PP11 : Metadata-Driven TLF Generation: A new approach to implement efficient and automated TLF in Clinical Trials

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Sophie Bellec is an employee of Sanofi and may have shares and/or stock options in the company.
Ivan Zou has nothing to disclose.

Metadata-Driven TLF

Today

Tedious TLF generation process
Static Shells Word documents
Manual algorithm writing
Prone to errors

Target

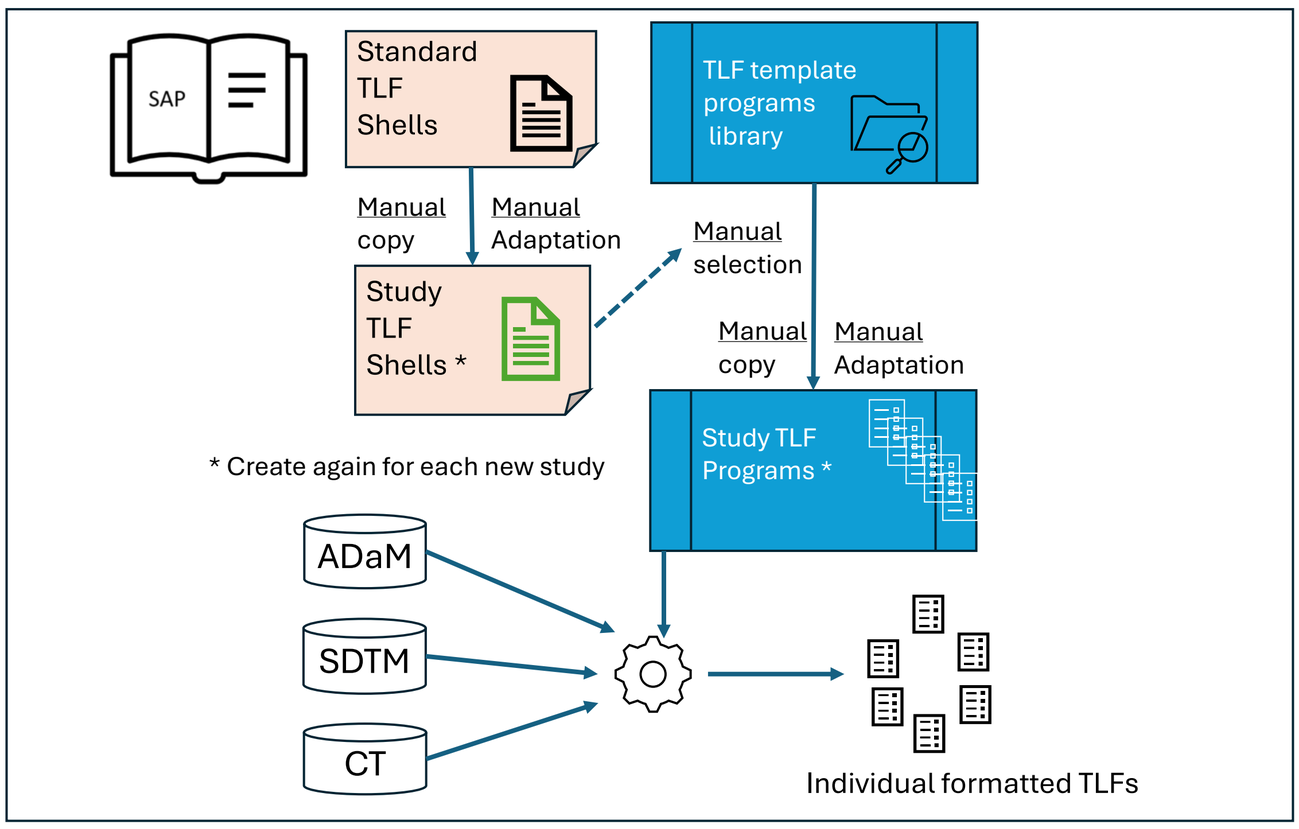
Metadata-driven approach transitioning from static to dynamic

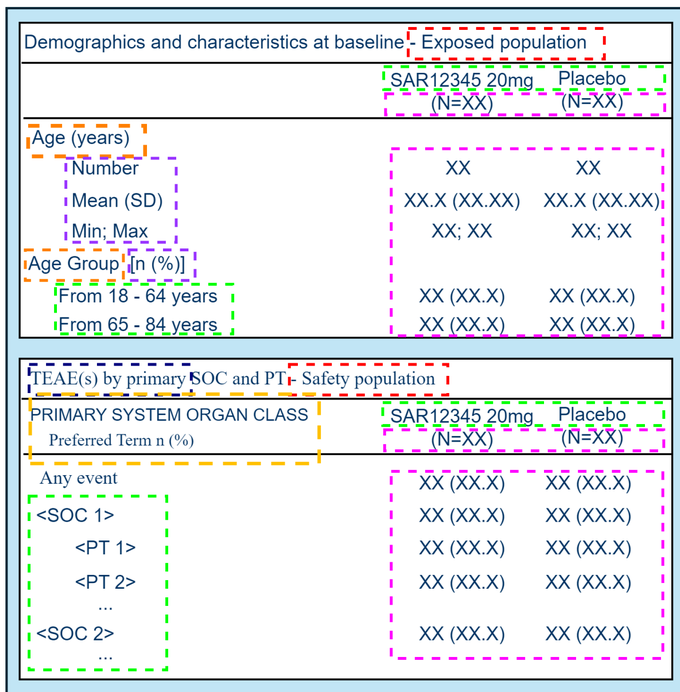
TLF shell designer application

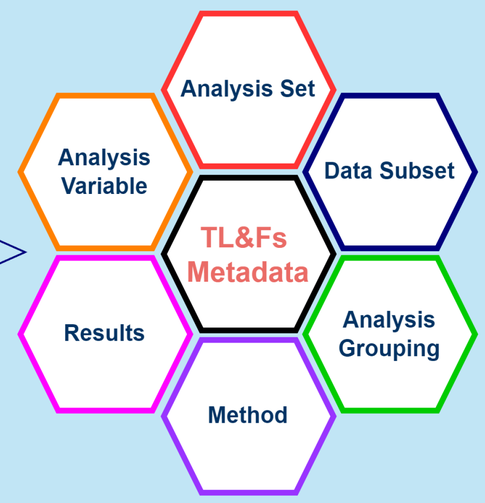
- Digitalize static shells into TLF metadata
- Automate from TLF shells to TLF creation

Current

custom

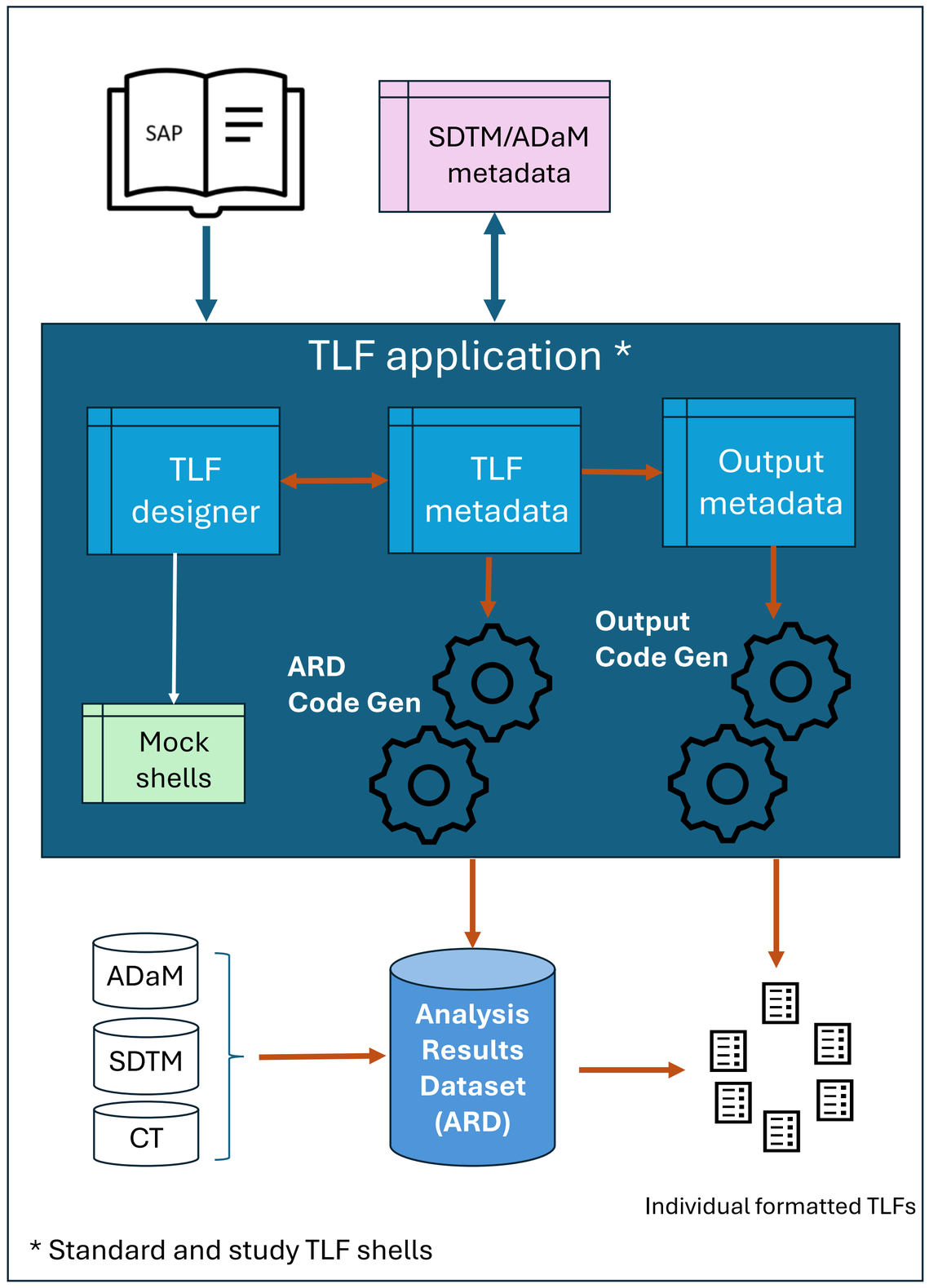






To be

Automation and custom



Current ongoing implementations

User interface
TLF shell design
Link with TLF metadata

Standard TLF metadata
Translation of Word templates into metadata

ARS & ARD standard metadata

Code Generator

Integrate GenAI

Increase automation

Tool Evolution

Next steps

Expected values

Improved Consistency
Standardized approach across studies
Easy study customization

Reduced Errors
Minimized manual intervention

Content Reuse
Efficient metadata utilization

Accelerated Reporting
Faster time to delivery

Increased Transparency
Through ARD implementation

Challenges and opportunities

Implementation complexity
→ Step by step approach

Legacy integration
→ Std TLF Steward

New technologies

User adoption
→ Change management
Training & support