LANGUAGE SCIENTIFIC

Development Safety Update Reports (DSURs) Use Case

If You Don't Understand It, You Can't Translate It!

At a glance

Development Safety Update Reports (DSURs) provide critical safety data for investigational drugs in clinical trials, ensuring ongoing monitoring and regulatory compliance. Accurate translations are essential for submitting reports to global regulatory agencies, maintaining data integrity, and supporting pharmacovigilance efforts across multiple regions.

Key metrics

10,000+
Pages translated annually for global submissions

99.7%
On Time Delivery

100%
Regulatory Compliance

CHALLENGES ⌄

DSURs contain complex safety data, requiring precise translation to meet strict regulatory standards while maintaining consistency across multiple regions. Any inaccuracies or delays in translation can result in regulatory setbacks, increased scrutiny, or trial disruptions. Additionally, the highly structured nature of DSURs demands absolute precision to ensure that adverse events, risk assessments, and safety updates are accurately conveyed in every language.

SOLUTIONS ⌄

AI-optimized translation with expert human validation ensures DSURs meet regulatory, linguistic, and scientific accuracy standards.

Pharmacovigilance Experience

12 Step Quality Control Process

Scalable To Meet Your Needs

BENEFITS ⌄

1 | **Regulatory Compliance**
Ensures adherence to FDA, EMA, PMDA, and ICH E2F guidelines, preventing regulatory setbacks.

2 | **Data Integrity and Consistency**
Accurately conveys safety updates across multiple languages, minimizing discrepancies.

3 | **Operational Efficiency**
Streamlined translation workflows keep clinical trials on schedule and reduce administrative burdens.

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