Steve Hamburg

Considerations for Implementing CDISC ARS: Balancing Flexibility and Standards

Meet the Speakers

Steve Hamburg

Title: **Director, Statistical Programming • Head of Clinical Analytics & Reporting**

Organization: Jazz Pharmaceuticals

Steve Hamburg is the Head of Clinical Analytics and Reporting at Jazz Pharmaceuticals and has over 20 years of industry experience leading clinical trial reporting and CDISC standards implementation. He spent several years contributing to the CDISC ADaM team as well as various sub-teams, and has recently led the development of multiple AI solutions for automating statistical programming workflows and gleaning insights from analysis results.

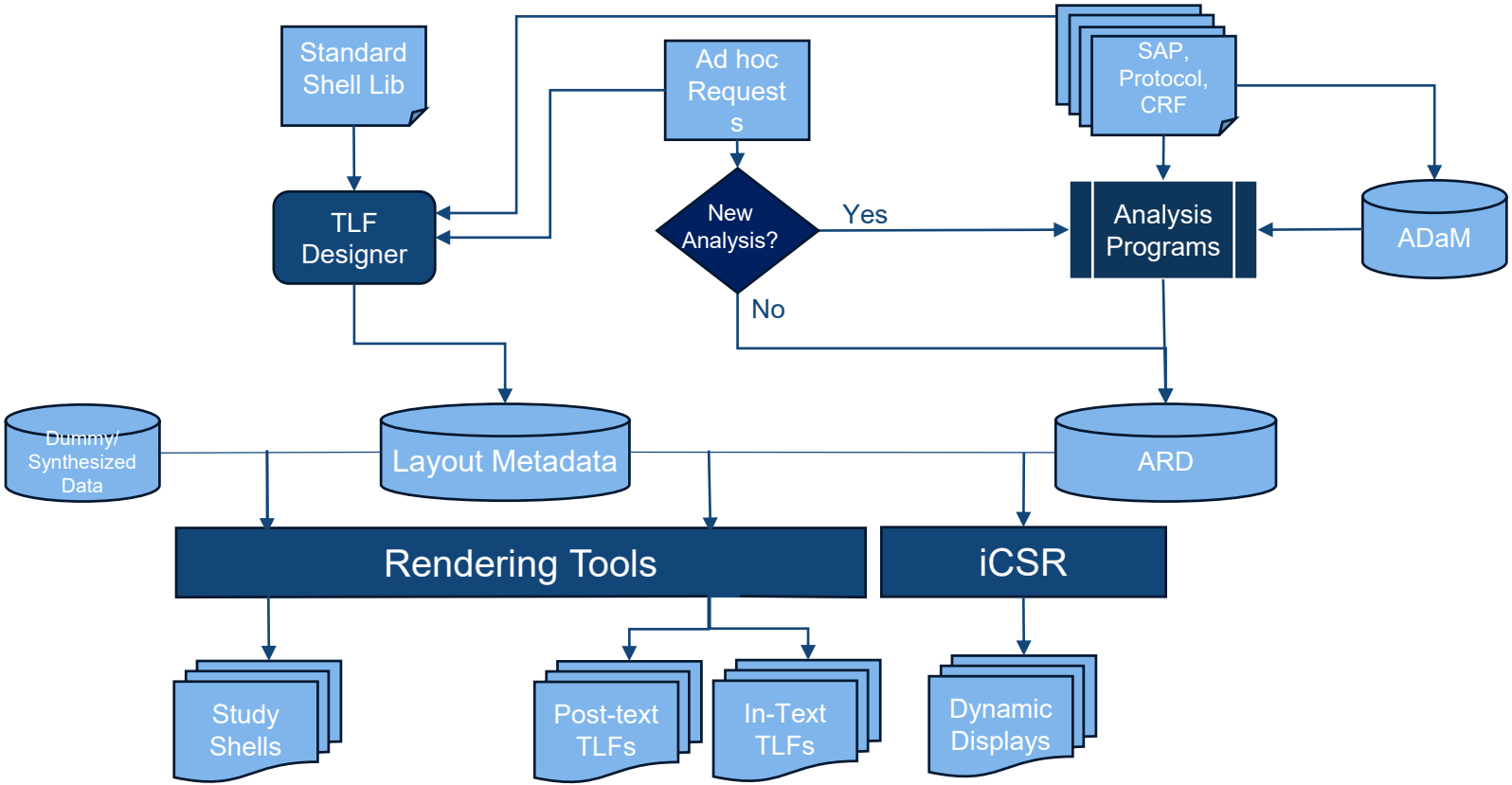
Disclaimer

- The views and opinions expressed in this presentation are solely those of the author and should not be interpreted as an endorsement by Jazz Pharmaceuticals.

Pre-ARS vision

- All Analysis Results live in a single repository
- Robust metadata contain labels and by-vars
- Analysis programs reuse results where available; update/create as needed
- Key Principle: Create analysis results data once, then flexibly map to multiple output formats:
  - Post-text tables
  - In-text summaries
  - Interactive R Shiny dashboards
  - Publication tables
  - Posters
  - Regulatory submissions

Pre-ARS Vision



The Crossroads

Custom ARD vs. CDISC ARS

Buy vs Build

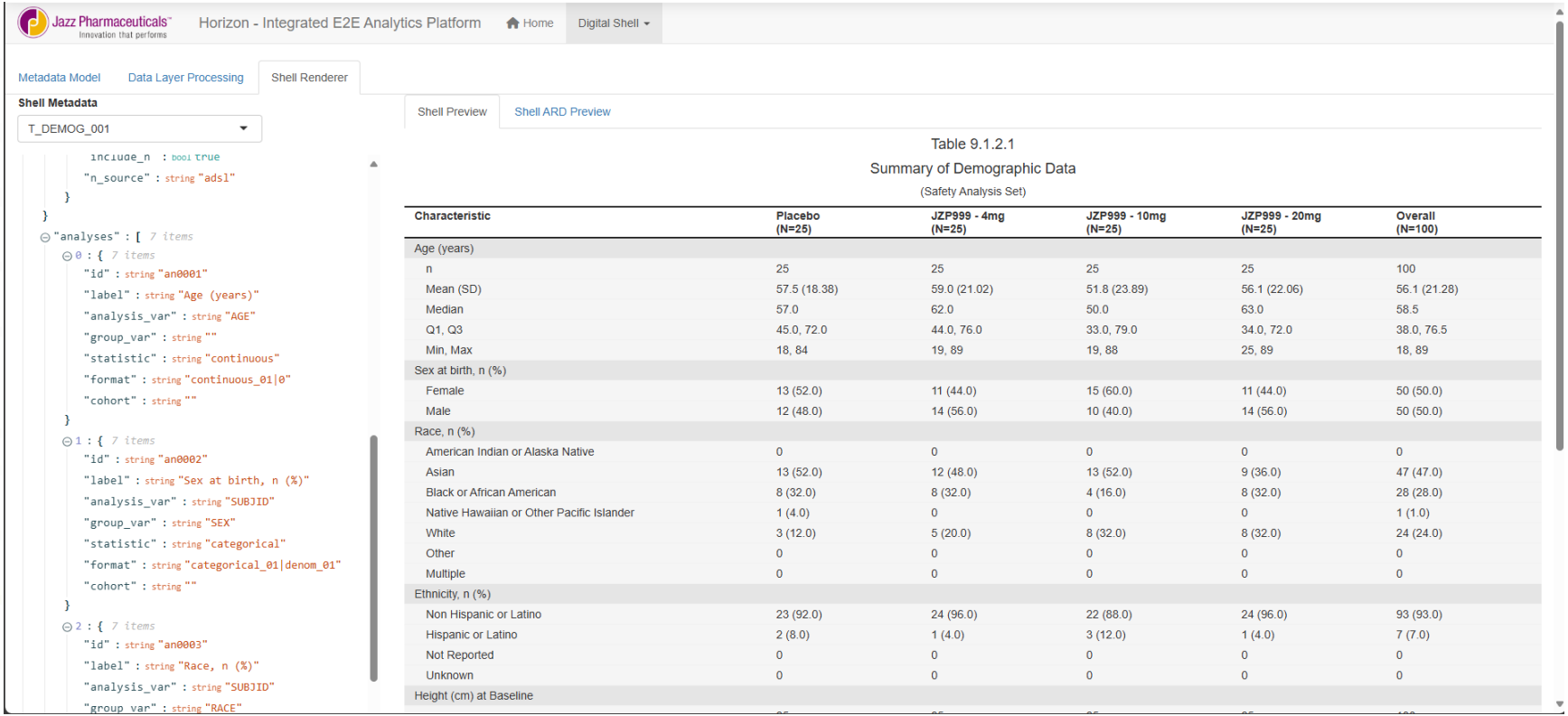
Need to balance immediate operational needs with long-term industry alignment

Option 1 - Custom ARD Solution

- Advantages:
  - Full control over design and implementation
  - Simple, fit-for-purpose structure tailored to organizational needs
  - Flexible many-to-many mapping of results to layout metadata

- Challenges:
  - Requires dedicated time and specialized skill sets to build
  - Resource constraints and competing priorities
  - Proprietary solution without industry standardization – Lack of interoperability
  - Unknown regulatory acceptance

Custom ARD Solution (PoC)



Acknowledgement: Developed by Chen Yang, Jazz Pharmaceuticals

Our Initial Exploration - Custom ARD POC

- Early Proof of Concept Development
  - Demonstrated feasibility of custom approach
  - Aligned with our reusability vision
  - Ultimately set aside to prioritize ARS evaluation

Option 2 - CDISC ARS Compliant Solution

- Advantages:
  - CDISC compliant with common industry structure
  - Future-ready for potential regulatory requirements
  - Early adopters already submitting ARS to FDA proactively
  - Industry momentum and tool ecosystem developing
- Challenges:
  - Extremely complicated design and specification
  - 1-to-1 linking of layout metadata with ARD (limits reusability)
  - Typically represented as separate ARD files per output vs. central repository
  - Diverges from "derive once, render many" vision

ARS Implementation - Buy vs. Build

- Tool Ecosystem for ARS Adoption
- Commercial Solution:
  - Clymb Clinical TFL Designer - Shell design and layout metadata generation
- Open-source R Tools for ARD and TFL generation:
  - siera – ingest ARS metadata to generate R-code for ARD generation
  - CARDS - Create ARD from ADaM
  - TFMRT - Table, Figure, and Listing creation from ARS
- Strategy: Hybrid approach leveraging both commercial and open-source tools

ARS Implementation Insights

- Template and metadata-driven tools [commercial and open-source] are key to generating CDISC ARS-compliant metadata efficiently for a successful ARD generation.
- Prospective metadata is essential to support standardized, automation-ready deliverables from study startup. Metadata setup takes upfront time.
- Iterative refinement - Metadata accuracy improves as teams align to ARS conventions and practices.
- Integrating ARS required change, prompting updates to established workflows and team processes.
- Learning curve - Many nuances not apparent upfront

Key Observation: Successful ARS implementation depends on prospective, metadata-driven design supported by adaptable tools (commercial and open-source) and evolving team practices.

Lessons Learned

- Key Takeaways:

- Gap between initial ARD vision and ARS reality requires pragmatic workarounds
- Tool maturity and process integration are critical success factors
- ARS adoption is a journey, not a destination

Questions & Discussion

LinkedIn

Steve Hamburg
Director, Statistical Programming • Head of Clinical Analytics & Reporting
Jazz Pharmaceuticals

Thank You!