



2025 Ennov User Meeting DRAFT Agenda Day 1

Date: Monday April 28, 2025

| | | |
|-------------------|--|-----------------|
| 08:00AM – 08:15AM | Welcome and Introductions | Chet SHEMANSKI |
| 08:15AM – 08:45AM | Keynote – Ennov 2025 | Leadership Team |
| 08:45AM – 09:15AM | Gens & Associates presentation What are key organization, process and advanced technology investment for regulatory organizations | Steve GENS |

Regulatory Track

| | Session | Content | Presenter |
|-------------------|--|------------------------------|-----------|
| 09:15AM – 09:45AM | Guest Speaker | Presentation | TBD |
| 09:45AM – 10:30AM | Morning Break | | |
| 10:30AM – 12:00PM | Ennov Regulatory Keynote: Discover our Latest Versions | Presentation | TBD |
| 12:00PM – 1:30PM | Lunch Break | | |
| 1:30PM – 3:00PM | Regulatory Roadmap (Product & Core Models): Understand the Technology Convergence Journey by Sharing the 5-year Vision | Presentation | TBD |
| 3:00PM – 3:45PM | Afternoon Break | | |
| 3:45PM – 4:15PM | Existing AI Features for Regulatory: How AI Already Improves Efficiency, Quality and Processes | Presentation / Demonstration | TBD |
| 4:15PM – 5:00PM | Integration (Inbound/Outbound) Validation Improvement Performance | Presentation | TBD |



2025 Ennov User Meeting DRAFT Agenda

Day 2

Date: Tuesday April 29, 2025

Regulatory Track

| | Session | Content | Presenter |
|-------------------|--|--------------|-----------|
| 08:00AM – 09:45AM | xEVMPD / IDMP / UDI: Compliance and Preparation for Future Updates | Presentation | TBD |
| 09:45AM – 10:30AM | Morning Break | | |
| 10:30AM – 12:00PM | Analytics and Reporting: Leverage Ennov Tools for Data Retrieval and Easier Reporting | Presentation | TBD |
| 12:00PM – 1:30PM | Lunch Break | | |
| 1:30PM – 3:00PM | Submission Documents: Management of Medicinal Drug and Medical Devices Documents and Dossiers | Presentation | TBD |
| 3:00PM – 3:45PM | Afternoon Break | | |
| 3:45PM – 5:00PM | Publishing: Keep Regulatory Updates & Imports with eCTD 4.0 and other M1 Specs | Presentation | TBD |



2025 Ennov User Meeting DRAFT Agenda Day 3

Date: Wednesday April 30, 2025

Regulatory Track

| | Session | Content | Presenter |
|-------------------|---|---------------------------|---------------|
| 08:30AM – 10:00AM | Development Opportunities and Idea Review | Interactive Game | Thierry Felix |
| 10:00AM – 10:45AM | Morning Break | | |
| 10:45AM – 11:15PM | Summary and Conclusions | Discussion | Thierry Felix |
| 11:15AM – 11:20AM | Return to Main Session | | |
| 11:20AM – 12:00PM | Closing Session | Presentation / Discussion | Various |
| 12:00PM | Meeting Closes / Grab and Go Lunch | | |