Structured Today, Intelligent Tomorrow: Transforming Bioequivalence Review for Abbreviated New Drug Application (ANDA)

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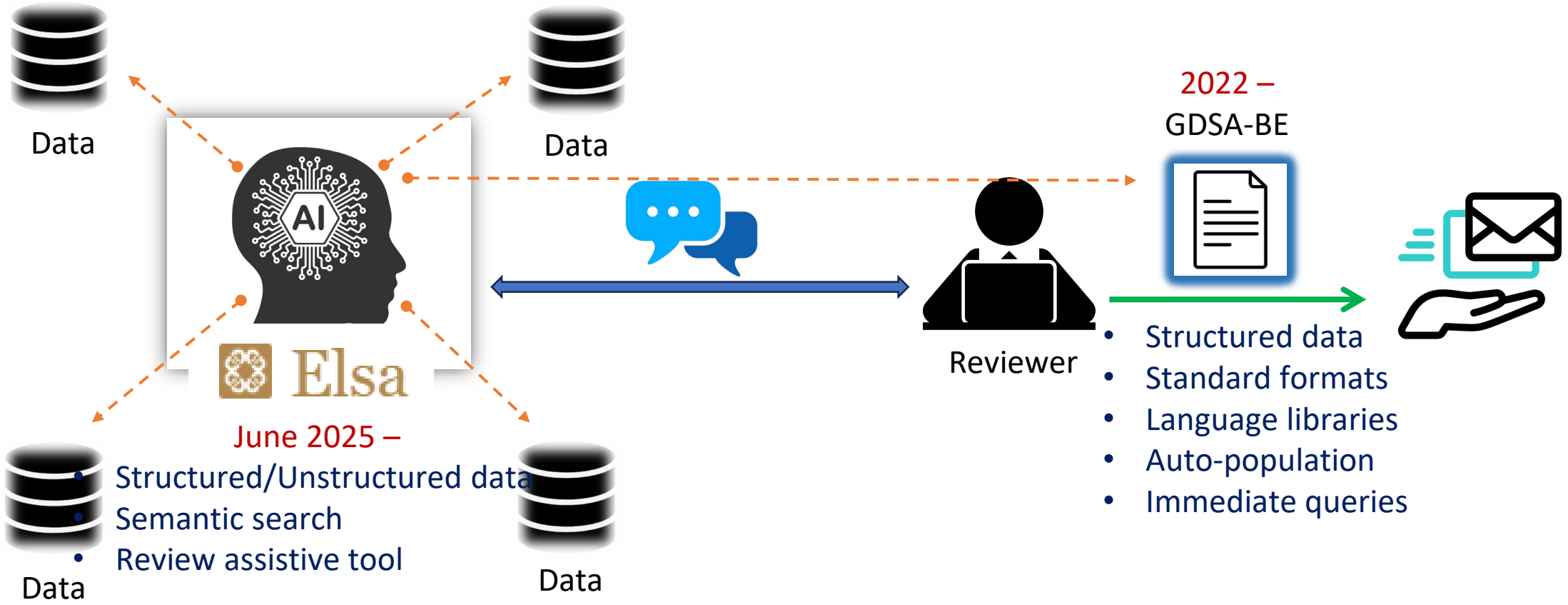
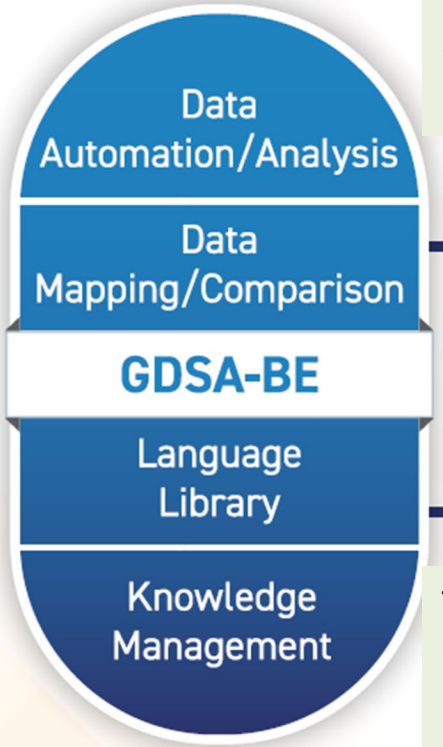
Outline

- Generic Drug Structured Assessment – Bioequivalence (GDSA-BE)
- FDA Artificial Intelligence (AI) Tool (“Elsa”)
- Use Cases
- Benefits (Regulatory/Industry)
- Summary

Modernizing Generic Drug Bioequivalence Review with Artificial Intelligence (AI) and Structured Review (GDSA-BE)



GDSA-BE: Current Bioequivalence Review Tool



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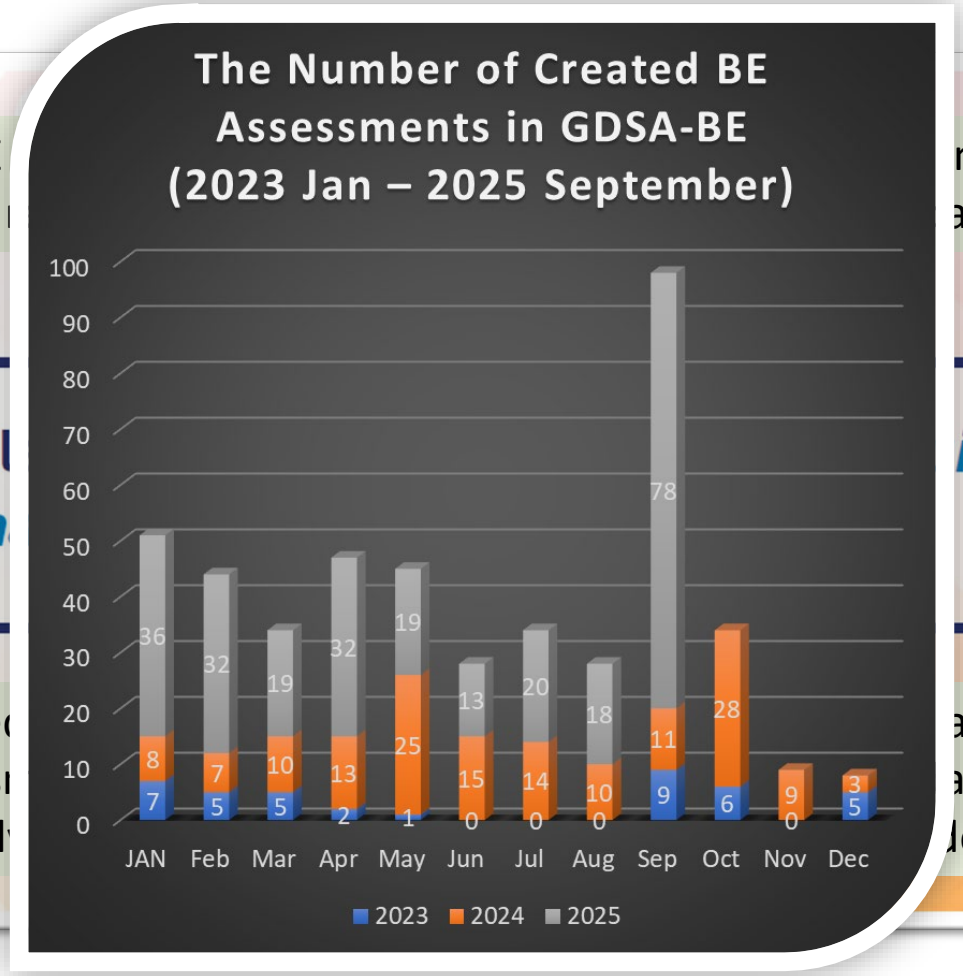

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As of September 2025, ***~430*** BE reviews created and ***~250*** BE reviews completed using GDSA-BE

What is FDA Elsa?

- On June 2nd, 2025, FDA Launched a generative Artificial Intelligence (AI) tool – Elsa
- A secure platform (high-security GovCloud environment)
- **NOT** trained on data submitted by regulated industry
- FDA Elsa development team continues to add more capabilities to the tool
- In the future, FDA will develop additional AI tools to further support the FDA's mission

FDA Elsa: “Human in the Loop”

- Assistive tool, not decision maker
- Regulatory outcomes, decisions, and enforcement actions must be determined by human experts
- Appropriate human oversight should be in place
- Human should always cross-check information provided by Elsa
- Human should rely on their expertise to validate Elsa’s responses

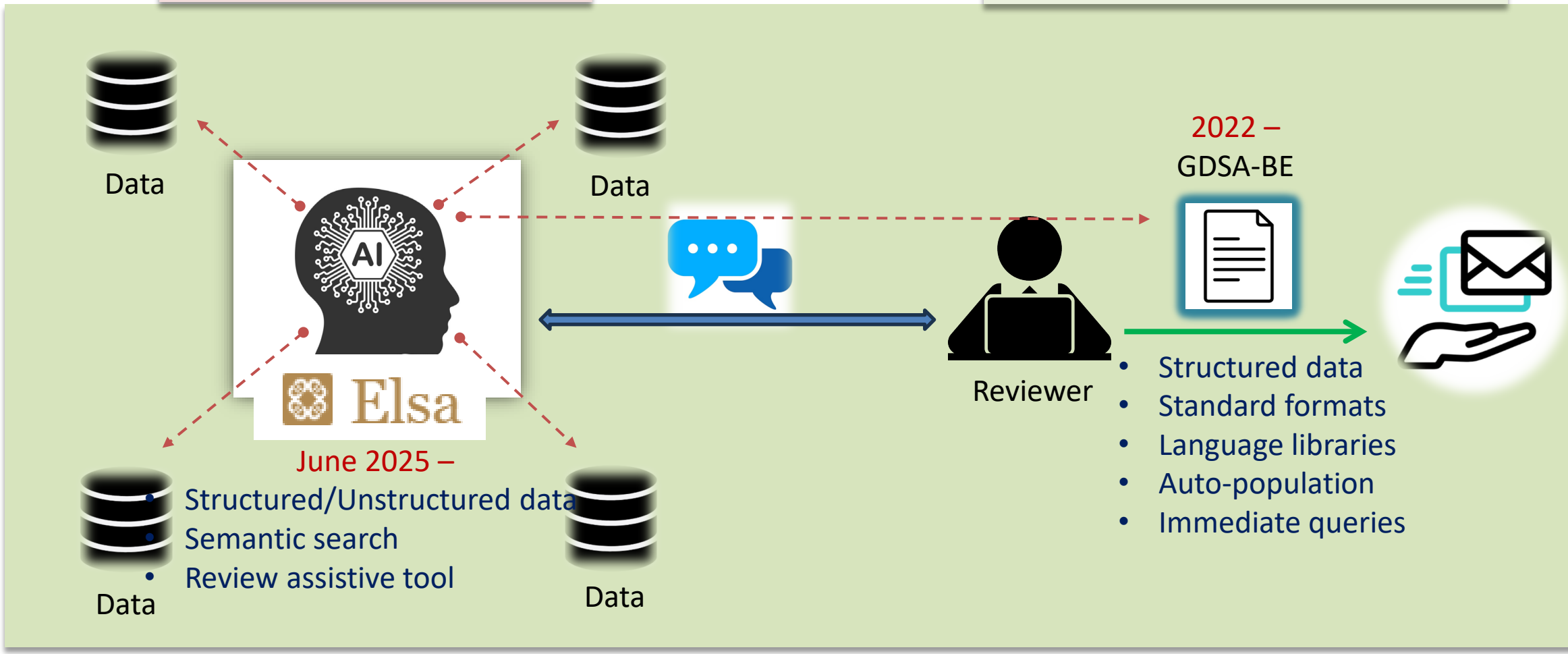
Elsa: Bioequivalence Reviewer's AI-Powered Assistant – ***Potential Use Cases***

- Prescreen submission and flag potential issues
- Draft an initial version of the response to questions raised in Controlled Correspondence
- Cut time spent in searching regulation and guidance
- Reduce time and efforts spent for data retrieval during review process
- Enhance communication compliance with Four-Part Harmony
- Data analysis and fraud detection

Vision for Modernizing Generic Drug Bioequivalence Review with Artificial Intelligence (AI) and Structured Review (GDSA-BE)

Future (AI-GDSA-BE)
AI-Powered Real-Time Review

Current (GDSA-BE)
Knowledge-Based Structured Review



Benefits of AI-Powered Bioequivalence Review
– Bioequivalence Reviewer

- **Enhanced Efficiency**: Reduces the time reviewers spend searching for data, allowing more focus on scientific analysis
- **Faster Decision-Making**: Accelerates the end-to-end review process by enabling quick retrieval and interpretation of critical information
- **Institutional Knowledge Capture**: Preserves insights from previous scientific discussion, creating a living knowledge base
- **Real-Time Review**: Transforming BE review from a static and deadline-driven process to a dynamic, real-time collaboration between FDA and the generic drug industry

Benefits of AI-Powered Bioequivalence Review
– Generic Drug Industry

- **Faster Review Times**: Enhanced reviewer efficiency contributes to shorten overall ANDA timelines
- **Predictable Decision-Making**: Access to consistent data supports more uniform regulatory interpretations across applications
- **Improved Communication Quality and Transparency**: Reviewers can provide clearer, data-informed feedback to sponsors
- **Knowledge Continuity**: As reviewers leverage prior review data more effectively, FDA decisions become increasingly aligned with established precedents

Support a more *transparent* and *efficient* generic drug review ecosystem

How Generic Drug Industry Can Prepare for This Change?

Robust Data Foundations

- Well-curated, standardized, and traceable
- Use recognized data standards (e.g., CDISC)
- Structured/computable submissions (e.g., M2 BE Summary Tables)

Digital Infrastructure Investment

- Build robust data management pipeline
- Explore electronic submission platforms optimized for structured data formats

Enhance Internal Capabilities and Training

- Develop internal tools that help enhance data accuracy and consistency before submission
- Encourage cross-functional collaboration to ensure submissions are both scientifically sound and digitally optimized

*Beyond technical readiness, the transition will require a **mindset shift***

Summary

- GDSA-BE provides the foundation for AI-powered intelligent review by organizing regulatory data into standardized, machine-readable formats. It enables FDA “Elsa” to operate on trusted and high-quality inputs for BE data.
- FDA “Elsa” is a generative AI tool that operates on a high secure GovCloud environment. It leverages structured/unstructured data and automation to make regulatory assessments more efficient, consistent, and data-informed.
- FDA “Elsa” can be leveraged in many use cases to streamline generic drug BE review process.
- AI-powered GDSA-BE review enables “Real-Time Review” in the future and provides benefits to both regulatory reviewers and pharmaceutical companies.
- Generic drug industry needs to proactively adapt their scientific, technical, and organizational practices to fully benefit from this transformation.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Ask me why...
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"When I reach for the medicine cabinet, I know I am safe, I am a patient, too!"
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