



BEYOND THE HYPE

Practical Guidance for LLM Adoption in Statistical Programming



Eyal Wultz

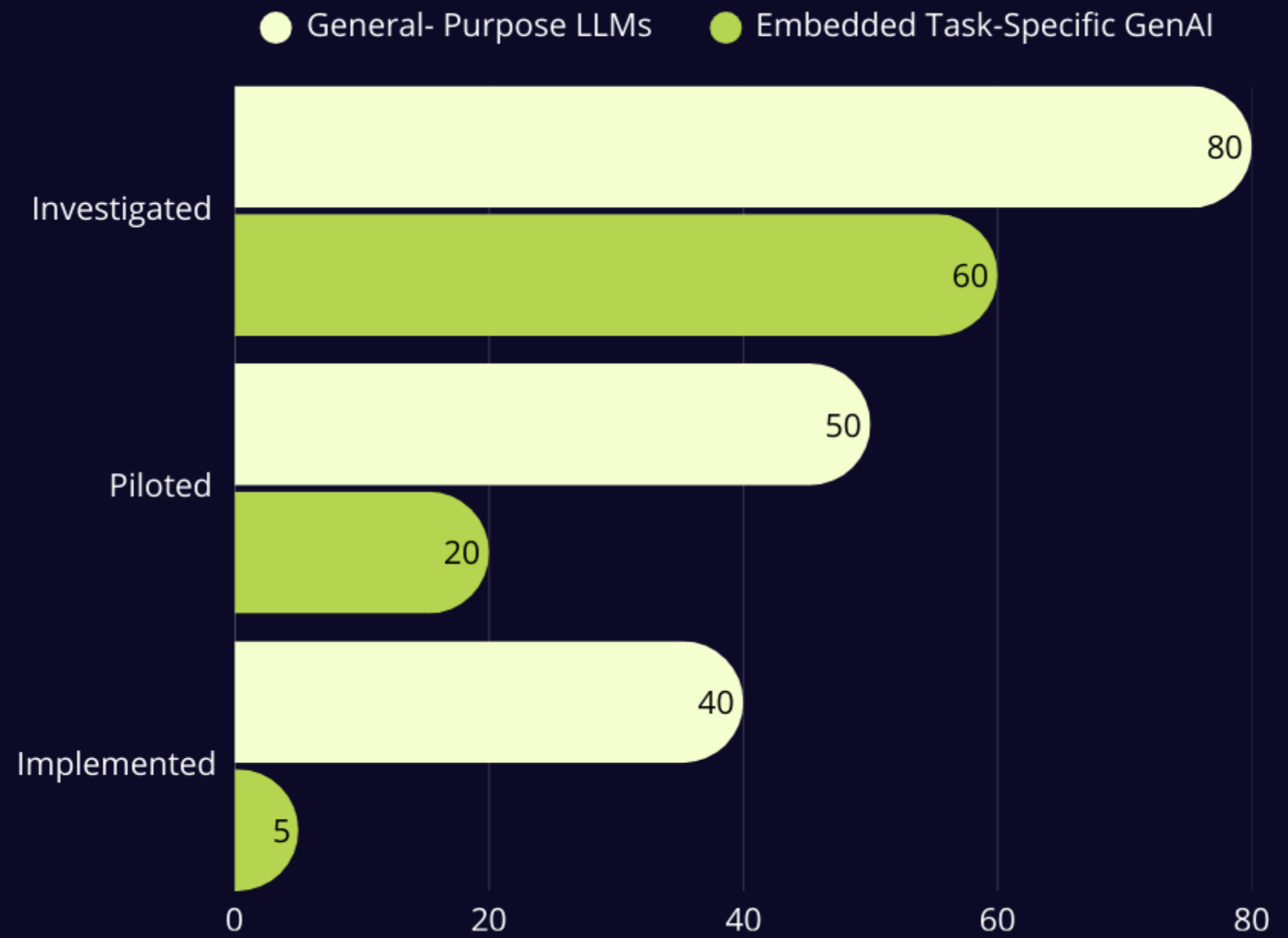
Bioforum Co-founder

- 25+ years of experience in Biometrics & Clinical Informatics.
- Co-Founder of Bioforum, a global Biometrics CRO
- Co-Founder and President of BionData, Biometrics Technology Provider



The GenAI Divide

Only **5%** of organizations get a return from GenAI investments



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*“This divide does not seem to be driven by model quality or regulation – but seems to be **determined by approach.**”*

General-purpose LLM Limitations

- **Quality is not consistent**
- **Continuous learning – almost doesn't exist**
- **Too much context required each time**



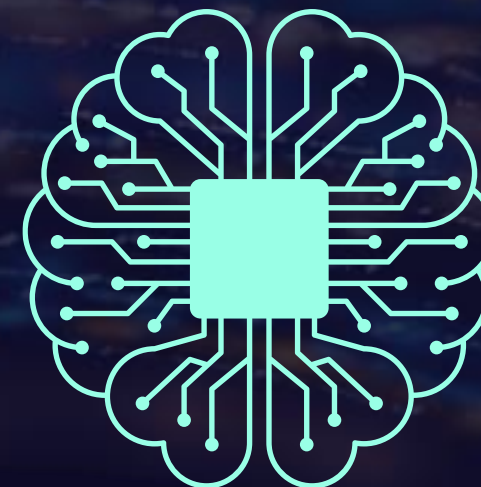
The Solution: Task-Specific Systems



User Interface



AI Agent



LLM

- Assemble context
- Construct Prompt
- Process response
- Validate output

Task-Specific Systems

- Focus on narrow high-value use cases
- Integrate deeply into workflows
- Scale through continuous learning
- Have a low configuration burden
- Show immediate and visible value

Use Cases – SDTM Conversion



Value Mapping

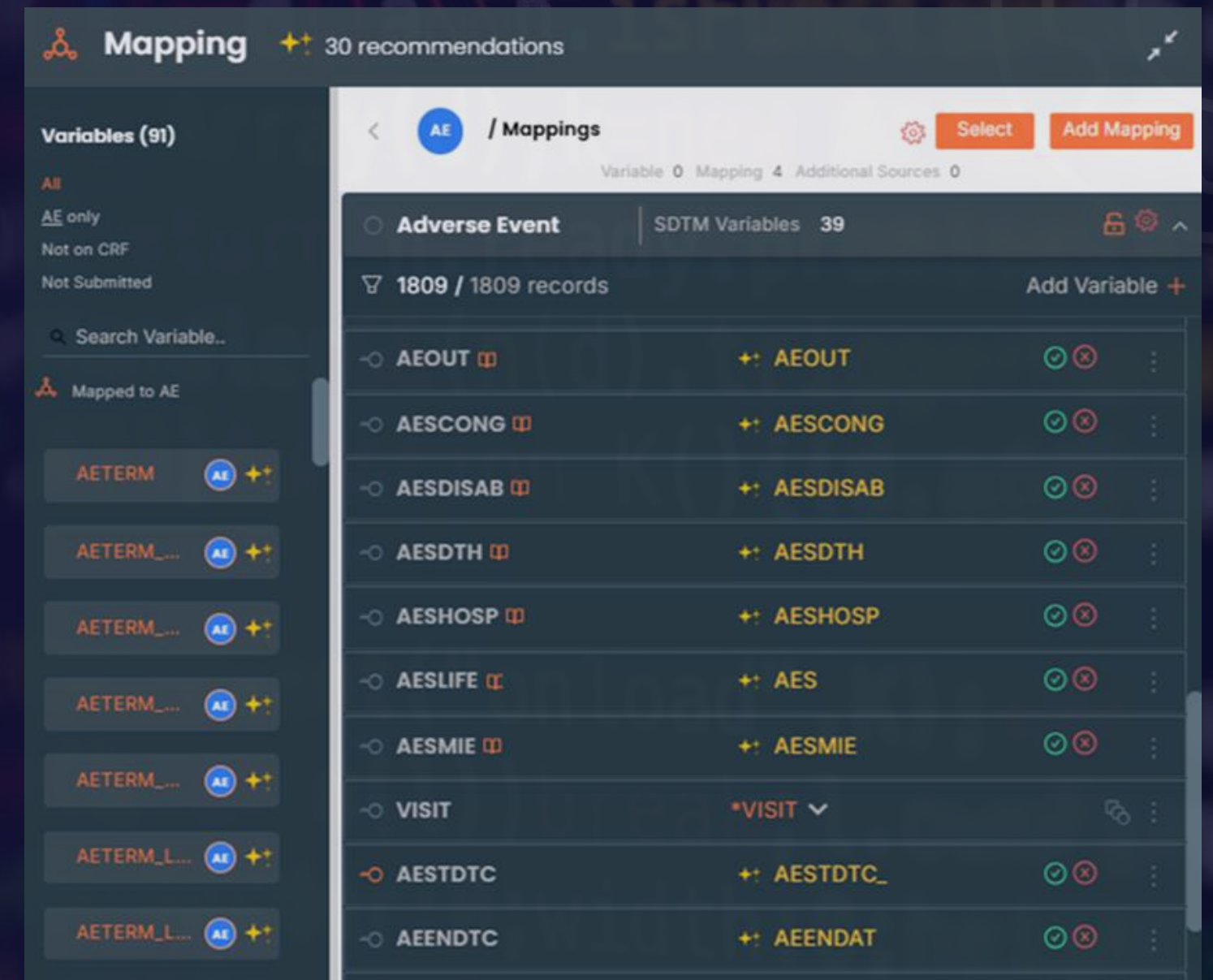
0% Completed 0/70

Default Value: Null

Raw Value	Target
Albumin	Albumin (100% Approved Mapping)
Alk. Phos.	Alkaline Phosphatase (80% Levenshtein)
ALT	Alanine Aminotransferase (100% Approved Mapping)
APTT	Activated Partial Thromboplastin Time (100% Approved Mapping)
AST	Aspartate Aminotransferase (100% Approved Mapping)
Bacteria	Bacteria (100% Approved Mapping)
Basophils	Basophils (100% Approved Mapping)
Basophils (%)	Basophils (80% Levenshtein)
Bicarbonate	Bicarbonate (100% Approved Mapping)
Calcium	Calcium (100% Approved Mapping)
Casts	Casts (100% Levenshtein)
Chloride	Chloride (100% Approved Mapping)
CK	Creatine Kinase (100% Levenshtein)
Creatinine	Creatinine (100% Approved Mapping)

Approve Clear All

Controlled terminology recommendations



Mapping 30 recommendations

Variables (91)

AE only
Not on CRF
Not Submitted

Search Variable..

Mapped to AE

- AETERM
- AETERM_...
- AETERM_...
- AETERM_...
- AETERM_...
- AETERM_...
- AETERM_L...
- AETERM_L...

AE / Mappings

Variable 0 Mapping 4 Additional Sources 0

Adverse Event SDTM Variables 39

1809 / 1809 records Add Variable +

AEOUT	AEOOUT
AESCONG	AESCONG
AESDISAB	AESDISAB
AESDTH	AESDTH
AESHOSP	AESHOSP
AESLIFE	AES
AESMIE	AESMIE
VISIT	*VISIT
AESTDTC	AESTDTC_
AEENDTC	AEENDAT

variable level mapping recommendations

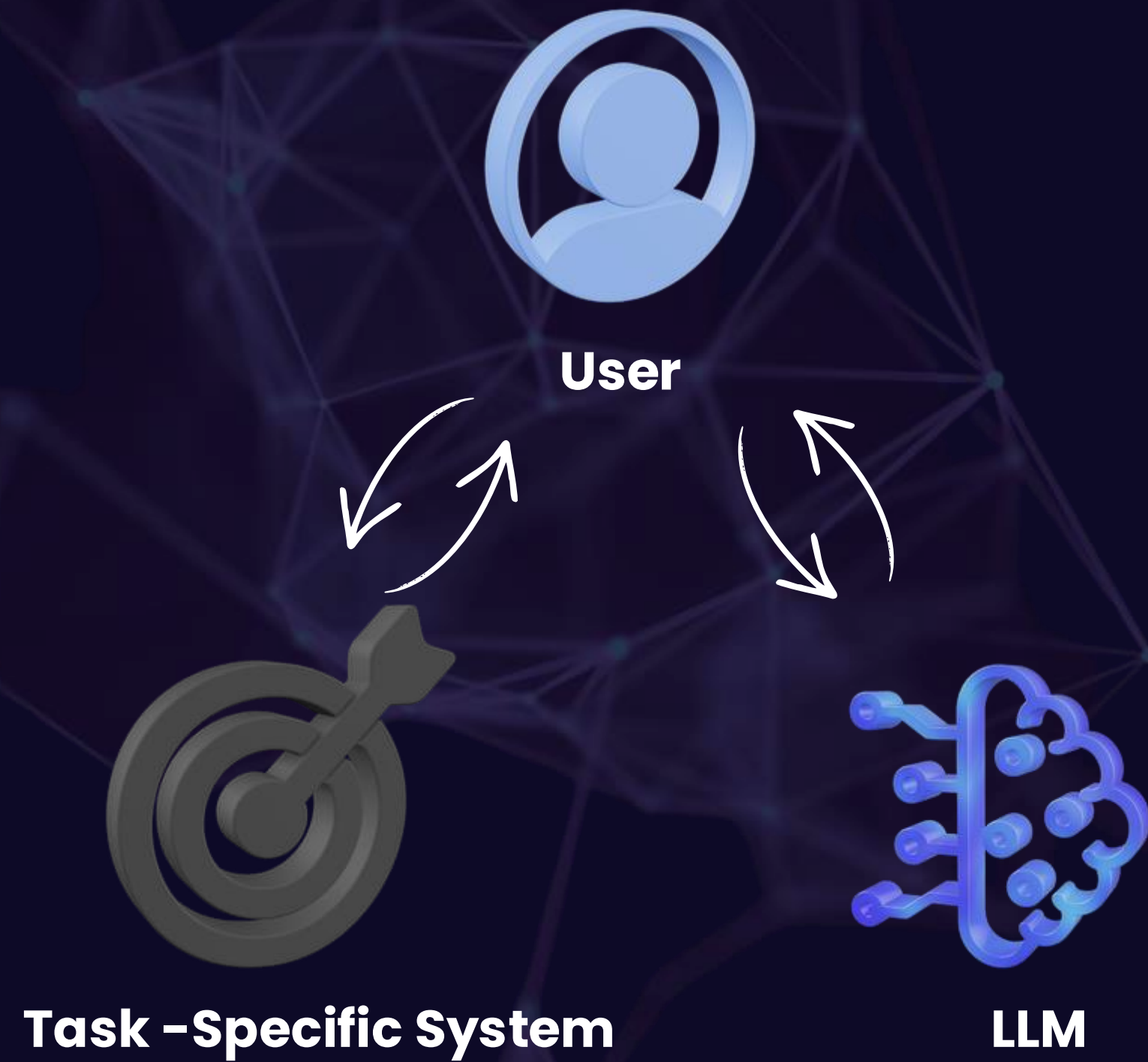
Use Cases – SDTM Conversion

Focus on Narrow High-Value Use Cases

- Complex internal logic
- Requires deep domain expertise
- General-purpose LLMs are impractical
- Dispersed context sources
- Reuse of approved mappings – challenging



SDTM is no easy task
Mission-critical work



USE CASE: CONTROLLED TERMINOLOGY

Workflow Integration



Textual Modifications

Value Mapping



Import External Mappings Codelists (1)

0% Completed 0/65

Mapped (0)

Original Value (0)

Unassigned (65)

Empty String (0)

Non-Codelist (0)

Raw Value 65 Unassigned

Target

Raw Value	Info	Info	Info	Info	Target
PT	>	∅	>	⚡	ⓘ ⚡ Prothrombin Time (Approved Mapping)
Red Cell Count	>	∅	>	⚡	ⓘ ⚡ ++ Erythrocytes (High)
Red Cells	>	∅	>	⚡	ⓘ ⚡ ++ Erythrocytes (High)
Reticulocytes	>	∅	>	⚡	ⓘ ⚡ ≡ Reticulocytes (High)
Serum Pregnancy	>	∅	>	⚡	ⓘ ⚡ ++ Choriogonadotropin Beta (High)
Sodium	>	∅	>	⚡	ⓘ ⚡ ⚡ Sodium (Approved Mapping)
Specific Gravity	>	∅	>	⚡	ⓘ ⚡ ⚡ Specific Gravity (Approved Mapping)
TB Quantiferon	>	∅	>	⚡	ⓘ ⚡ ≡ TB TFS (Medium)
Total Bilirubin	>	∅	>	⚡	ⓘ ⚡ ⚡ Bilirubin (Approved Mapping)
Total Cholesterol	>	∅	>	⚡	ⓘ ⚡ ++ Cholesterol (High)
Triglyceride	>	∅	>	⚡	ⓘ ⚡ ≡ Triglycerides (High)
Troponin I	>	∅	>	⚡	ⓘ ⚡ ≡ Troponin I (High)
Ur. Bilirubin	>	∅	>	⚡	ⓘ ⚡ ≡ Direct Bilirubin (High)
Ur. Blood	>	∅	>	⚡	ⓘ ⚡ ++ Macroscopic Blood (High)

Controlled Terminology in JetConvert™

Approve

Clear All

USE CASE: CONTROLLED TERMINOLOGY

Workflow Integration



USE CASE: CONTROLLED TERMINOLOGY

Continuous Learning

Do It Once

- Reuse Approved Mappings
- Auto Map Direct Matches
- Map, review and approve only once

USE CASE: CONTROLLED TERMINOLOGY

Configuration Overhead

Do It Once

Configure context only once within the task-specific system – and reuse across all system's modules

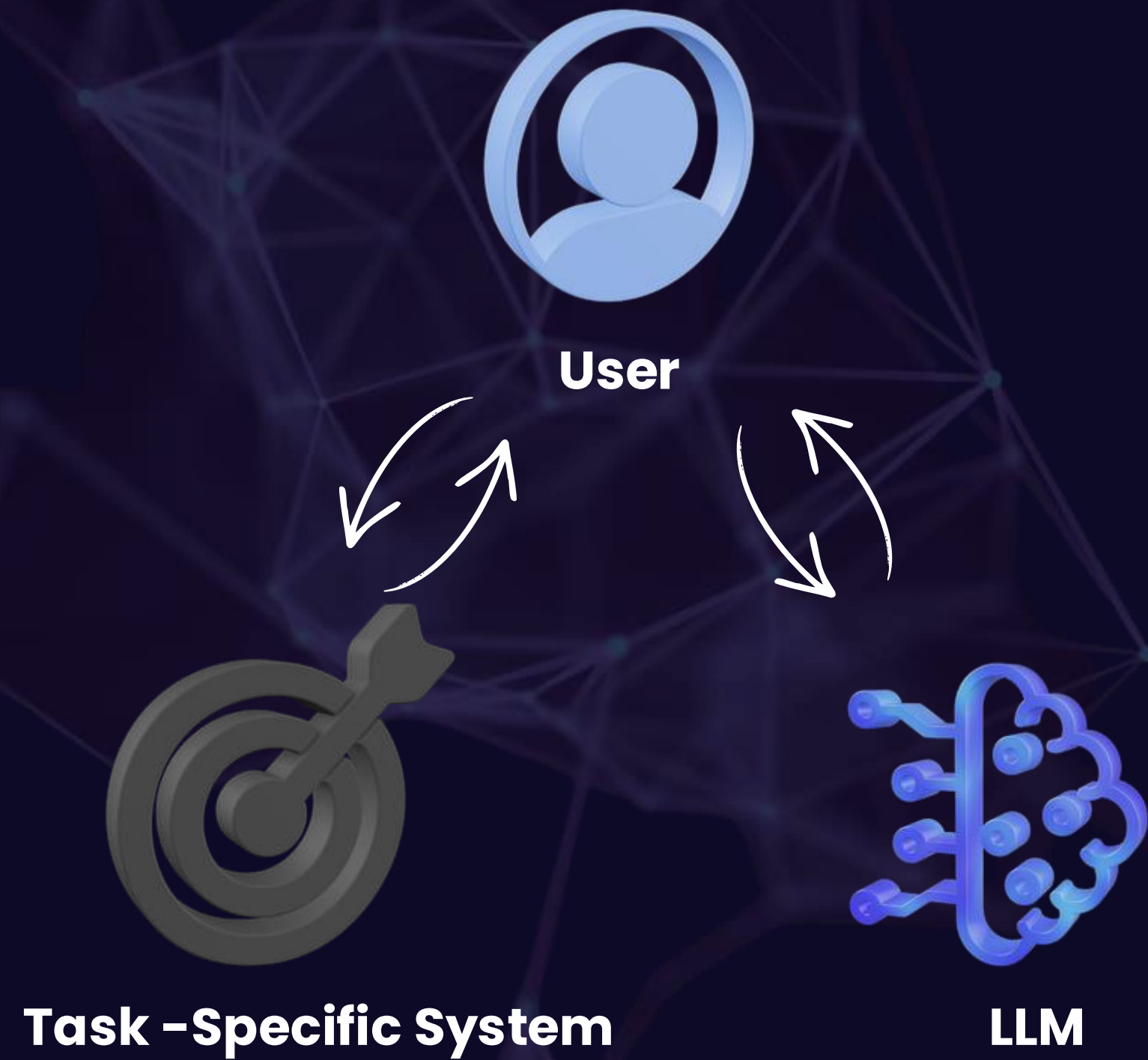


Task	Performance	Time Saving	Total per 1000 terms
Auto Mapped	40%	2 min	13.3 hrs
Correct Result	52%	1 min	8.6 hrs
Incorrect Result	2%	-	-
No Result	6%	-	-

22hrs / 33.3hrs = 66%

USE CASE: CONTROLLED TERMINOLOGY

Measurable Value



USE CASE: VARIABLE LEVEL MAPPING

Workflow Integration

Variables Mapping in JetConvert™

Mapping ✨ 28 recommendations 👁

Variables (82)

All
 AE only
 Not on CRF
 Not Submitted

🔍 Search Variable..

- OnsetDt AE ✨
- OnsetDt_R... AE ✨
- OnsetDt_INT AE ✨
- OnsetDt_Y... AE ✨
- OnsetDt_M... AE ✨
- OnsetDt_DD AE ✨
- ResolveDt AE ✨
- ResolveDt_... AE ✨
- ResolveDt_... AE ✨

AE / Mappings ⚙️ **Select** **Add Mapping**

Variable 0 Mapping 1 Additional Sources 1

Adverse Event Term | SDTM Variables 26 🔒 ⚙️ ^

🔍 1809 / 1809 records All (26) Add Variable +

AEOUT	Resolution	✓	✗	⋮
AESCONG	BirthDefectFI	✓	✗	⋮
AESDISAB	IncapacityFI	✓	✗	⋮
AESDTH	FatalFI	✓	✗	⋮
AESHOSP	InpatientFI	✓	✗	⋮
AESLIFE	LifethrtnFI	✓	✗	⋮
AESMIE	MedicallyImpFI	✓	✗	⋮
AESTDTC	OnsetDt	✓	✗	⋮
AEENDTC	ResolveDt	✓	✗	⋮
AESURGRY SUPP	ActnReoperate	✓	✗	⋮

⊗ Remove Mapping | 🔒 Mark as complete | ⏏ Commit

USE CASE: VARIABLE LEVEL MAPPING

Continuous Learning

EVOLVING GUIDELINES

AI agent

Context Assembly & Prompt Construction

- SDTM implementation guide • FDA technical conformance guide
- Sponsor-specific instructions
- PHUSE papers
- Industry best practices
- Standardized CRFs & DTAs
- New edge cases

USE CASE: VARIABLE LEVEL MAPPING

Workflow Integration & Low
Configuration Overhead



User



JetConvert™



LLM

System Input

- Source data & metadata
- CRF annotations
- SDTM standards
- Sponsors guidelines



Task	Performance	Time Saving	Total per 300 variables
Correct Result	80%	60%	48 hrs ¹
No Result	15%	-	-
Incorrect Result	5%	-	-
			48hrs / 100hrs = 48%

USE CASE: VARIABLE LEVEL MAPPING

Measurable Value

¹ 300 variables, 2.5 weeks mapping time = 20 min/mapping

CONCLUSION

- Focus on narrow high-value use cases
- Integrate deeply into workflows
- Scale through continuous learning
- Have a low configuration burden
- Show immediate and visible value



CONCLUSION

Potential Use Cases

- Data insights – data structures, values, discrepancies, multi-source handling...
- Trial domain generation
- “Talk to your data” analytics
- Define.xml SDRG generation
- ADaM & TFL generation





THANK YOU

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