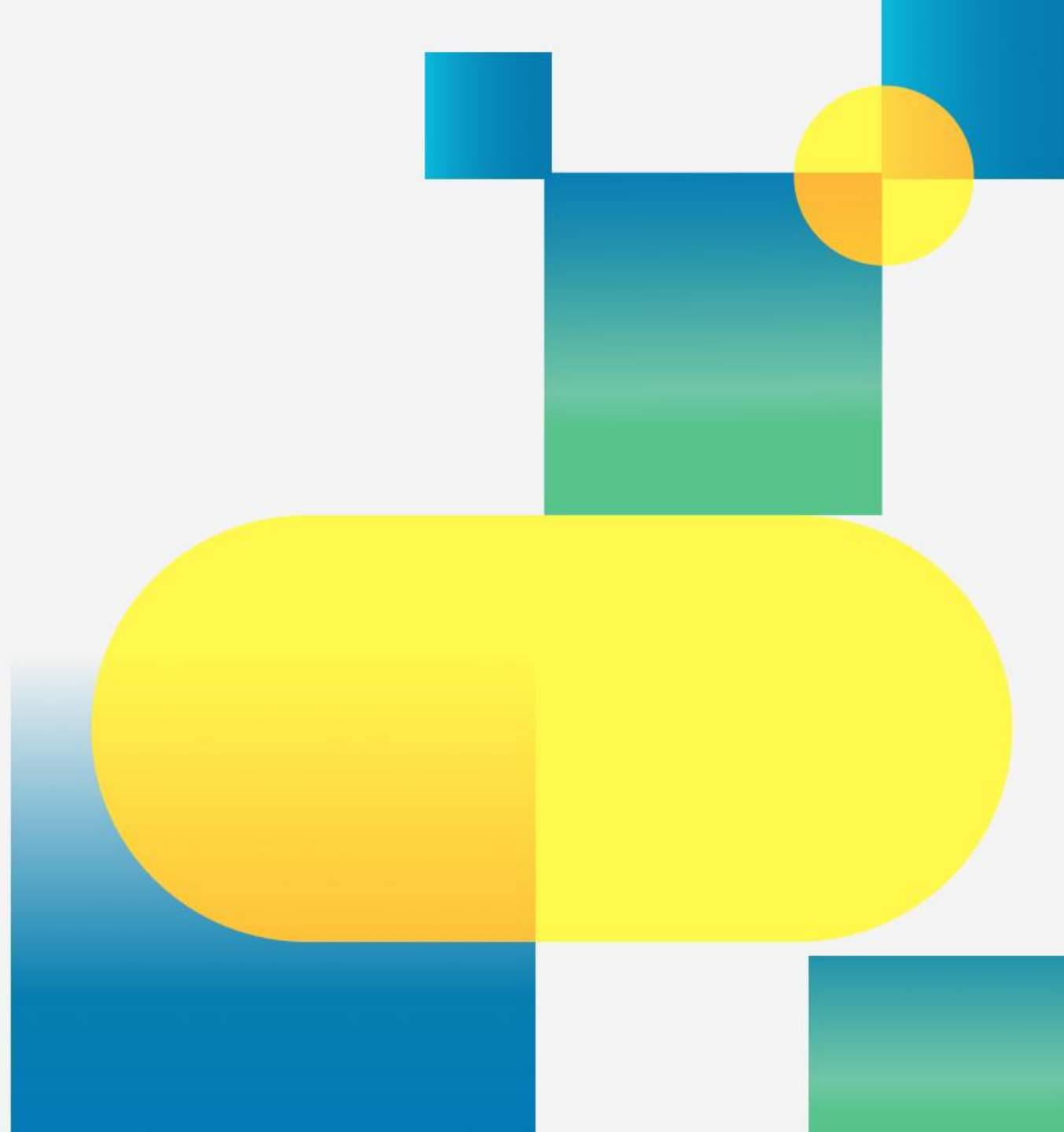


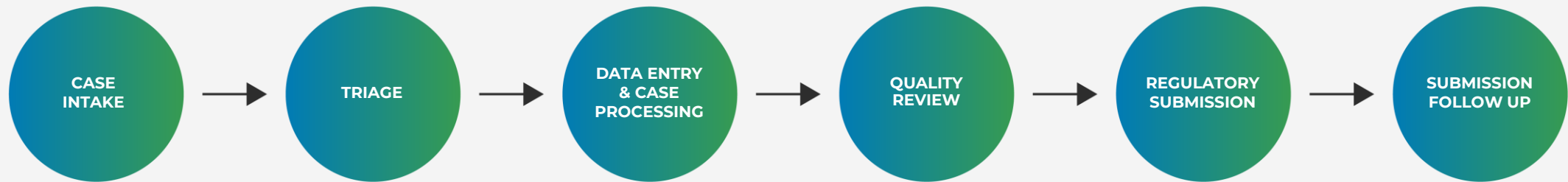


# Harmonizing Pharmacovigilance Translations: Ensuring Compliance and Quality with AI-Enhanced Solutions.

**A Regulatory and Quality  
Assurance Perspective**



# The Language Component in Case Processing



- Need for Reporting in English
- Different Traditional Approaches
- AI & professional teams to overcome the challenges the language element encompasses to guarantee you are:
  - Compliant
  - Fast
  - Cost efficient
  - Accurate
  - ( Working in a )  
secure environment





Historic  
approach to  
the translation  
of ICRSs



# Understanding the Complexity of ICSR Content

## Diverse Formats

- **Audio files and documents:** Including structured and unstructured forms.
- **Non-editable formats:** Images, handwritten text, etc.

## Challenges

- **Accuracy risks:** Especially with handwritten and non-editable content.
- **Rapid turnaround:** Typically required within 24 hours.

## Volume and Complexity

- Average of **300 words** per report.
- Information may be **unexpected** and vary widely in format.



# Navigating the Regulatory Landscape

## EMA Guidelines

- **Accurate Translations Required:** "The reports should include the verbatim text as used by the primary source or an accurate translation of it." (EMA's GVP, Module VI)
- **AI and Human Oversight:** "EMA encourages that any AI-generated content is overseen and audited by a human." (Reflection paper on AI in the medicinal product lifecycle, draft July 2023)

## Global Regulatory Bodies

- **FDA (U.S.):** Similar emphasis on accuracy and timeliness in pharmacovigilance translations.
- **MHRA (UK):** Enforces strict translation standards to ensure safety and compliance.
- **Other Regulatory Bodies:** Health Canada and Japan's PMDA follow comparable guidelines

## Influence on Processes

- **Impact:** These regulations drive the need for structured workflows that combine human expertise and AI to meet global compliance requirements.

## References

[https://www.ema.europa.eu/system/files/documents/regulatory-procedural-guideline/wc500232767\\_en.pdf](https://www.ema.europa.eu/system/files/documents/regulatory-procedural-guideline/wc500232767_en.pdf)

[https://www.ema.europa.eu/en/documents/scientific-guideline/draft-reflection-paper-use-artificial-intelligence-ai-medicinal-product-lifecycle\\_en.pdf](https://www.ema.europa.eu/en/documents/scientific-guideline/draft-reflection-paper-use-artificial-intelligence-ai-medicinal-product-lifecycle_en.pdf)

# PV Requirements from the Industry

## Costs

- Translation costs must be aligned with the volume of work in number of words translated.
- Necessity to avoid minimum fees and other extra surcharges.

## Turnaround Times

- 24 hours or less is the standard for this type of translation.
- Consistency in delivery times is also critical, since translations are just one step in the case process.

## Quality

- Reduces patient risks due to case misinterpretations.
- It also reduces the number of cases requiring follow up with authorities.

## Security

- Ensure all data is encrypted during transmission and storage to prevent unauthorized access.
- Implement robust access controls to restrict sensitive information to authorized personnel only.



# Pharmacovigilance Translations – Industry Approaches

## Who Performs Translations

- **LSOs:** Local safety officers handle initial translations.
- **Agencies:** Translation agencies or freelancers manage bulk work.
- **PV Service Companies:** CROs and specialized firms provide comprehensive translation services.

## Translation Methods

- Machine translation
- Translation by non-English PV specialist
- Translation by native English translator
- ISO 17100-Compliant Translation





# Modern Approach





## CASE STUDY

# Enhancing Compliance and Efficiency

### Challenge

- **24-Hour Turnaround:** Meeting deadlines without sacrificing quality.
- **Freeing LSO Time:** Easing the burden on LSOs in 90 countries
- **Cost Reduction:** Ensuring high-quality translations cost-effectively.

<https://www.welocalize.com/insights/case-study-pharmacovigilance-translations-on-a-global-scale/>

### Enhancement

- **Regulatory Compliance:** Adhered to global guidelines, leading to successful audits and consistent quality.
- **Cost-Benefit Analysis:** Showed reduced costs, improved efficiency, and maintained regulatory standards.

### Solution

- **Global Teams:** Translation hubs in Barcelona, China, Argentina.
- **Language Assets:** Glossaries, translation memories, MT engines.
- **Automation:** Streamlined workflows.
- **Pricing:** Consistent, transparent structures.





# Results

**30%**

in translation savings

## Cost avoidance

- More free time for LSOs
- Fewer local resources destined to these tasks.

**100%**

quality in more than 50 lang

Consistent short 24 hour and 6 hour TATs

Less follow ups



# The Hybrid approach: Technology with a human touch



## Automations

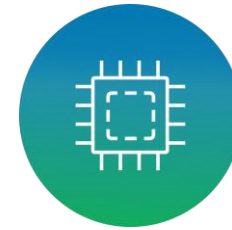
- Content Capture from CMS.
- Original Language Detection.
- Format Conversion to Editable Text.
- Task Assignment to Linguists.
- Delivery to Client's CMS.



## MT and TM

(Machine Translation and Translation Memories)

- Automated Translation of Repeated Phrases.
- Full Content Translation MT.
- Quality Enhancement with Trained Engines.

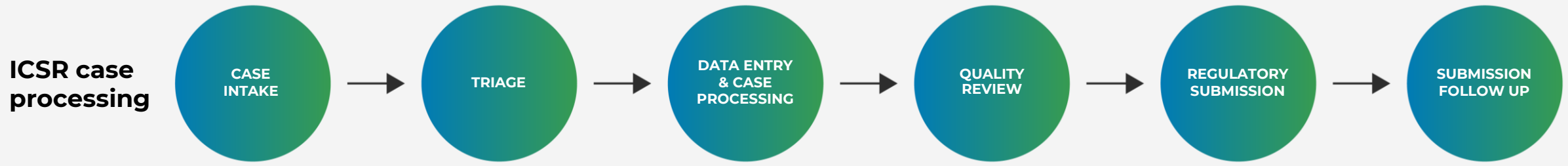


## AI

- Case Detection within Content.
- Machine Translation Quality Assurance.
- Automatic E2B File Generation from Translations.
- Automated Narrative Creation.



# Welocalize AI & Automations for ICSR Processing



## Welocalize solutions for every step

AUTOMATED CASE RECEIPT FROM CLIENT CMS	AUTOMATED REAL TIME TRANSLATION	AUTOMATED PHI REDACTION	HUMAN TRANSLATION INTO ENGLISH 24 HRS - ANY LANGUAGE	AUTOMATED E2B R3 FILE CREATION*	AUTOMATED NARRATIVE CREATION GEN AI*	AUTOMATED REAL TIME TRANSLATION OF AUTHORITY COMMUNICATIONS	TRANSLATION OF AUTHORITY RESPONSES, PSURs & DSURs
<ul style="list-style-type: none"> <li>• Robot/ Connector</li> <li>• Automatic reception of PV projects</li> <li>• Conversion into editable files</li> </ul>	<ul style="list-style-type: none"> <li>• MT translation</li> <li>• All languages</li> <li>• Content and audio files</li> </ul>	<ul style="list-style-type: none"> <li>• File's storage in a protected server workspace.</li> <li>• Automated personal information anonymization.</li> </ul>	<p>ISO certified human translation 2 linguists + QA</p>	<p>Automated creation of E2B files from translated AE documents.</p>	<ul style="list-style-type: none"> <li>• First version of the narrative following specific templates.</li> <li>• Information is taken from translated AEs documents</li> </ul>	<p>MT translation</p>	<p>ISO certified human translation by two linguists + QA</p>

# Ensuring Quality and Managing Risks



01

## Quality Metrics

- **Tracking Accuracy:** Measure quality using metrics like error rates and audit outcomes.
- **Compliance Checks:** Regular audits ensure adherence to regulatory standards.

03

## Computer System Validation

- **Validation Protocols:** Ensure all systems in the translation process are validated per industry standards (e.g., GAMP5).
- **System Integrity:** Regular testing to maintain data integrity and compliance.

02

## Risk Management

- **AI Oversight:** Mitigate risks with rigorous human oversight and review processes.
- **Regular Audits:** Frequent audits identify and address issues early.

04

## Enhancements

- **Continuous Improvement:** Use feedback loops to refine processes and enhance quality.
- **Proactive Adjustments:** Update workflows based on audit results and best practices to improve performance and mitigate risks.

# Safeguarding Data: Privacy and Security in Translations

01

## PHI Handling

- **GDPR Compliance:** PHI is protected under GDPR and global privacy regulations.
- **Data Anonymization:** PHI is anonymized to reduce risk.

02

## Security Measures

- **Encryption:** Advanced encryption secures data in transit and at rest.
- **Access Controls:** Strict controls ensure only authorized access.
- **Regular Audits:** Frequent audits to detect and address vulnerabilities.

03

## Enhancement

- **Certifications:** ISO/IEC 27001 & 27701 certification underscores our commitment to top-tier data security.
- **Continuous Monitoring:** Systems are continuously monitored for compliance and threat response.



# Impact of AI and language technologies on Pharmacovigilance

01

## Enhanced Safety and Compliance

- **Error Reduction:** AI minimizes translation errors, improving safety and compliance.
- **Regulatory Alignment:** Short turnaround times ensure that all content meets reporting requirements.

02

## Increased Efficiency

- **Cost-Effectiveness:** AI-driven processes reduce costs and speed up decision-making.
- **Optimized LSO Resources:** Local Safety Officers can focus on high-level tasks, enhancing overall productivity.

03

## Accessibility and Scalability

- **Broader Access:** Companies with fewer cases can benefit from established workflows and reduced costs.
- **Global Impact:** AI advancements protect patients and ensure the safe use of medications worldwide.

# Looking Ahead: Future Trends in Translation

## Regulatory Evolution

- **AI Act & ISO 42001:** Established standards for AI, focusing on transparency, accuracy, and oversight.
- **Future Focus:** Anticipate stricter rules on AI in data security and compliance.

## Industry Collaboration

- **Extended Role of Language Services:** LSPs will increasingly support more phases of case processing, partnering closely with PV service providers.
- **Best Practices:** Welocalize can lead initiatives on solid workflows, including security and risk management.

## Enhancement

- **Automation Growth:** Greater AI use for case detection, E2B files, and narratives.
- **Scalability:** These solutions will become accessible to companies of all sizes, increasing workloads.





Any  
Questions?





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Thank you!

