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:





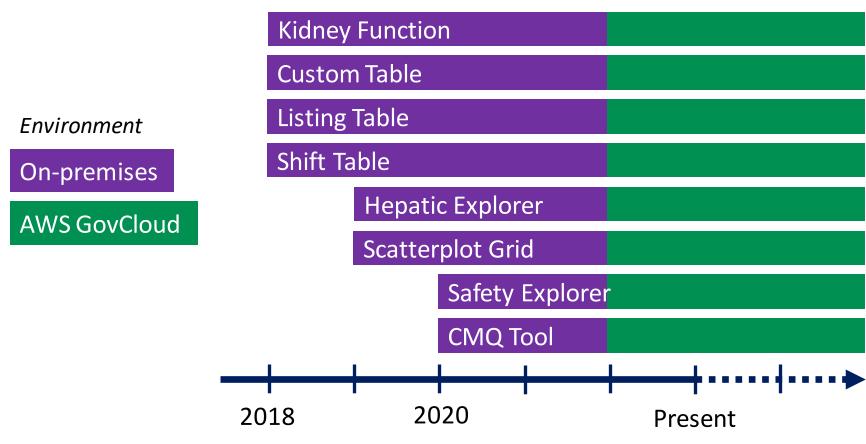


Features

- 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.

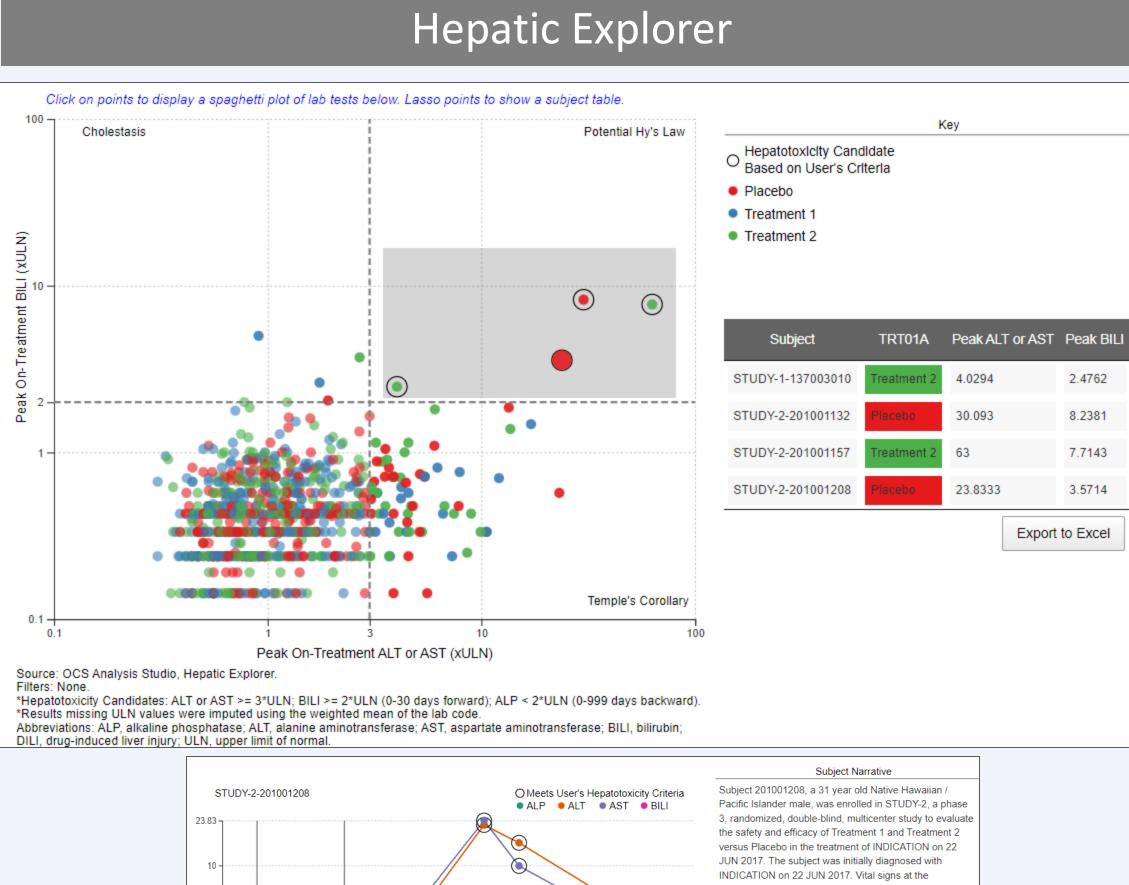
Resources

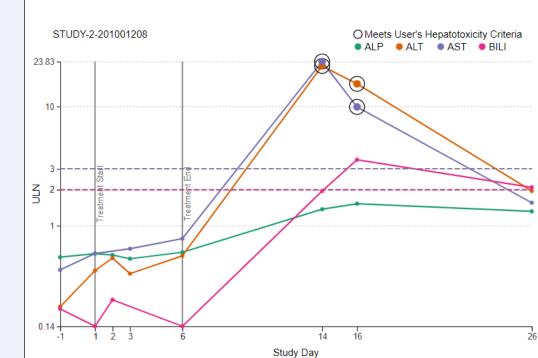
OCS Analysis Studio link: <u>https://analysis-studio.fda.gov/</u> Help Documentation: <u>https://ocsconnect.fda.gov/#/analysis-studio</u> For assistance, email OCS Service Desk: <u>OCSServiceDesk@fda.hhs.gov</u>

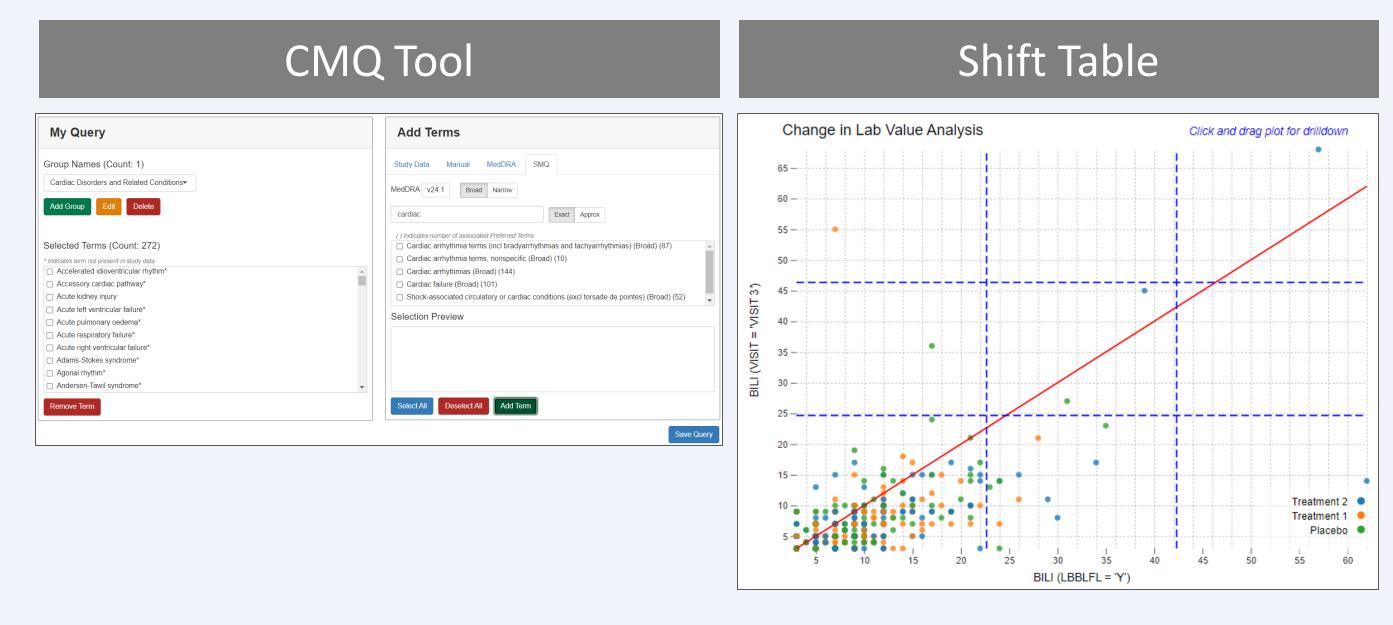
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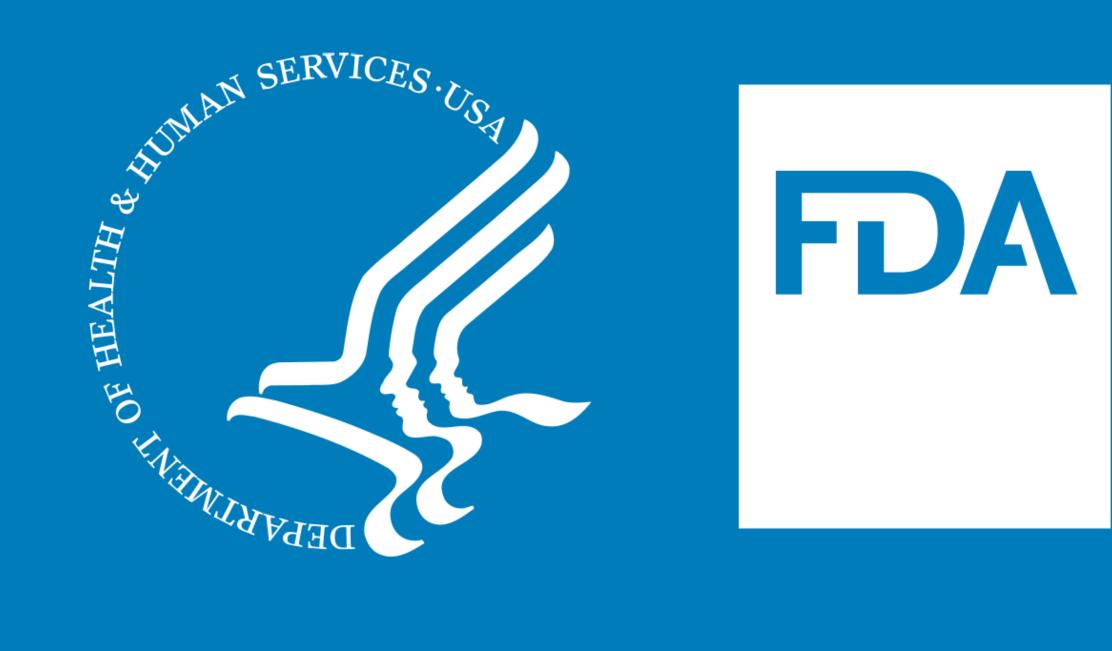
Custom Table				Safety Explorer				
	Treatment			Summary of TEAEs				
Any TEAE	(N=593) 291 (49.1)	(N=290) 127 (43.8)	(N=883) 418 (47.3)	Preferred Term	Treatment (N=593)	Placebo (N=290)	Risk Difference	
TEAEs by SOC and PT		. ,			(n=330)	(n=230) ♦ n (%)	- RD (95% CI)	Forest Plot
Gastrointestinal disorders	78 (13.2)	38 (13.1)	116 (13.1)	Cellulitis	27 (4.6)	4 (1.4)	3.17 (1.03, 5.32)	
Diarrhoea	13 (2.2)	12(4.1)	25 (2.8)	Fatigue	18 (3.0)	3 (1.0)	2.00 (0.19, 3.81)	
Nausea	46 (7.8)	17 (5.9)	63 (7.1)	Nausea	46 (7.8)	17 (5.9)	1.90 (-1.56, 5.35)	
Vomiting	21 (3.5)	13(4.5)	34 (3.9)	Skin bacterial infection	23 (3.9)	6 (2.1)	1.81 (-0.45, 4.07)	
General disorders and administration site conditions	91 (15.3)	40 (13.8)	131 (14.8)	Headache	37 (6.2)	17 (5.9)	0.38 (-2.95, 3.71)	•
Fatigue	18 (3.0)	3(1.0)	21 (2.4)	Aspartate aminotransferase increased	12 (2.0)	5 (1.7)	0.30 (-1.58, 2.18)	
Infusion site extravasation	27 (4.6)	13 (4.5)	40 (4.5)	Oedema peripheral	12 (2.0)	5 (1.7)	0.30 (-1.58, 2.18)	•
Oedema peripheral	12 (2.0)	5(1.7)	17 (1.9)	Infusion site extravasation	27 (4.6)	13 (4.5)	0.07 (-2.84, 2.98)	•
Pyrexia	19 (3.2)	11 (3.8)	30 (3.4)	Pyrexia	19 (3.2)	11 (3.8)	-0.59 (-3.21, 2.03)	•
nfections and infestations	99 (16.7)	31 (10.7)	130 (14.7)	Alanine aminotransferase increased	11 (1.9)	8 (2.8)	-0.90 (-3.08, 1.27)	•
Cellulitis	27 (4.6)	4(1.4)	31 (3.5)	Vomiting	21 (3.5)	13 (4.5)	-0.94 (-3.75, 1.87)	
Skin bacterial infection	23 (3.9)	6(2.1)	29 (3.3)	Diarrhoea Source: OCS Analysis Studio, Safety Explorer.	13 (2.2)	12 (4.1)	-1.95 (-4.52, 0.63) —	•
nvestigations	35 (5.9)	17 (5.9)	52 (5.9)	Filters: TRT01A = "Treatment 1" or "Treatment 2" and SAFFL = "Y" (Treatment); TRT01A = "Placebo" and SAFFL = "Y" (Placebo); TRTEMFL = "Y" (Adverse Events). Percent Threshold: Any Column ≥ 2%. Risk Difference calculated by comparing the left column (Group 1) to the right column (Group 2).				
Alanine aminotransferase increased	11 (1.9)	8(2.8)	19(2.2)					
Aspartate aminotransferase increased	12 (2.0)	5(1.7)	17 (1.9)					
lervous system disorders	48 (8.1)	20 (6.9)	68 (7.7)					
Headache	37 (6.2)	17 (5.9)	54 (6.1)					

Any TEAE - Dataset: Adverse Events; Filter: TRTEMFL = " TEAEs by SOC and PT - Dataset: Adverse Events; Filter: TRTEMFL = 'Y'; Percent Threshold: >= 2%









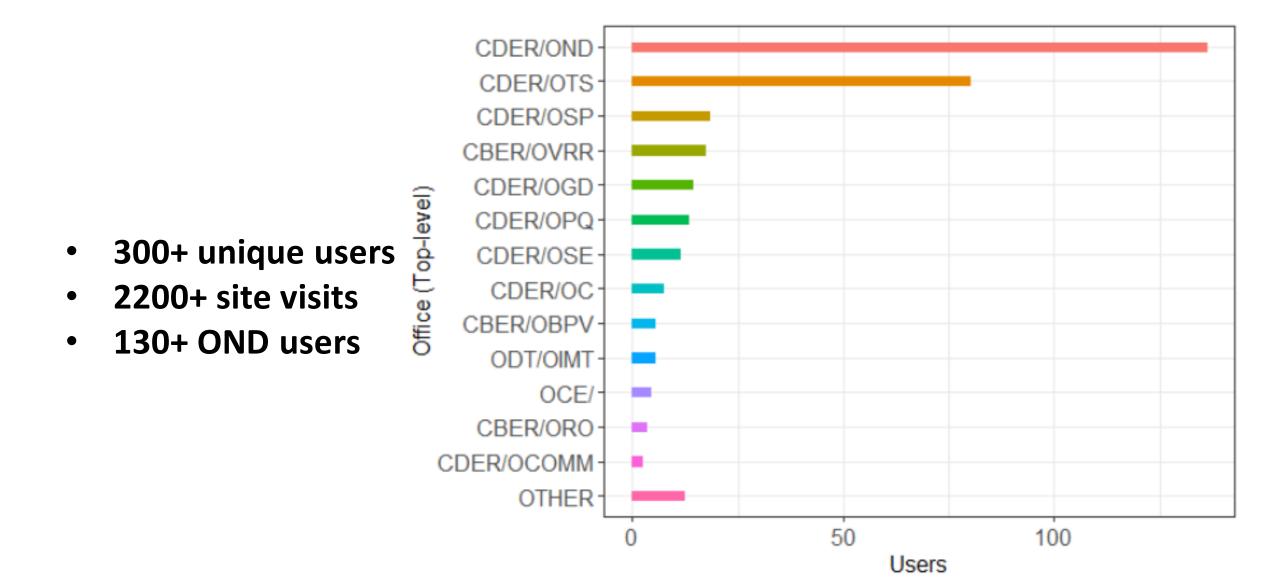
Tool Outputs

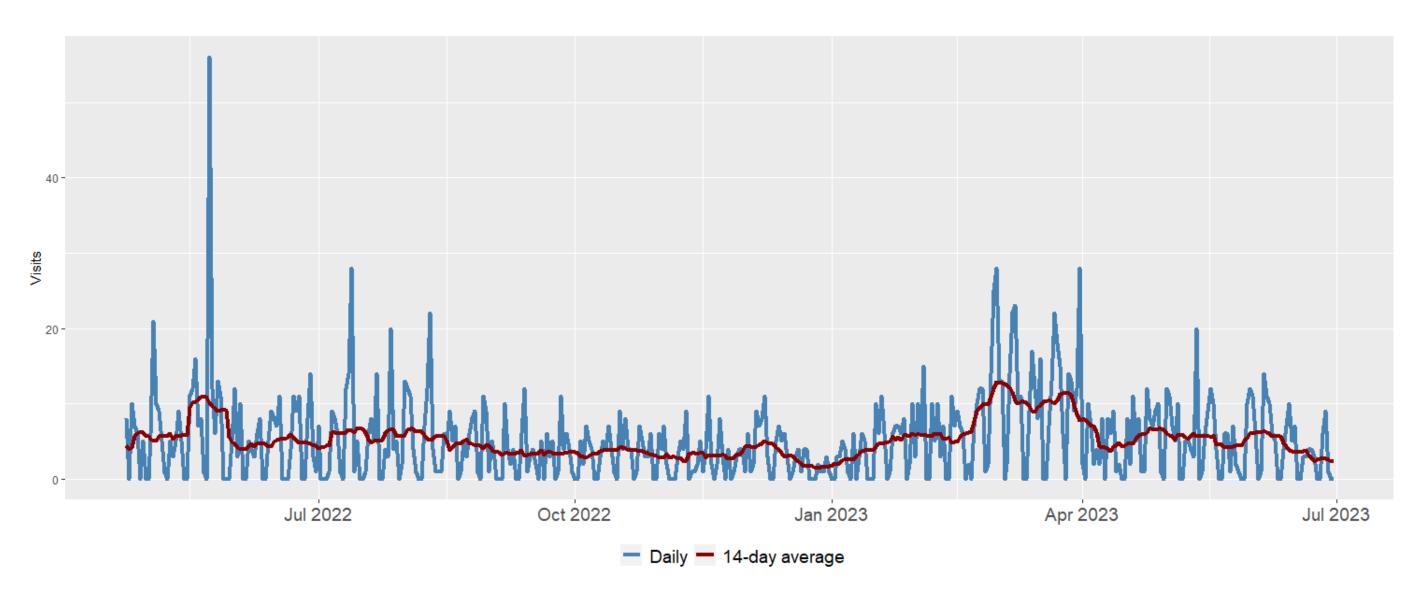
screening visit on 22 JUN 2017 revealed heart rate 78 opm, temperature 37°C, respiration 18 breaths per minute, and blood pressure of 136/65 mmHg. He had known past medical history significant for intravenous neroin abuse. He had no prior history of hepatic disorde or hepatitis infections. The subject received the first dose of Placebo at 11:55 AM on 22 JUN 2017, and last dos was at 12:08 PM on 27 JUN 2017. He received 10 dose of study drug over 6 days. On 03 JUL 2017, the subjec presented with an adverse event of Hepatitis C (Hepatitis C). This was a serious adverse event as it was an important medical event. Vital signs were unavailable Unspecified symptoms of a hepatitis C infection began

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.





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.



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.

Results

Conclusion

Acknowledgements