

LIONBRIDGE

Mature Clinical Labeling Models & Language Excellence



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LIONBRIDGE LIFE SCIENCES

Language partner and consultant through clinical development and registration



- Translations for initial clinical trial applications
- Clinical Outcome Assessment services
- AI-powered readability testing for patient-facing materials



- **Clinical Labeling for multinational clinical trial initiation**
- Translations for protocol amendments
- SAE translations



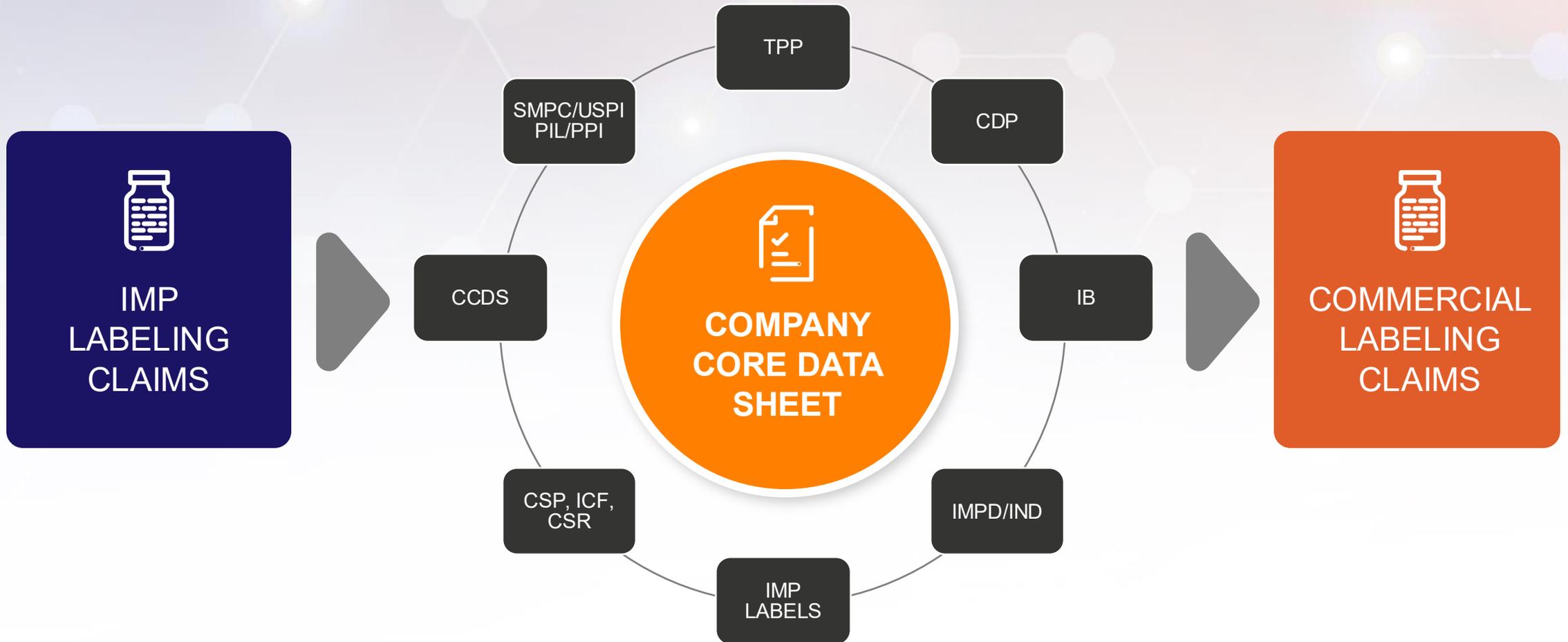
- Translations for plain language summaries of clinical trial results
- AI-powered drafting of plain language summaries of clinical trial results



- Translations of Product Information (SmPC/PI, PIL, etc.)
- Linguistic review/QRD coordination on behalf of sponsor/Applicant

CLINICAL LANGUAGE EXCELLENCE

LANGUAGE CENTRALIZATION SUPPORT CONSISTENCY AND ACCURACY THROUGH LABELING EVOLUTION AND CLAIMS DEVELOPMENT



LABELING DELAYS ARE DRIVEN BY **AVOIDABLE REWORK CYCLES**

Unstructured inputs at kickoff

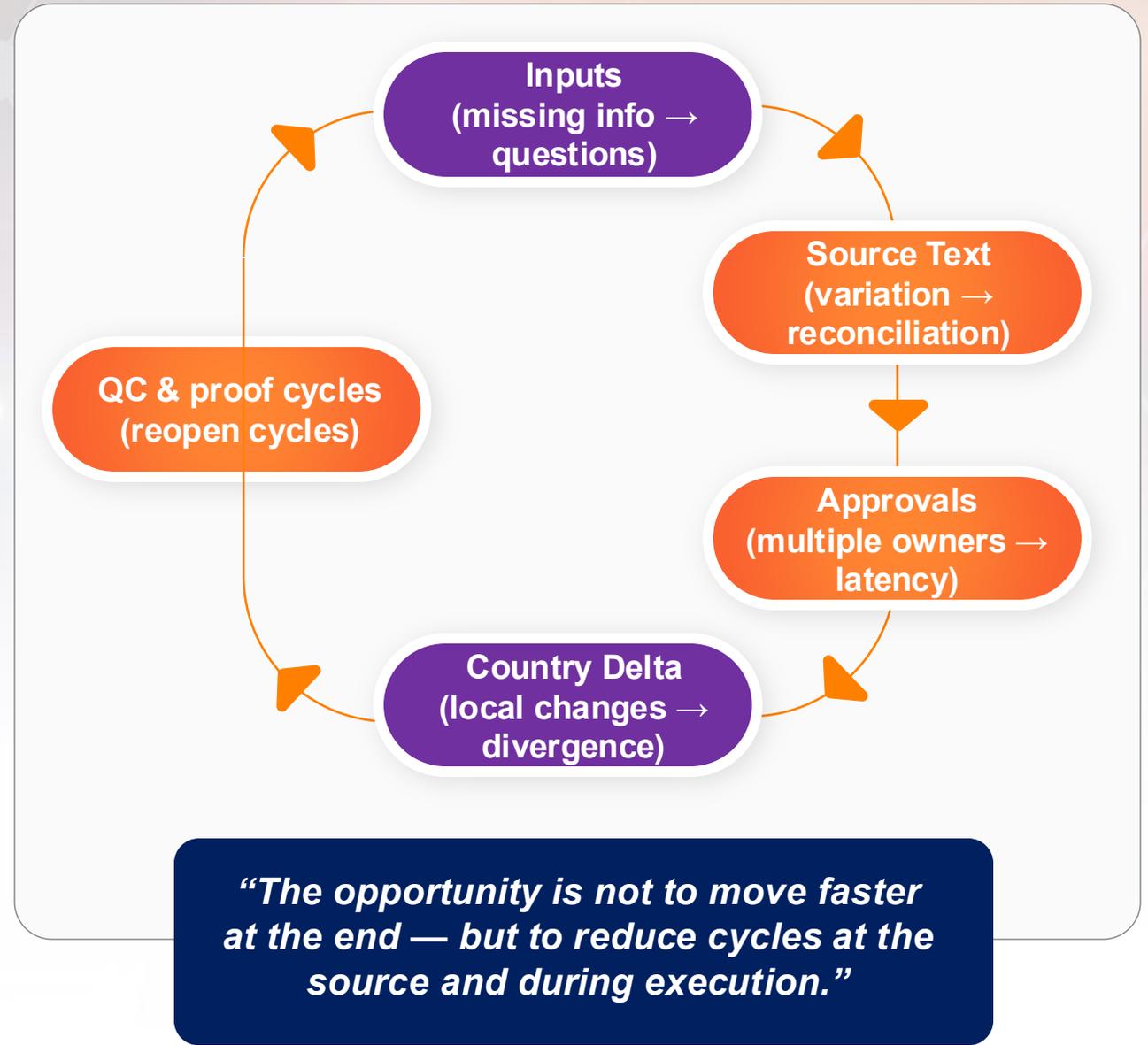
→ *clarification loops later*

Inconsistent source text (MELT)

→ *reconciliation + approval churn*

Late changes (countries, safety)

→ *QC and proofs reopen*



MATURE LABELING MODELS REDUCE FRICTION ACROSS TEAMS AND UPDATES



Ownership Clarity

Clear decision ownership across Regulatory, Clinical, Supply, Artwork

Prevents approval stalls



Language Consistency

Controlled terminology
Consistent intent
MELT → CLT

Reduces reconciliation work



Controlled Change Execution

Impact-driven updates across countries

Avoids reopening everything

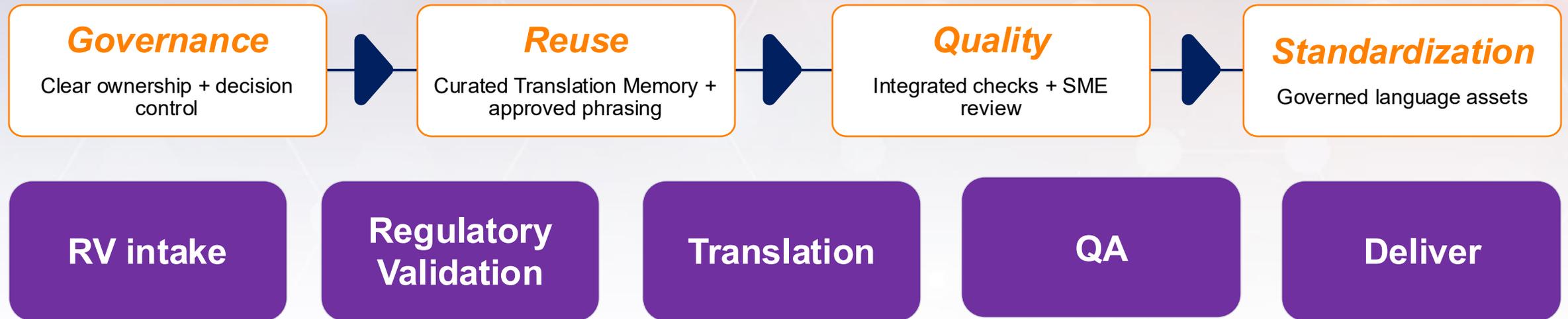
Fewer decisions → Fewer cycles → Predictable timelines

The difference isn't whether these elements exist, it's how consistently they are applied in execution.



A MATURE CLINICAL LABELING MODEL

GOVERNANCE + LANGUAGE EXCELLENCE + INTEGRATED EXECUTION



Fewer handoffs → Fewer cycles → Predictable timelines



35+ years sponsor-side experience (Sandoz / Novartis) in R&D and global roles



Senior **Global Regulatory Affairs** leader with end-to-end lifecycle perspective (clinical → commercial)



Extensive **affiliate + health authority engagement** across major regions (EU/US/APAC/LatAm)



Known for aligning cross-functional inputs into **clear, consistent, globally usable regulatory content**



Pharmacist with PhD in Medicinal Chemistry (strong scientific + regulatory foundation)

— Panel Discussion —



— Q&A —

The logo for Lionbridge, featuring the word "LIONBRIDGE" in a white, sans-serif font. The letter "I" in "LION" has a horizontal line underneath it. The logo is positioned in the top right corner of the image, which has a background of overlapping orange and red curved shapes.

LIONBRIDGE

The words "THANK YOU" in a large, bold, white, sans-serif font. The text is centered in the lower half of the image, set against a background of overlapping orange and red curved shapes.

THANK YOU

We break barriers and build bridges to new opportunities. **Everywhere.**