



PharmaSUG Japan 2026

Presentation Schedule

Track legend: ■ AI – AI & Generative AI in Clinical Programming ■ DS – Data Standards, Statistical Methods & Regulatory Submissions ■ AT – Automation Tools, Platforms & Visualization ■ OS – Open-Source Adoption & Organizational Transformation ■ KN – Keynote ■ PO – Poster

Day 1 — October 28

Time	Next1 (Booth)	Next2	Next3	UDX Theater
09:30–10:10		<i>Registration</i>		
10:10–10:30		Opening Remarks KN-001 Open-Source Software and AI at PMDA: Current Status and Recent Considerations (tentative) Presenter: <i>Masanao Sasaki</i> Next-2: Japanese only. Next-3: Live streaming with English subtitle.		
10:30–11:00				
11:00–11:15	<i>Sponsor booth</i>	<i>Coffee Break</i>		
11:15–11:45		AI-001 Beyond the Prompt: Engineering a Specialized AI Engine for Clinical SAS Code and TLF Generation Presenter: <i>Niharikka Tyagi</i> Authors: <i>Niharikka Tyagi, SUHAS GIRIRAJ</i>	DS-007 Bridging SAS and R for PMDA Submissions: A Scalable Hybrid Programming Framework Presenter: <i>Mrityunjay Kumar</i> Authors: <i>Mrityunjay Kumar, Shashikant Kumar</i>	
11:45–12:15		AI-011 Human in the Driver's Seat: AI-Assisted SAS and R Programming for Modern Clinical Development Presenter: <i>Kala Shivali</i> Authors: <i>Kala Shivali, Bill Qubeck</i>	DS-023 The Hidden Cost of Study Amendments: A Metadata-Driven Approach to Assessing Downstream Impact Across the Clinical Data Lifecycle Presenter: <i>Pratiksha Wani</i> Authors: <i>Pratiksha Wani, Mustafa Lussanwala</i>	
12:15–13:30		<i>Lunch Break</i>		
13:30–14:00		AI-002 Accelerating Submission Readiness: An AI-Driven Framework for CSR Automation Presenter: <i>Niharikka Tyagi</i>	DS-009 Define.xml v2.1 Automation Using SAS and R for Accurate Metadata Submissions Presenter: <i>Yash Patel</i> Authors: <i>Yash Patel, Anuj Gandhi</i>	
14:00–14:30		AI-049 Making Your Studies AI-Ready: From Analysis to Regulatory Review Presenter: <i>Tomás Sabat Stofsel</i>	DS-018 Operationalizing the CDISC Analysis Results Standard (ARS v1.0): From Metadata Specification to Machine-Readable Clinical Trial Outputs Presenter: <i>Hemalatha Selvan</i>	

Time	Next1 (Booth)	Next2	Next3	UDX Theater
14:30–15:00	Sponsor booth	Coffee Break & 1st Poster Session (at Foyer) PO-047 / PO-052 / PO-054		
15:00–15:30		AI-004 Identifying Illness Episode Misclassification in ADaM Using AI-Assisted Temporal Logic and Explainable Decision Tree Models Presenter: <i>Purvi Kalra</i>	DS-040 Reimagining Clinical Reporting: Metadata-Driven Analysis Results Automation with MOSAIC Presenter: <i>Yui Kimura</i> Authors: <i>Yui Kimura, Shunsuke Goto</i>	—
15:30–16:00		AI-027 Code Generation Using R Template Programs with Agent Skills Presenter: <i>Masahito Katayama</i>	DS-022 Why Is Clinical Trial Automation Still Difficult? The Role of Metadata in Improving Study Execution Presenter: <i>Pratiksha Wani</i> Authors: <i>Pratiksha Wani, Mustafa Lussanwala</i>	—
16:00–16:30		AI-031 Transforming Statistical Analysis and Programming in Clinical Development with GitHub Copilot CLI Presenter: <i>Yohei Takanami</i> Authors: <i>Yohei Takanami, Ryo Nakaya</i>	DS-038 From R to Regulatory Submission: Lessons Learned from Creating, Validating, and Submitting R-Generated XPT Files to PMDA Presenter: <i>Jun Hasegawa</i>	—
16:30–16:45		Break		
16:45–17:15		AI-013 Agentic AI in Clinical Computing: From Automation to Intelligent Collaboration Presenter: <i>Kala Shivali</i> Authors: <i>Kala Shivali, William Qubeck</i>	DS-037 Bridging Toxicity Grading and Data Standards: Evolution of CTCAE and Expansion of SDTM and ADaM Frameworks Presenter: <i>Haruka Takagi</i> Authors: <i>Mathura Ramanathan, Umayal Annamalai, Haruka Takagi</i>	—
17:15–17:45	Networking Reception	AI-029 AI-Powered Drug Development Acceleration Across the Lifecycle Presenter: <i>Simon Lin</i> Authors: <i>Chunmei Peng, Yu Yang, Simon Lin, Shanshan Zhao</i>	DS-003 An R-based Workflow for Indirect Treatment Comparison and Comparative Effectiveness Analysis Presenter: <i>Charles Osudhe</i>	—
17:45–18:00		Break		
18:00–20:00				

Day 2 — October 29

Time	Next1 (Booth)	Next2	Next3	UDX Theater
09:00–09:30	<i>Sponsor booth</i>		<i>Registration</i>	
09:30–10:00		AT-010 An R Shiny Framework for Automated and Intelligent Validation of Clinical TLFs Presenter: <i>Dineshkumar Subbu</i>	—	—
10:00–10:30		AT-046 From Spec to Code: Automating ADaM Program Generation Using R Shiny Presenter: <i>Reshma Radhakrishnan</i> Authors: <i>Reshma Radhakrishnan, Dineshkumar Subbu</i>	OS-016 Building Apps Made Easy: From R Shiny to Organizational Impact Presenter: <i>Yasutaka Moriguchi</i> Authors: <i>Yasutaka Moriguchi, Santhosh N</i>	—
10:30–11:00		<i>Coffee Break & 2nd Poster Session (at Foyer)</i> PO-025 / PO-042 / PO-050 / PO-053		
11:00–11:30		AT-026 PharmaForest: Building a Collaborative Open-Source SAS Package Ecosystem for Standardized Clinical Trial Reporting and Analytics Presenter: <i>Hiroki Yamanobe</i> Authors: <i>Hiroki Yamanobe, Ryo Nakaya, Yutaka Morioka, Sharad Chhetri</i>	OS-024 Designing R Programming Flow for Open-Source Package Composition in Statistical Programming: Illustrated with Patient Profile Visualization Presenter: <i>KuenHung Lin</i>	—
11:30–12:00		AT-043 Apache Arrow as a Data Representation Across Pharmaceutical Data Workflows Presenter: <i>Ken Nakamatsu</i>	OS-036 Translating SAS Analysis Macros into R Functions: Practical Strategies and Key Insights Presenter: <i>Hiroaki Fukuda</i>	—
12:00–12:30		AT-033 Rich Kaplan–Meier Plot: A Practical Extension of the Kaplan–Meier Curve Presenter: <i>Yutaka Morioka</i>	OS-032 Practical Approaches to the SAS to R Transition in Pfizer Japan: A Bottom-Up Initiative Presenter: <i>Takumi Koyama</i> Authors: <i>Takumi Koyama, Taku Uryu, Masayo Koike, Xiaoxuan Fu, Hiroyuki Ohara</i>	—
12:30–13:45		<i>Lunch Break</i>		
13:45–14:15		AT-017 Integrated SAS and R Programming for Automated Disease Progression Memo Notifications to Clinicians for Enhanced Patient Care and Expedited Drug Approval Process Presenter: <i>Pradeep Acharya</i>	OS-041 R Transition: A Sustainable Journey towards Scalable Statistical Programming Capability Development Presenter: <i>Saumilkumar Tripathi</i>	—

Time	Next1 (Booth)	Next2	Next3	UDX Theater
14:15–14:45	Sponsor booth	AT-039 Practical Search Tool for Regulatory Request Based on Past Knowledge Presenter: <i>Junko Tsutsumi</i>	OS-044 Beyond Technology: Transforming Statistical Programming Organizations in the AI and Open-source Age Presenter: <i>Prashant Srivastava</i>	—
14:45–15:15		AT-051 10 Quick Tips for Getting Tippy with SAS® Presenter: <i>Richann Watson, Lisa Mendez</i> Authors: <i>Richann Watson, Lisa Mendez</i>	OS-048 Task-Aligned Statistical Gating Identifies Synthetic Clinical Data With Higher Downstream AI Utility Presenter: <i>Meishuo Ouyang</i>	—
15:15–15:45		<i>Coffee Break</i>		
15:45–16:15	—	—	—	AT-028 The Power of the Unified Data and AI Platform: Harmonizing SAS, R, and GenAI on SAS Viya Presenter: <i>William Kuan</i>
16:15–16:45	—	—	—	AI-034 Verifiable Synthetic Clinical Data: A Zero-Knowledge Proof Framework for Certifying Statistical Fidelity Without Data Disclosure Presenter: <i>Meishuo Ouyang</i> Authors: <i>Meishuo Ouyang, Pochu Hsu, Yiyi Yang, Binliang Liu, Yukun Liu</i>
16:45–17:00		<i>Break</i>		
17:00–17:30	—	—	—	KN-002 Empower People with AI: Creating Momentum for Transformation Presenter: <i>Nobuyuki Tsuji</i>
17:30–18:00				<i>Closing Remarks</i>

Poster Presentations

1st Poster Session: Day 1, 14:30–15:00 | 2nd Poster Session: Day 2, 10:30–11:00

Date	Session ID	Title	Presenter
Day 2	PO-025	Oncoplotter: A Next-Generation Open-Source SAS Package for Oncology Research	Presenter: <i>Yutaka Morioka</i> Authors: <i>Yutaka Morioka, Hiroki Yamanobe, Sharad Chhetri, Ryou Nakaya</i>
Day 2	PO-042	A Python-Based Approach for Semi-Automated aCRF Creation and Revision Handling Using Rave ALS Metadata	Presenter: <i>Shuya Takashima</i> Authors: <i>Shuya Takashima, Hiroshi Sakahara, Hideaki Miyagishi</i>
Day 1	PO-047	My Journey Building an R-Generating AI Coding Agent: Lessons from a Statistical Programmer	Presenter: <i>Ippei Akiya</i>

PharmaSUG Japan 2026 — Multiday Event Schedule



Date	Session ID	Title	Presenter
Day 2	PO-050	CDISC Open Rules: Progress, Performance, and Foundations for the Future	Presenter: <i>Tomás Sabat Stofsel</i>
Day 1	PO-052	Delivering Value with Generative AI: In-House, Rapid App Development in Partnership with Business Units at Shionogi	Presenter: <i>Tadashi Matsuno</i>
Day 2	PO-053	A High-Throughput Epidemiologic Screening Framework for Drug Discovery Using Real-World Data	Presenter: <i>Takashi Misawa</i>
Day 1	PO-054	MS Copilot Cowork with Agent Skill	Presenter: <i>Yohei Takanami</i> Authors: <i>Yohei Takanami, Ryo Nakaya</i>