysis Studio migrated from an on-premises environment to the AWS GovCloud environment in April 2022.

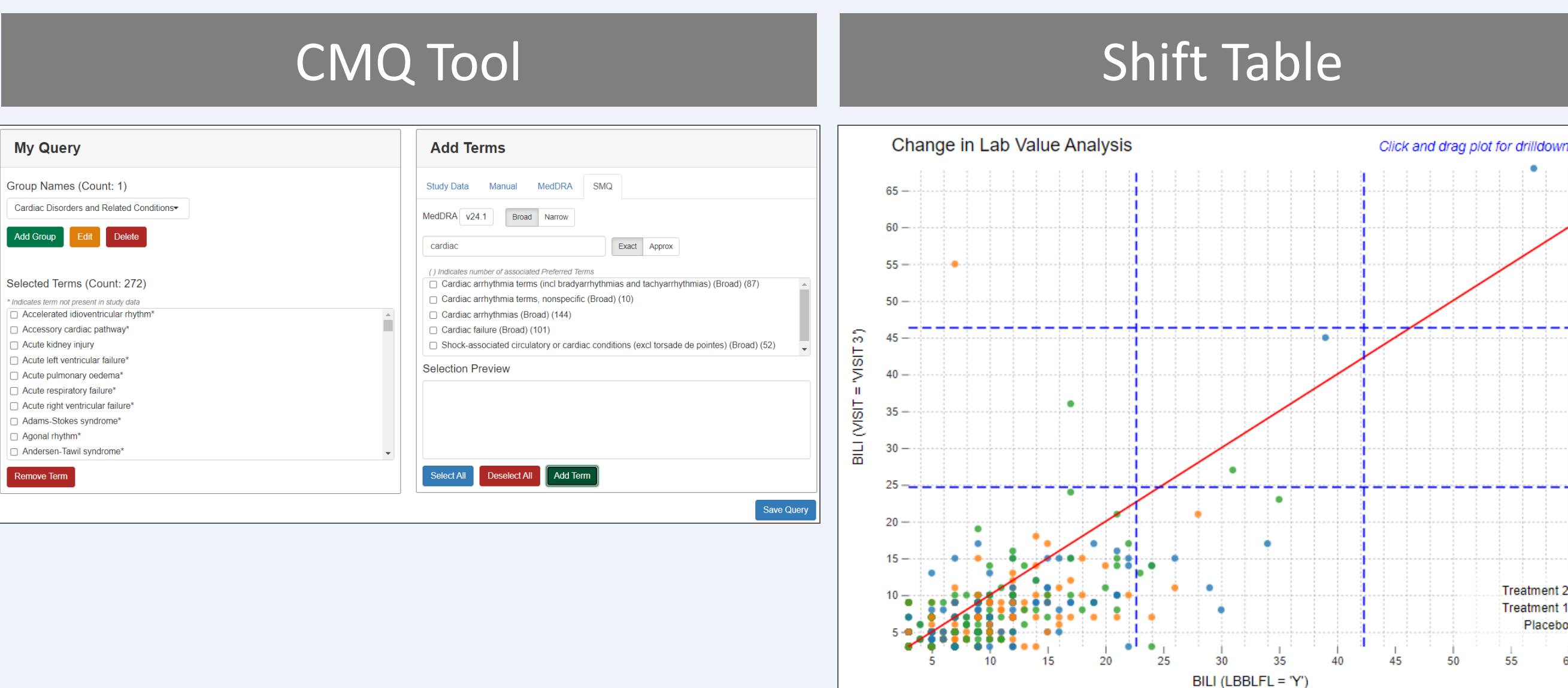
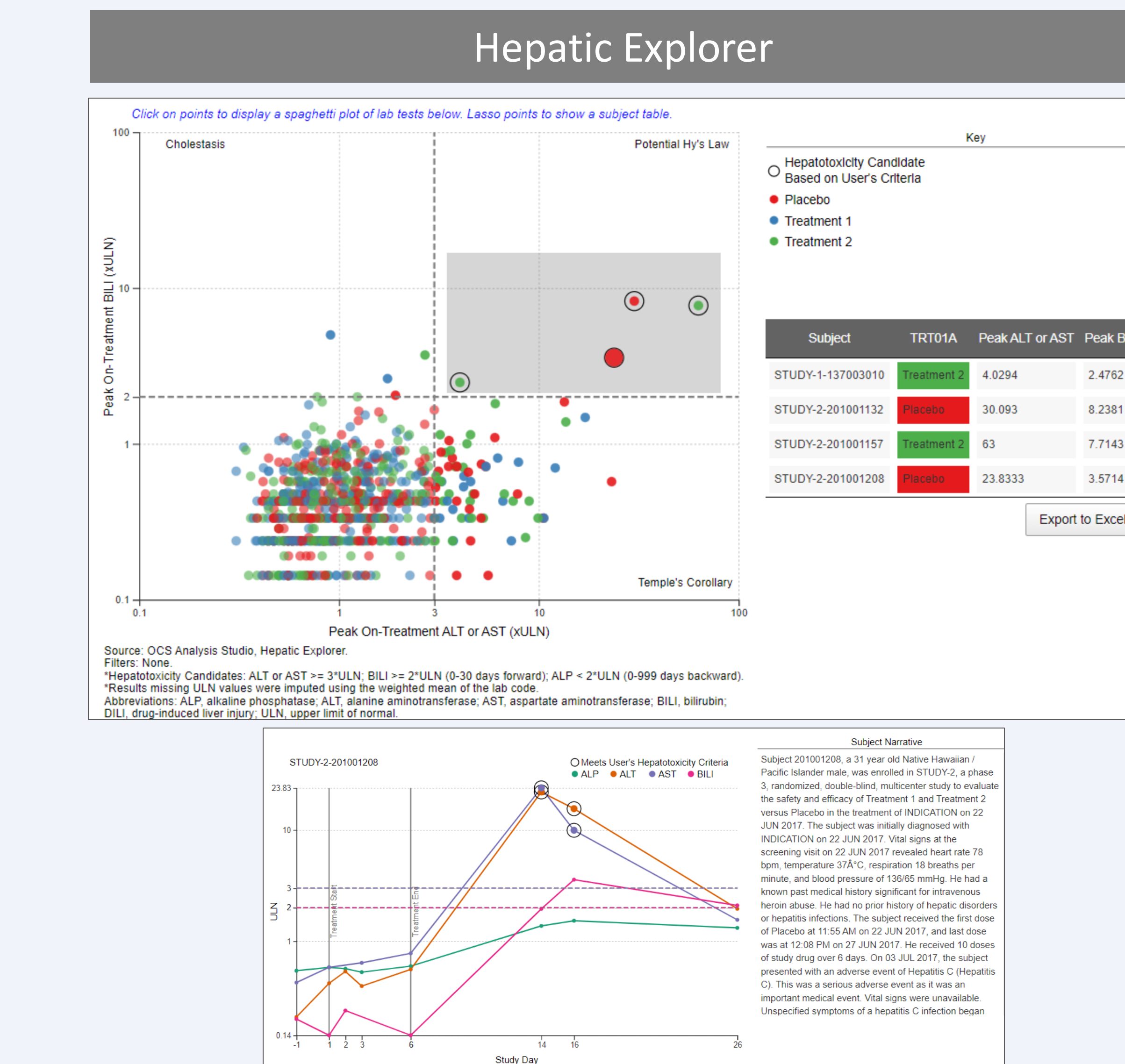
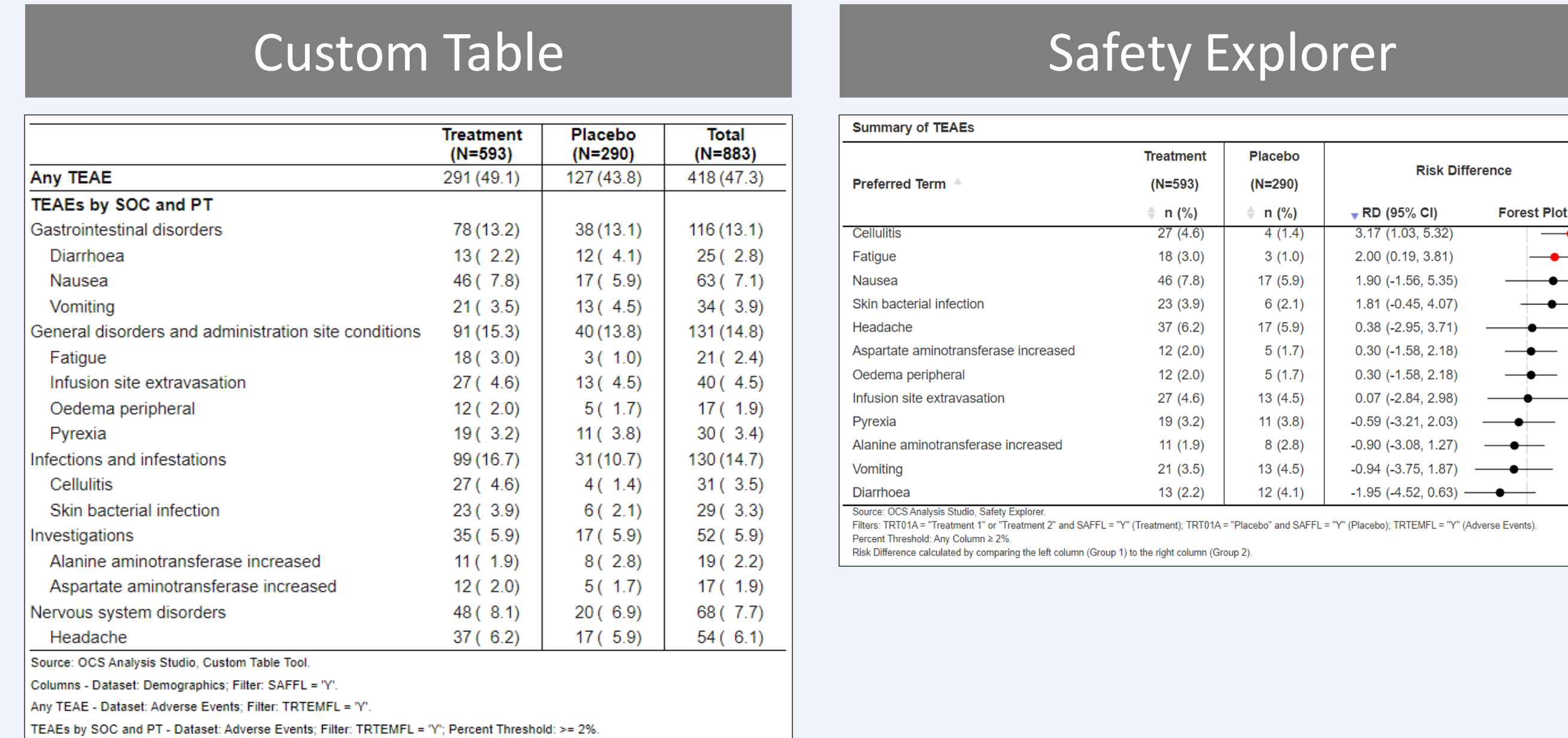


Tool development is continuous, with enhancements and requested features being released on a rolling basis. Feedback from clinical reviewers is a crucial component for informing development priorities.

## Resources

OCS Analysis Studio link: <https://analysis-studio.fda.gov/>  
 Help Documentation: <https://ocsconnect.fda.gov/#/analysis-studio>  
 For assistance, email OCS Service Desk: [OCSServiceDesk@fda.hhs.gov](mailto:OCSServiceDesk@fda.hhs.gov)

## Tool Outputs



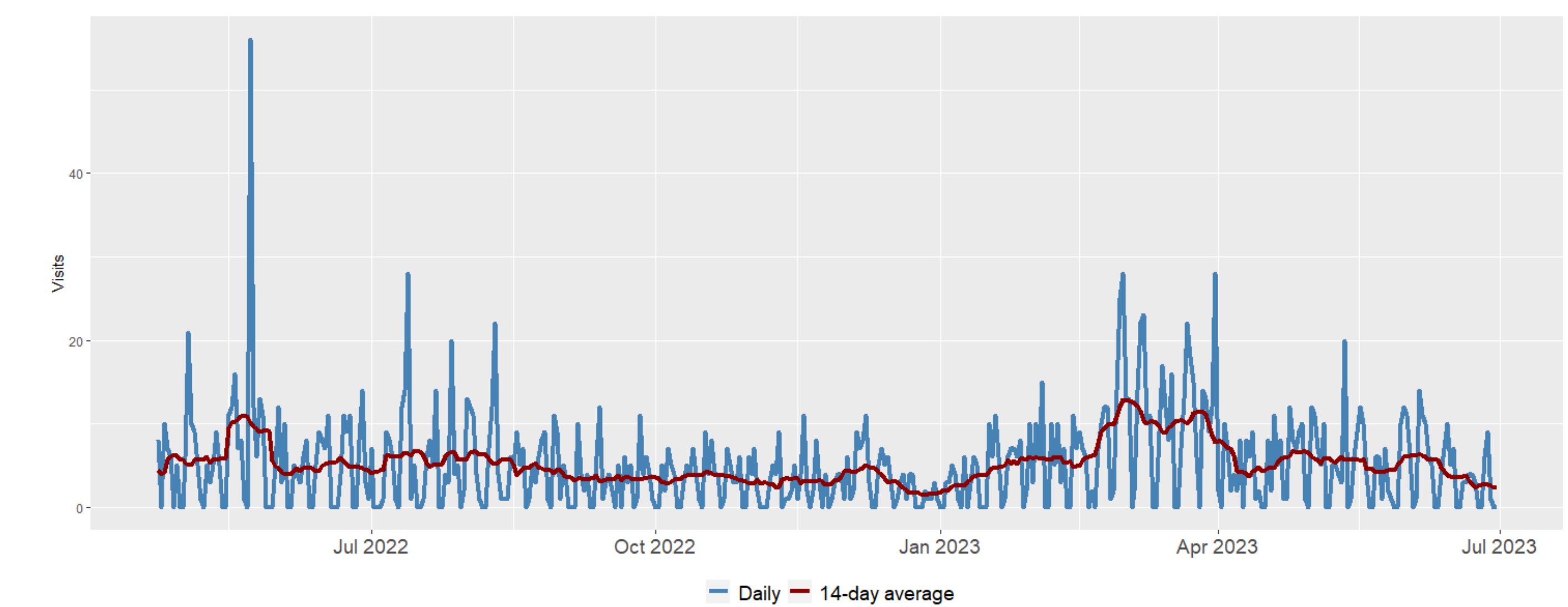
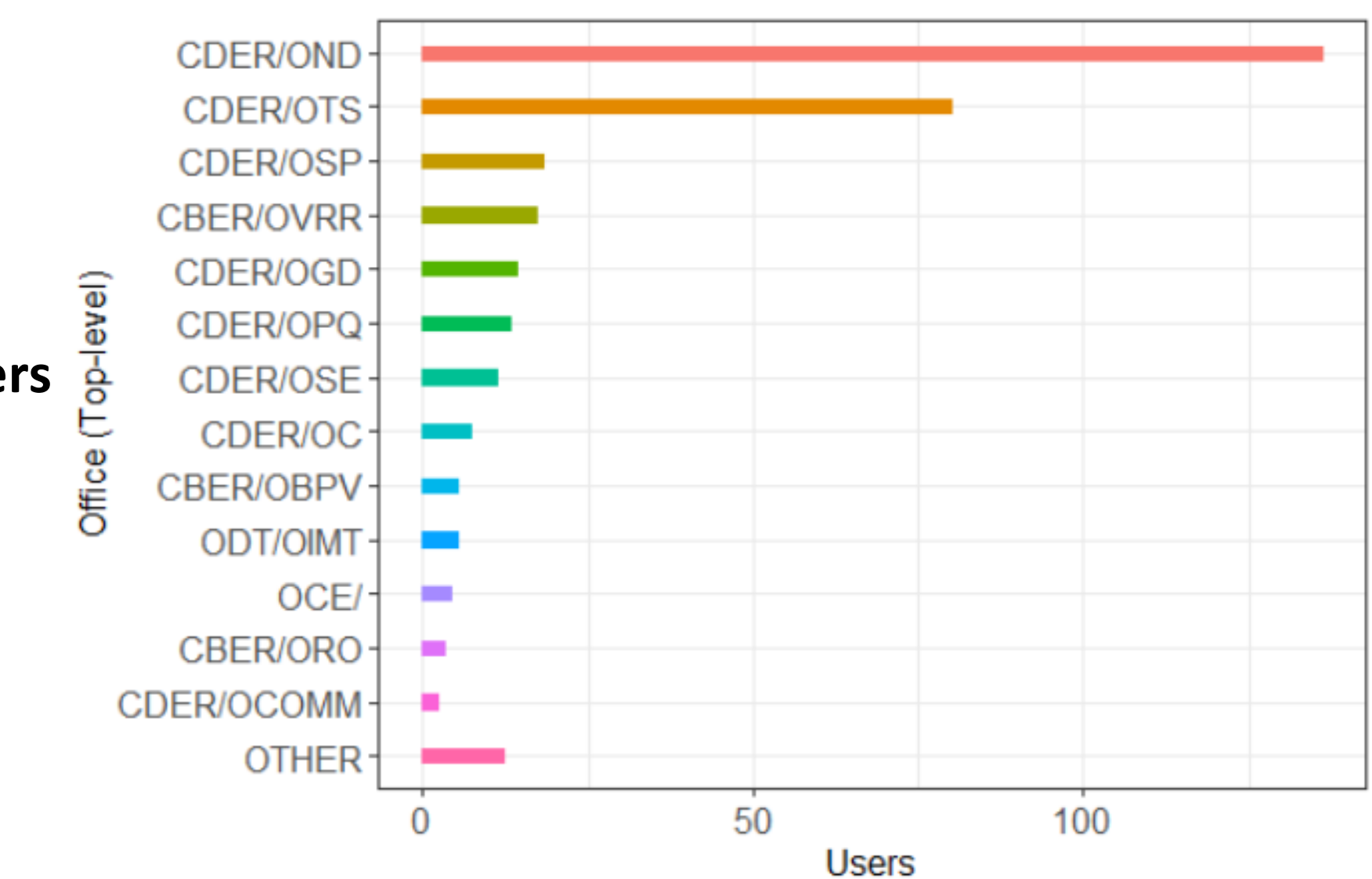
## Results

The tool suite has improved the efficiency of clinical reviewers at the FDA by enabling the rapid generation of tabular and graphical outputs which were previously made via more time-intensive software or custom coding. Since April 2022, the site has over 2,200 analysis sessions performed by more than 300 unique users.

## User Reception

Usage statistics show broad adoption throughout the FDA. Usage metrics by office, Analysis Studio tool, and individual user are shown below. These metrics help guide our training programs and assist with development objectives.

- 300+ unique users
- 2200+ site visits
- 130+ OND users



## Conclusion

OCS Analysis Studio contains a set of powerful and flexible tools that can be leveraged to aid clinical review through a range of general and specialized analyses. This suite helps to improve the efficiency and thoroughness of clinical review at the FDA.

## Acknowledgements

We would like to thank the RAPID team for their assistance in provisioning and maintaining the environments that run Analysis Studio. We are thankful for tool feedback from users across the FDA.