Enhancing Efficiency in Clinical Evaluation Reports (CERs) with Basil Systems

Case Study by Compliance Solutions Life Sciences with Basil Systems

2024

CS LIFESCIENCES
www.cslifesciences.com

Background

In the EU, obtaining approval for medical devices mandates a Clinical Evaluation Report (CER), a crucial step for securing the CE marking necessary for marketing these devices.

Challenges:

- The process is time-consuming and complex.
- Requires extensive analysis of clinical data.
- Gathering post-market surveillance and adverse event reports from databases such as FDA MAUDE, TGA Australia, and Health Canada is particularly challenging.

Significance:

- Summarizing clinical evidence is crucial to confirm the safety and effectiveness of medical devices.
- Companies face substantial challenges in ensuring compliance with these regulatory requirements.

Video: Click here to see the ease of comprehensive AE Comparison in Basil Systems

Challenges Industry Faces with Traditional Methods

- **Export Limitations:** Only 500 adverse events can be exported at a time, requiring repetitive searches.
- **Manual Filtering:** Significant manual effort needed to exclude duplicates and irrelevant entries, increasing the risk of errors.
- **Lack of Specific Filters:** No ability to filter by Global Medical Device Nomenclature (GMDN), complicating the search for specific device-related data.
- **Detailed Manual Analysis:** Each report requires a manual breakdown to identify specific issues related to devices and patients, which is labor-intensive.

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Case Study: CS Life Sciences

About Compliance Solutions (Life Sciences):

CS Lifesciences is a specialized consultancy dedicated to the medical device and in vitro diagnostics (IVD) industry. With extensive experience collaborating with regulatory bodies such as the MHRA, FDA, and Notified Bodies, they assist companies in navigating complex regulatory landscapes. Their expertise ensures that clients can efficiently and effectively bring their products to market while maintaining compliance with all necessary regulations.

Case Study Overview:

This case study focuses on comparing spinal devices classified under KWP, NKB, and OSH product codes. It involves analyzing over 35,497 adverse events in the MAUDE database, TGA Australia, and Health Canada, filtering, and comparing against specific competitive devices using predetermined search words. The aim is to illustrate the complexity of the traditional method and highlight the need for more efficient approaches.

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Challenges of Traditional CER Processes

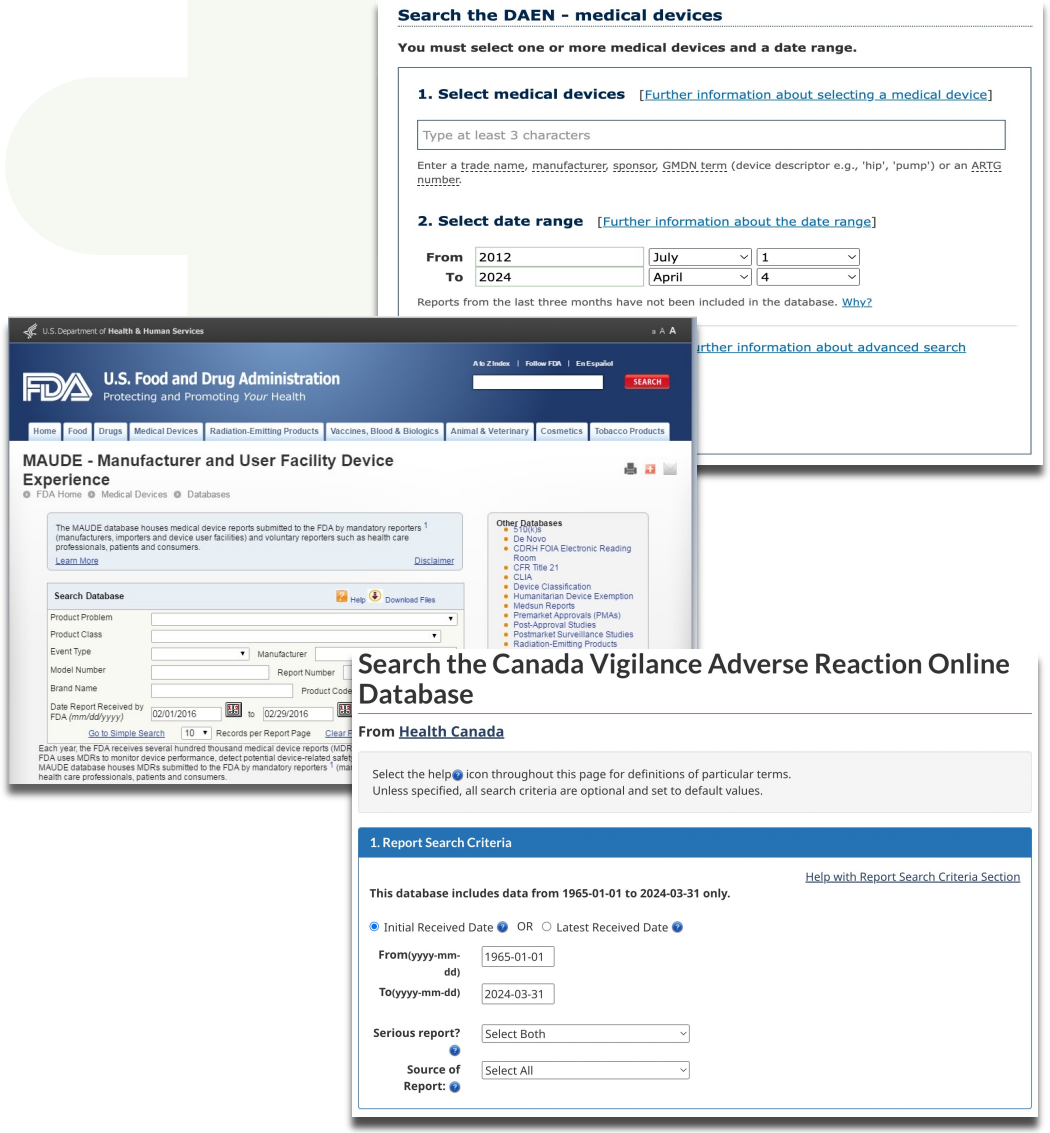
Multiple Steps Involved:

- Conducting numerous searches due to export limitations.
- Manually filtering out irrelevant data and duplicates.
- Integrating data from various sources, all of which require significant manual input and time.

Time-Intensive:

- Weeks worth of effort focused on gathering and filtering data before even writing report.

All while having a high potential for human error and data duplication.



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Solution with Basil Systems

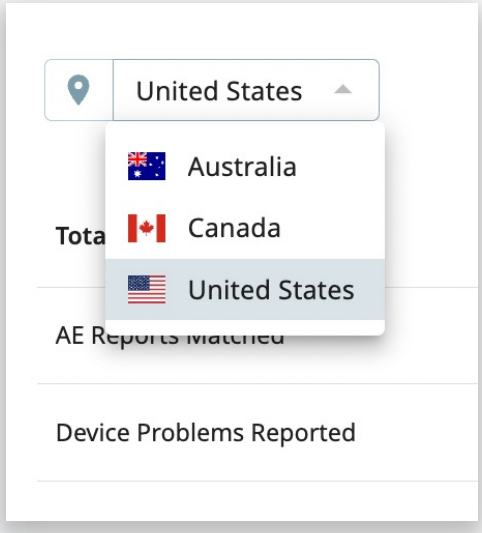
Discover how CS Life Sciences revolutionized adverse events analysis within their Clinical Evaluation Report process, achieving a 93% time reduction and enhanced accuracy through the implementation of Basil Systems' advanced AI tools

No Export Limits: Unlimited exports of adverse events with all available information, minimizing the need for multiple searches. ***See which fields Basil exports that MAUDE cannot.***

Automated Filtering: Built-in filters automatically exclude irrelevant devices and events, reducing manual labor.

Efficient Data Analysis: Facilitates straightforward export of datasets and tables, which are directly usable in the CER.

Enhanced Accuracy: Automation minimizes human error, ensuring accurate data capture and analysis.



The New Process with Basil Systems

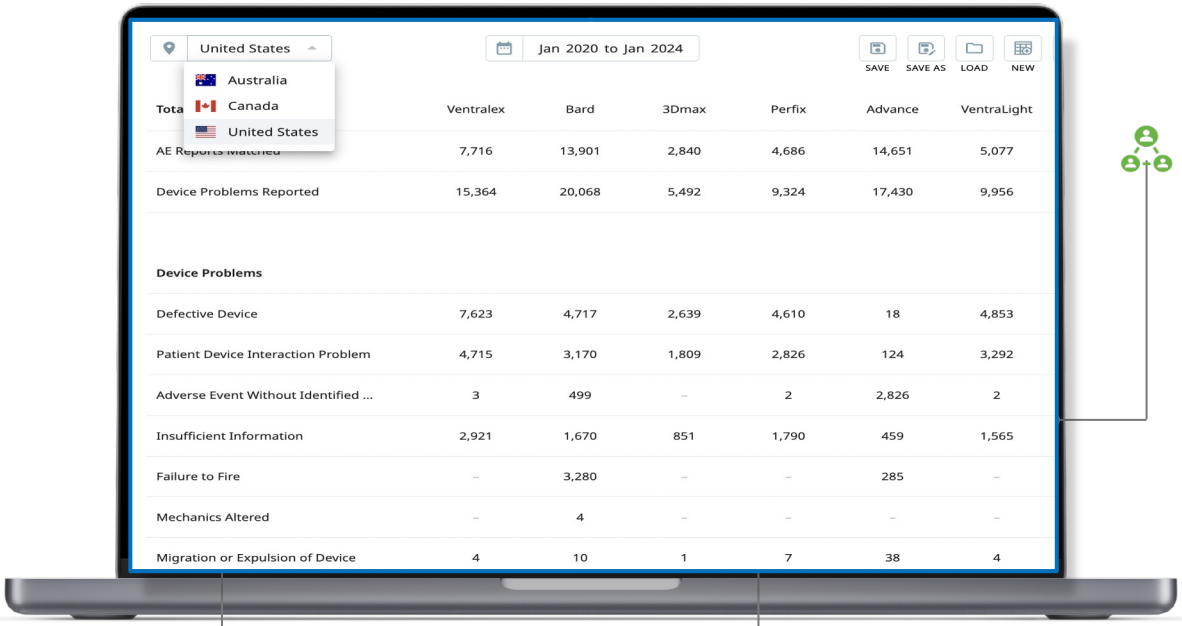
What are the Steps?

- Simply enter the brands you want to compare into the table column headers
- Columns will automatically populate adverse events broken down by device problem
- Add your filters: Product codes, GMDN Codes, etc..
- Pick your view: Device problems, patient problems, event type.
- Select your geography: FDA, TGA, and Health Canada
- Export an already filtered & formatted adverse event comparison table

Save & reload with an updated time frame for your next PSUR

Get to know Basil System's Adverse Event Comparison Table Creator

Adverse Event Comparison Table Creator



	Ventralex	Bard	3Dmax	Perfix	Advance	VentraLight
AE Reports Matched	7,716	13,901	2,840	4,686	14,651	5,077
Device Problems Reported	15,364	20,068	5,492	9,324	17,430	9,956
Device Problems						
Defective Device	7,623	4,717	2,639	4,610	18	4,853
Patient Device Interaction Problem	4,715	3,170	1,809	2,826	124	3,292
Adverse Event Without Identified ...	3	499	–	2	2,826	2
Insufficient Information	2,921	1,670	851	1,790	459	1,565
Failure to Fire	–	3,280	–	–	285	–
Mechanics Altered	–	4	–	–	–	–
Migration or Expulsion of Device	4	10	1	7	38	4

Save all of your created adverse event tables. Next PSUR cycle, reload and update the date.

Easily filter between comparing patient problems, device problems, or event types. Then view across FDA, TGA, or Health Canada.

Export all individual adverse events or the pre-formatted table, including metadata, categorized by device problems. Handles multiple device issues per adverse event.

Video: See how to create an Adverse Event Comparison Table

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What benefits did CS Life Sciences Experience?

Time Savings:

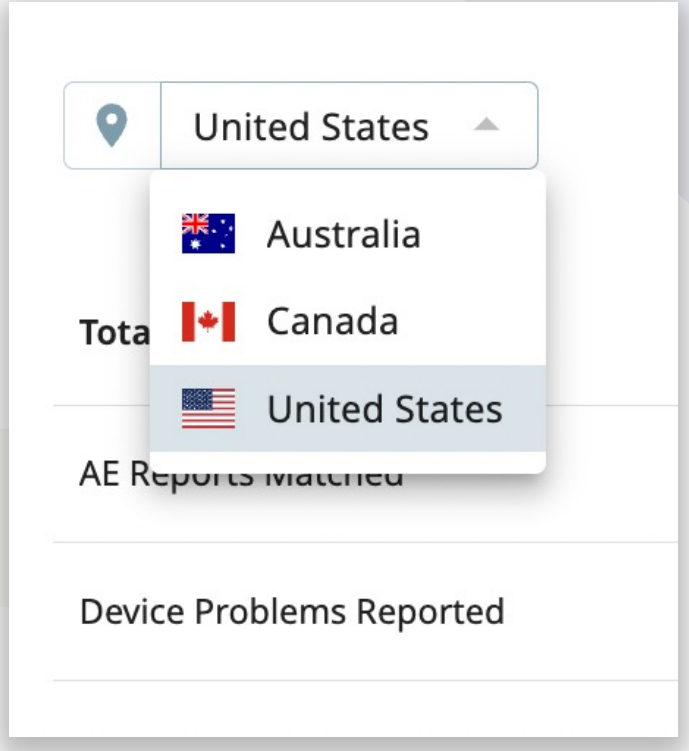
- Over ***93% reduction in time*** compared to the traditional method.
- Manual work reduced from ***21.5 hours to 1.5*** hours per report.

Reduction in Steps:

- Simplified workflow with fewer operational steps, reducing the potential for errors.

Improved Accuracy:

- Automation minimizes human error, ensuring reliable data.



Download a comprehensive workflow comparison between the Traditional CER process and the process with Basil Systems

Case Study by Compliance Solutions Life Sciences

Side by Side Comparison of Efforts

The Traditional Way

~ 21.5 hours

36 Individual Searches

Each MAUDE Search & Export Limited to 500 Hits

No Option to Filter by GMDN in MAUDE

Time-Consuming Manual Filtering to Exclude Duplicates, Irrelevant Devices & Irrelevant Events

Manual Analysis of Reports

MAUDE Outputs Composite Patient Problems & Device Problems: Time-Consuming Manual Breakdown Required to Obtain Counts of Individual Problems

The Basil Way

1.5 hours

8 Searches

Exclusion of Irrelevant Devices through Built-in Filters

Exclusion of Irrelevant Events through Search Terms

No Duplicates

Easy Export of Final Datasets and Tables for Analysis

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Outcome and Impact

Enhanced Productivity:

Significant reduction in time and effort allows staff to focus on more strategic tasks, such as deeper data analysis and interpretation.

Improved reliability:

Automation features minimize human error, ensuring accurate capture and analysis of adverse event data.

Streamlined Process:

Simplified workflow expedites report generation and minimizes delays accelerating time to market.

Increased Competitiveness:

Faster and more reliable CER preparation provides a competitive edge & faster response to market needs.

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Other Measured Advantages

Time Efficiency: Approximately 20 hours saved per report.

Reduction in Manual Labor: Extensive manual effort required in the traditional process is drastically reduced.

Process Simplification: 78% reduction in procedural complexity increasing consistency and reliability of data.

Increased Data Handling Capacity: No export limits ensure comprehensive and in-depth clinical evidence compilation.

Cost Savings: Efficiency gains allow for budget and resource reallocation to other critical areas, optimizing overall operational costs.

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Transformative efficiency gains with Basil Systems

"Basil Systems revolutionized the regulatory process for CS Lifesciences. By streamlining a critical hurdle within the creation of Clinical Evaluation Reports (CERs), they dramatically cut down on time and resources. The advanced, automated data handling and seamless data generation from FDA, TGA, and Health Canada databases ensured reliable accuracy and compliance. We saw impressive efficiency gains, resulting in faster, more straightforward product approvals, elevating our consulting services to a whole new level."

- Flora Shewan

Lead Consultant (Clinical Regulatory)

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Sample Customers

Some of the Companies Leveraging Basil Systems

Don’t be left behind!

Let’s add your logo here to join the growing number of leading MedTech companies that trust Basil Systems to accelerate and simplify their regulatory intelligence and post-market insights.

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Johnson & Johnson

IQVIA™

Boston Scientific

BAYER

Hogan Lovells

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