PHUSE/FDA CSS 2023

Monday September 18

Time (EDT)		Time (EDT)
12:00pm–3:00pm	Registration	12:00pm–3:00pm
1:30pm–3:00pm	**Hands-on Workshop: Dataset-JSON Submission Pilot Preparation Workshop** Sam Hume, *CDISC* & Stuart Malcom, *Veramed*	1:30pm–3:00pm
3:00pm–5:00pm	**FDA Plenary: Collaboration Driving Technology Adoption** **Welcome** – Lilliam Rosario, *FDA* **Dataset-JSON** – Jesse Anderson, *FDA*, Sam Hume, *CDISC* & Stuart Malcolm, *Veramed* **Open Source Technologies** – Michael Stackhouse, *Atorus Research* & Paul Schuette, *FDA* **PHUSE/FDA Innovation Challenge** – Chris Hurley, *PHUSE Americas Director* **PHUSE/FDA CSS Plane Builder Award** – Chris Price, *PHUSE Working Groups Director* & Lilliam Rosario, *FDA*	3:00pm–5:00pm
5:00pm–6:00pm	Welcome Mixer	5:00pm–6:00pm

Tuesday September 19

Time (EDT)		Time (EDT)
9:00am–12:30pm	Working Group Breakout Sessions **Hands-on Workshop: Recreating Environments on the Other Side with pharmaverse – A Practical Guide to Pass Environments Through the FDA's Submission Gateway Today** Michael Stackhouse, *Atorus Research* & Ari Siggaard Knoph, *Novo Nordisk*	9:00am–12:30pm
12:30pm–1:30pm	**Lunch Break – Supported by Deloitte**	12:30pm–1:30pm
1:30pm–3:00pm	Working Group Breakout Sessions **Workshop: Good Governance for Anonymised Data** *Facilitated by Privacy Analytics*	1:30pm–3:00pm
3:00pm–3:30pm	**Afternoon Break – Supported by Deloitte**	3:00pm–3:30pm
3:30pm–5:00pm	Working Group Breakout Sessions	3:30pm–5:00pm
5:00pm–6:30pm	Poster Session – Supported by Entimo	5:00pm–6:30pm

Wednesday September 20

Time (EDT)		Time (EDT)
9:00am–10:30am	**Plenary Session with Updates from Health Authorities:** **Overview of FDA's RWE Guidances and RWE Demonstration Projects** – Kenneth Quinto, *FDA* **Health Authority Update** – Anne-Sophie Henry-Eude, *EMA* **Risk Based Monitoring** – Cheryl Grandinetti, *FDA* **CSS Awards** – Jean-Marc Ferran, *Qualiance & PHUSE Data Transparency Working Group Lead*	9:00am–10:30am
10:30am–11:00am	**Morning Break**	10:30am–11:00am
11:00am–12:30pm	Dataset-JSON – Business Requirements including the Emerging Trends & Technologies, Data Visualisation & Open Source Technology, Optimizing the Use of Data Standards and Nonclinical Topics Working Groups. Working Group Breakout Sessions for all other Working Groups	11:00am–12:30pm
12:30pm–1:30pm	**Lunch Break**	12:30pm–1:30pm
1:30pm–4:00pm	Dataset-JSON Technical Session including the Data Visualisation & Open Source Technology and Emerging Trends & Technolgies Working Groups. Working Group Breakout Sessions for all other Working Groups	1:30pm–4:00pm
4:00pm	**CSS Close**	4:00pm

Agenda is subject to change. Version correct as of 7 August.

Thank You to Our Contributors

Platinum Contributor

PINNACLE 21 BY CERTARA

Hands-on Workshops

TrialTwin™ Accelerating Clinical Trials

Poster Session

entimo®

Tuesday Catering

Deloitte.

Working Group Breakout Sessions

Data Transparency	Data Visualisation and Open Source Technology	Emerging Trends & Technologies	Nonclinical Topics
• Image De-Identification • Educating the General Population • EU CTR Forum • Regulatory Update: Policy 0070 and PRCI with Anne-Sophie Henry-Eude (EMA) and André Molgat (Health Canada) • Internal Data Sharing • Sharing of Rare Disease Data • Workshop: Good Governance for Anonymised Data *Facilitated by Privacy Analytics*	• Dataset-JSON Business Requirements (Joint Session) • Dataset-JSON Technical Session (Joint Session) • R Shiny Interactive Forest Plot • Recreating Environments on the Other Side with pharmaverse – A Practical Guide to Pass Environments Through the FDA's Submission Gateway Today	• Dataset-JSON Business Requirements (Joint Session) • Dataset-JSON Technical Session (Joint Session) • AI/ML Digital Health Technologies (DHTs)	• Dataset-JSON (Joint session) • Future of SDRG • Protocol Automation • Virtual Controls

Optimizing the Use of Data Standards	Real World Evidence	Risk Based Monitoring	Safety Analytics
• Dataset-JSON (Joint session) • Best Practices in Data Standards Implementation Governance • Implementation of Estimands (ICH E9 (R1)) Using Data Standards • Document Management of ODS Regulatory Referenced Deliverables • BIMO FAQ • icSDRG	• Quality and Reusability of Real World Data • Submitting Real World Data • Real World Evidence Guidance, Playbook, and Other New Real-World Evidence Plans	• Future Direction of Risk Based Monitoring Quality Management and Centralised Monitoring • Explore New Potential Projects *Please note, the Risk Based Monitoring Breakout Sessions will be running on Wednesday only.*	• Safety Analytics WG (Overview Session) • Adverse Event Collection Recommendations • Treatment Emergent Definition Recommendations • Analyses & Displays for Laboratory Data • Analyses & Displays for Hepatotoxicity • Adverse Event Groupings in Safety (AEGiS) • FDA Standard Safety Tables and Figures Document – Follow-on from PHUSE CSS Breakout Session

Find Out More

Advance Hub

Breakout Sessions



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