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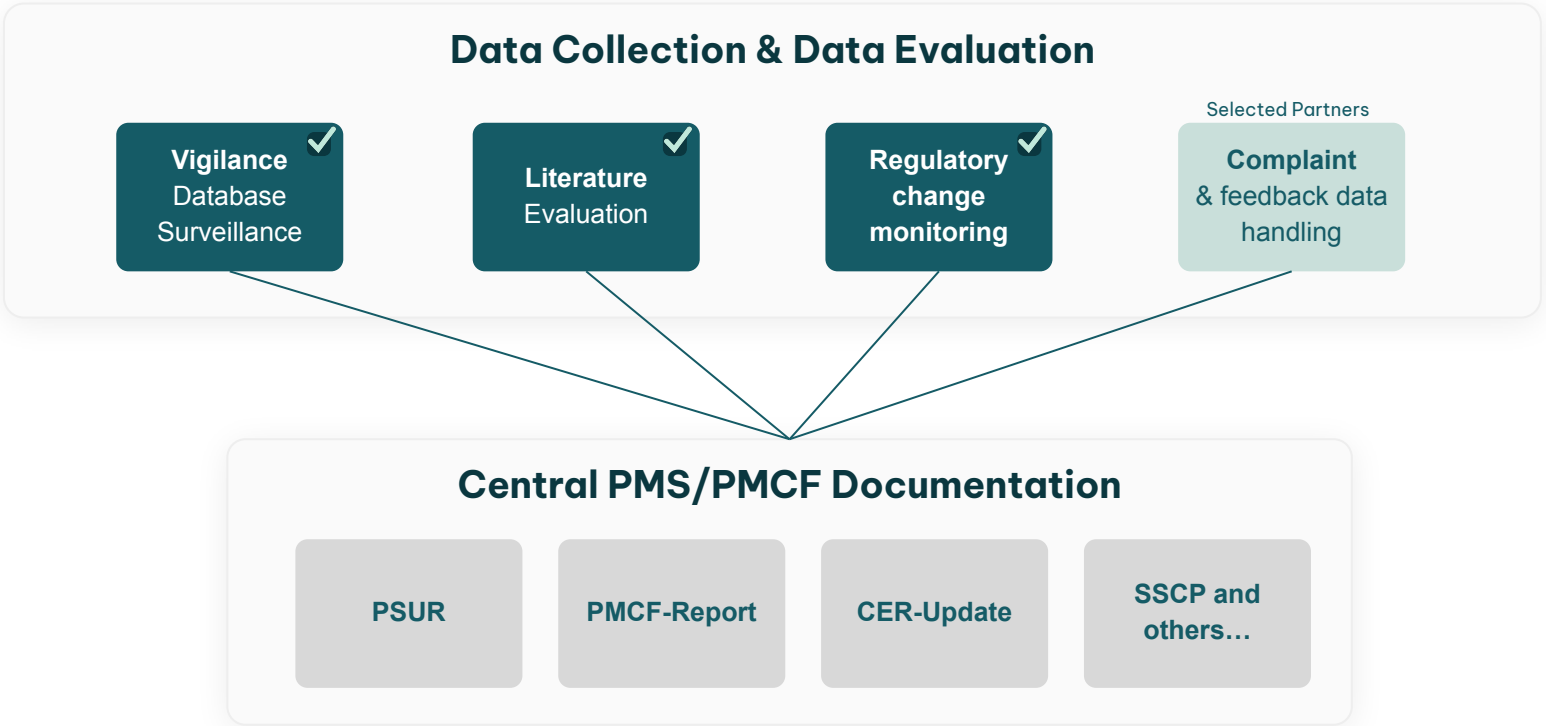
PMS Automation with AI:

Potentials and challenges in applying AI in MedTech

Flinn is the leading partner for AI in MedTech Compliance.

Flinn Areas of Activity



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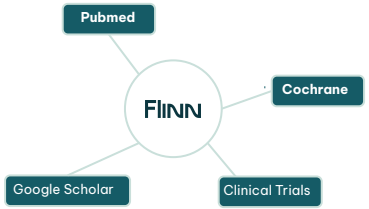
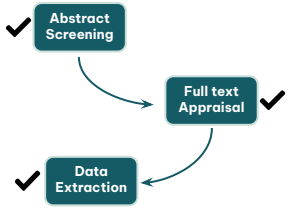
Literature Evaluation

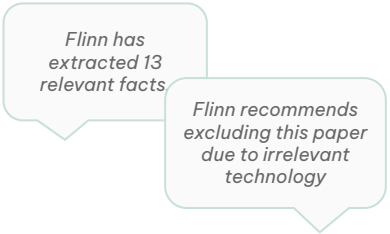
Literature Evaluation | Safety DBs | Complaint Handling | Risk Management | ...



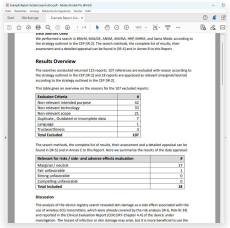
Automated Data Collection across multiple Databases



AI Recommendation for Exclusion & Inclusion (e.g., during Abstract Screening)



Automatic Organization of Full Text and Extraction of Key Data (e.g., Medical Device in Study)



One-Click Reporting (For CER, PSUR, PMCF...)

Increased efficiency & reduced errors in Literature Evaluation

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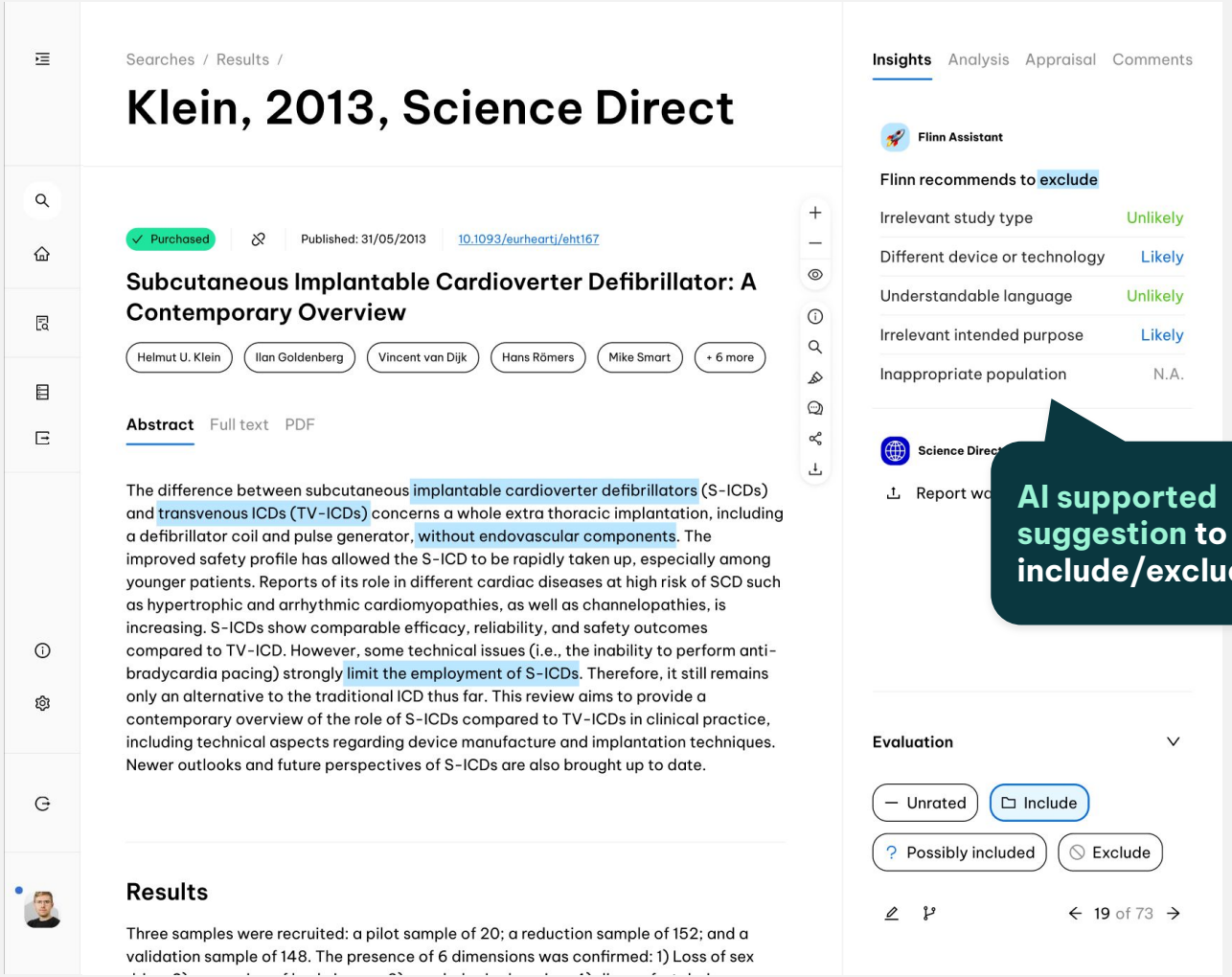
Opportunities of AI in Literature Evaluation

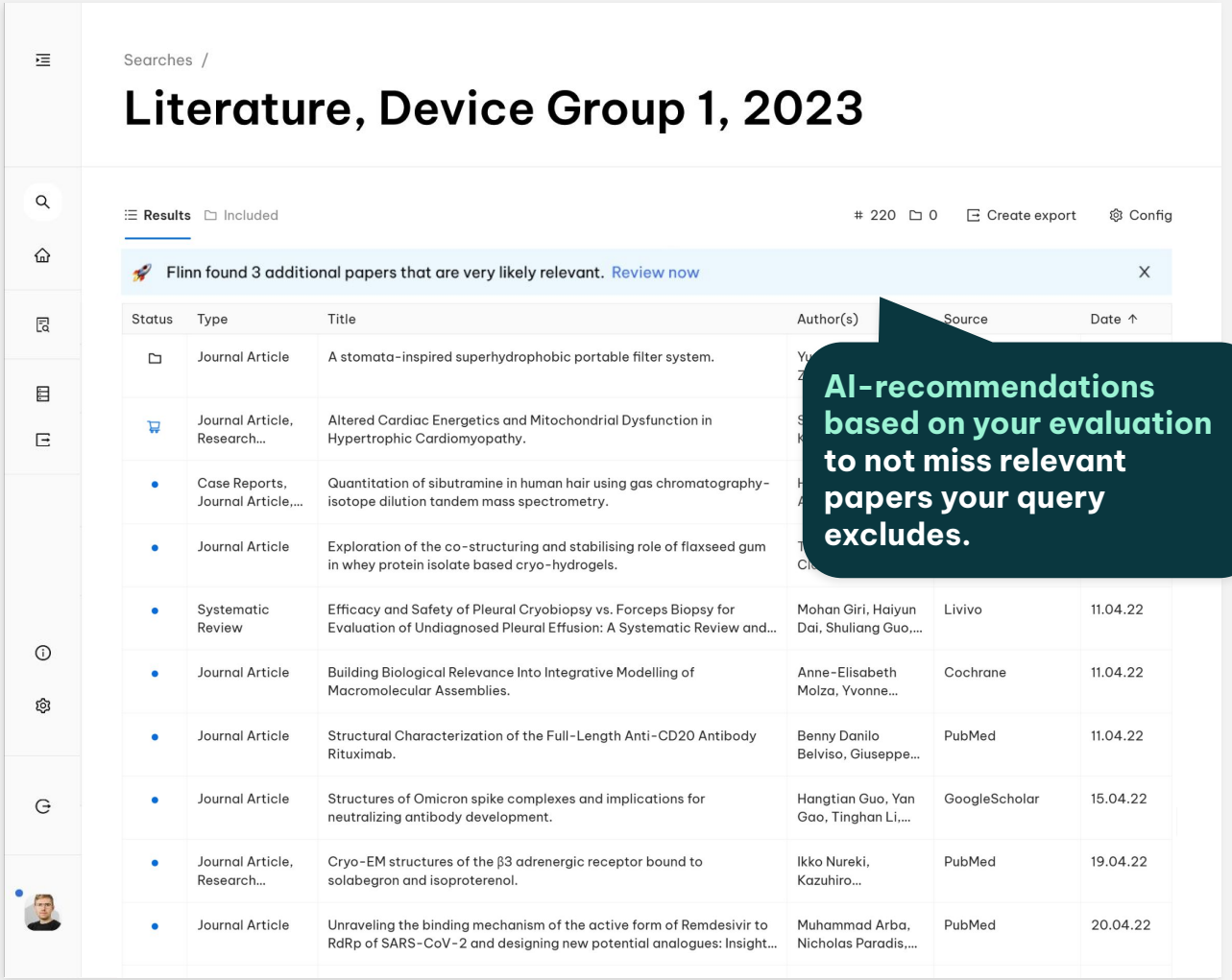
Example 1

Generate Efficiency



Example 2

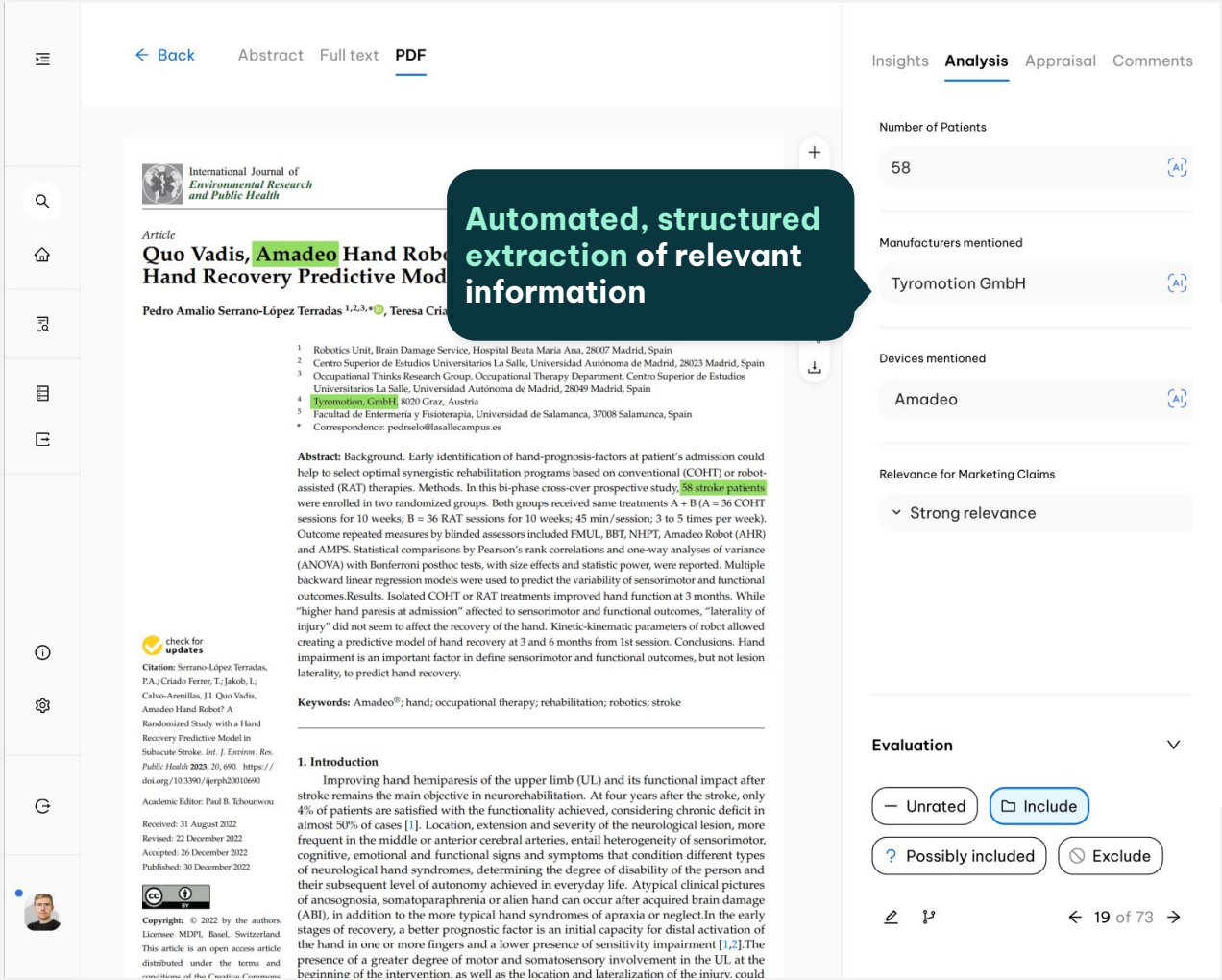
Increase Compliance & Avoid Non-Conformities



Example 3

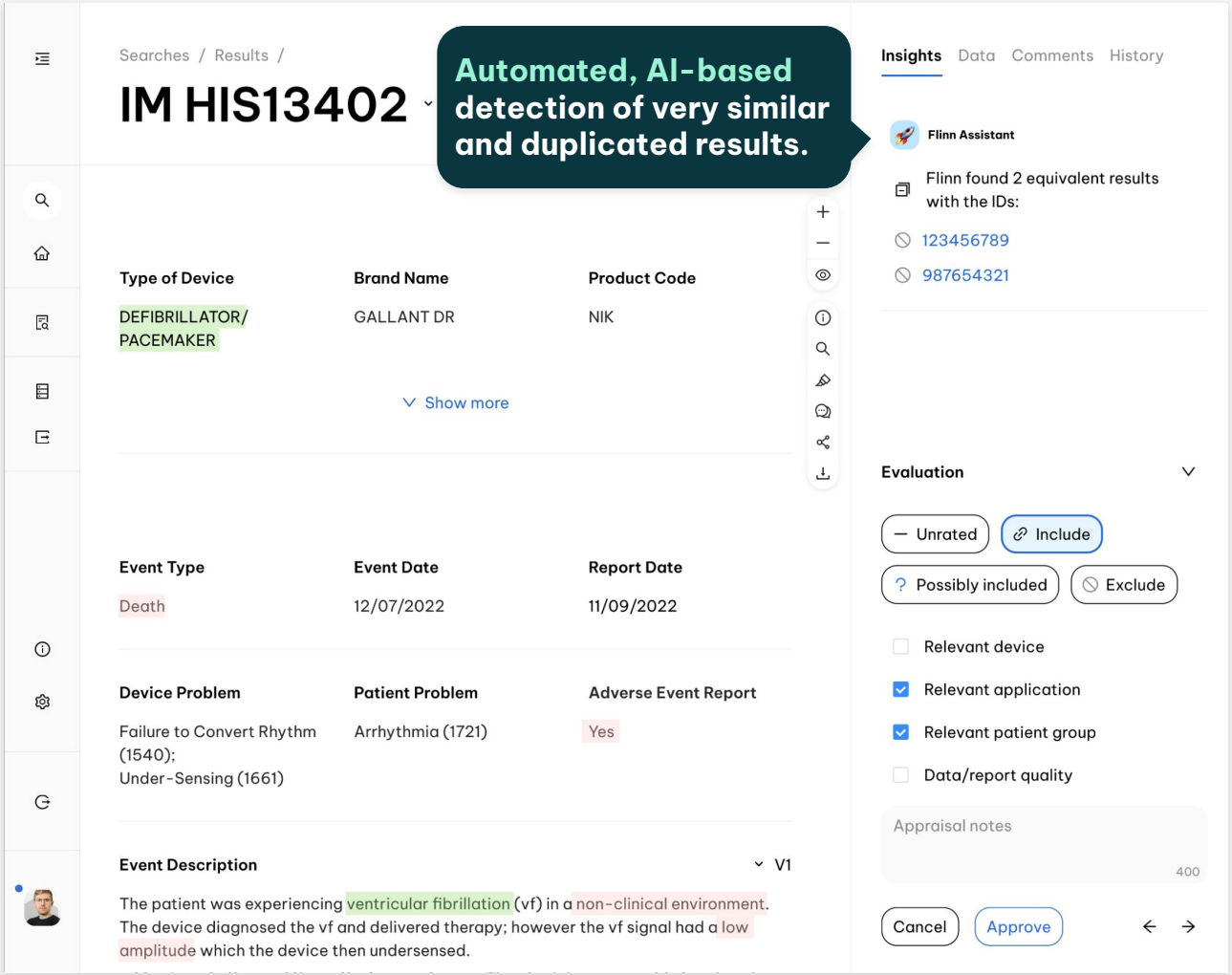
Convert Unstructured Data in Structured Data

Reduce Repetitive Tasks



Example 4

Increased Consistency



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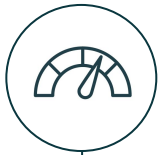
Challenges of AI in MedTech

Some challenges you should be aware of using AI in MedTech

Data Privacy

Ensure Confidentiality:

Select the right safety measures to prevent unauthorized sharing or exposure.



Model Performance & Hallucination

Achieve Model Reliability:

Use fine-tuned models for each specific use case instead of a standard model for all.

Validation

Choose Optimal Validation:

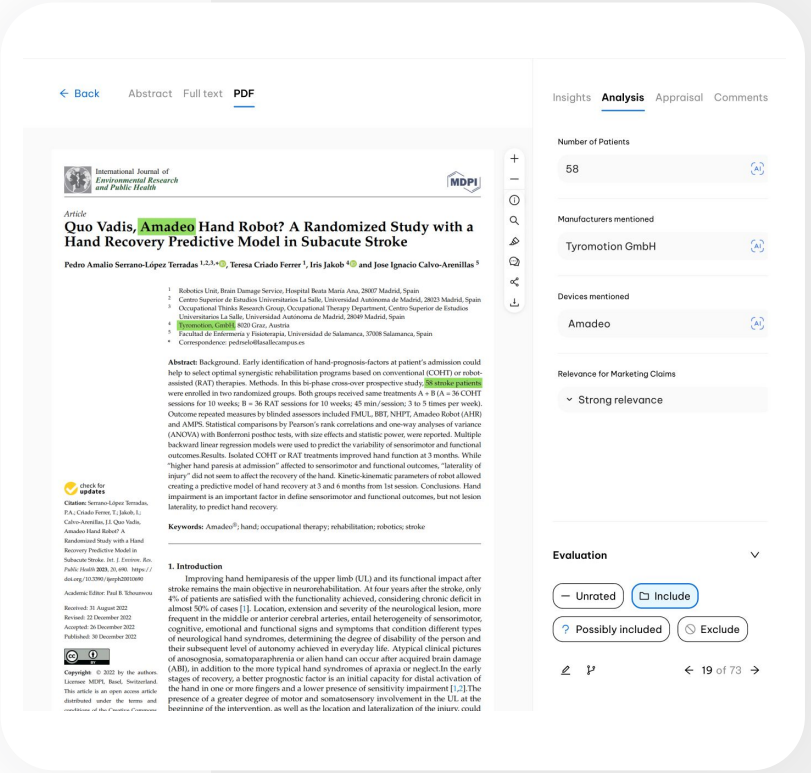
Select the approach that best fits each specific application to achieve reliable & compliant outcomes.

Validation of AI

Example 1 - Gold Standard Validation:

Extraction of specific Data (e.g., device used in study)

- There is a clear answer to the question, thus a 100% accurate test-set can be derived.
- A performance threshold is set for the validation, e.g., 99% accuracy.
- AI evaluated results are compared to the correct test set; only if there is a match it counts.



Validation of AI

Example 2 - Majority Vote Consensus Validation:

Categorizing a device problem according to IMDRF code

Very complex question, not one exact truth: Multiple codes may apply simultaneously, as there's no single "correct" answer.

The formulation of the validation threshold is different: e.g., the goal is for the model's classification accuracy to match the level of human experts.

Both the AI model and an expert user group classify the same dataset. An independent board reviews the results and makes a majority vote for each case, without knowing the source of each answer.

The validation succeeds if the AI model performs as accurately as the human expert group in the majority of cases.

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Handelsblatt

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