



Enhanced efficiency of regulatory submissions for a Medtech company

Navigate the Medtech regulatory landscape and efficiently drive strategic decisions.

Customer

Global Medtech company

Challenge

A mid-size global Medtech company specializing in innovative diagnostics, targeted therapeutics, and artificial intelligence solutions for healthcare

providers, needed to streamline its regulatory workflows and gain quicker access to key insights. The company is dedicated to improving patient outcomes and quality of life by empowering clinicians to better identify, combat, and track diseases.

Understanding the importance of complying with regulatory standards, the company is

committed to ensuring that all its products adhere to the highest standards of safety, efficacy, and quality. To achieve this, they work closely with regulators and industry partners to stay up to date with the latest guidelines and regulations in each market they operate.

Historically, their regulatory team would manually

search and track regulatory changes in different geographical regions. With minimal access to helpful tools, their mostly manual research process proved time consuming and cumbersome. This resulted in ever increasing workload, uninformed regulatory decisions and filing delays.

Need of the customer

The regulatory professionals, including the regulatory affairs manager responsible for the regulatory strategy of new medical devices in a target market and the global pharmacovigilance manager responsible for coordination and reporting of domestic and foreign, serious and non-serious, adverse incidents involving the use of medical devices, required an intelligence solution to:

- Access both original documents and the understandable information on the pharmacovigilance related requirements for the regions of interest.
- Efficiently monitor regulatory changes.
- Compare specific requirements across different countries within their regions.
- Search for and clarify necessary information.

Solution

Our regulatory consultants provided the data, intelligence and expertise required to resolve the primary roadblocks and improve the efficiency of regulatory submissions.

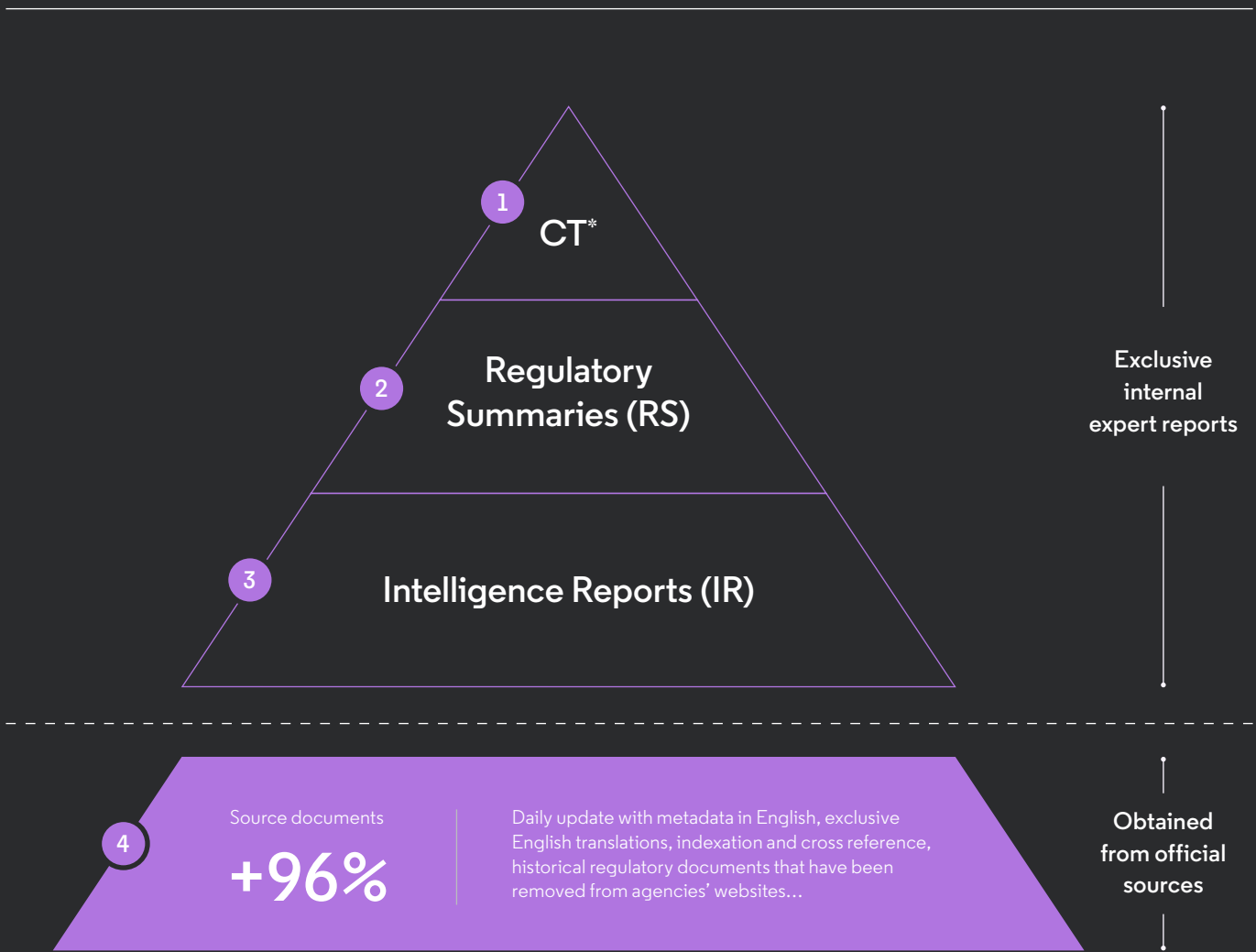
The Clarivate™ team comprised of professional customer support, multilingual subject matter experts, local consultants, and regulatory

consulting services ensured unmatched support to the company.

The team, fluent in over 20 languages and holding Master's Degrees or higher, had expertise in various areas, including Biochemistry, Chemistry, Clinical Research, CMC, Market Access, Medical Services, Pharmacology, Pharmacy, Pharmacovigilance, Pricing, QA, Regulatory, and Reimbursement.



Figure 1: Data and solution.



- 1 Compare the key requirements across countries and regions — all linking back to Regulatory Summaries and source documents. (18 tables)
- 2 Structured reports covering all topics along the product life cycle to help you navigate through local regulatory practices. (275)

- 3 In-depth analyses providing critical insights on one topic within one or across different territories/organizations. (700)
- 4 Official documents give you a complete history of the regulatory landscape, giving you additional insights and more added-value for your research. (63K+)

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* Comparison table

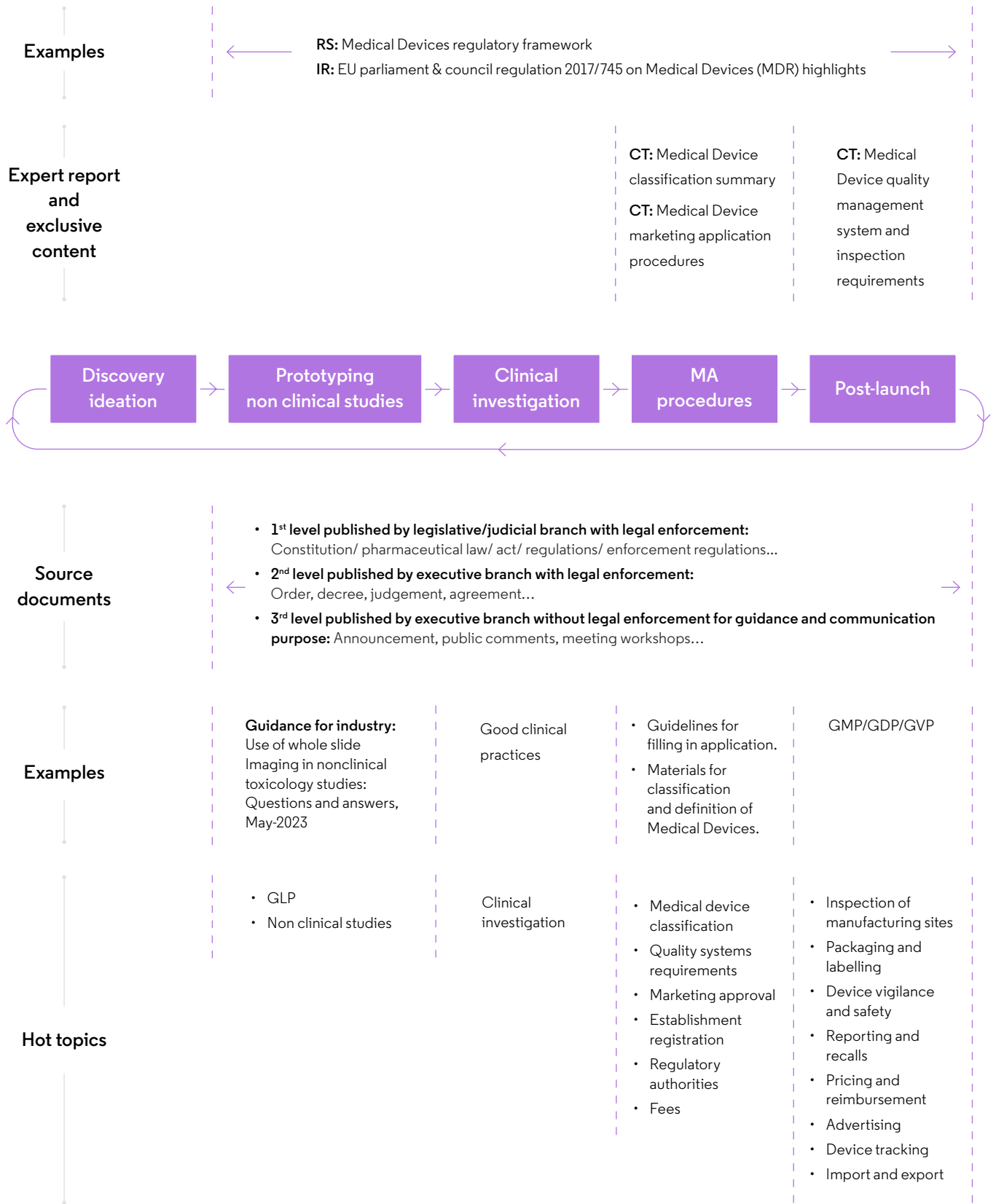
Table 1: Insights example 1.

How CRI helped the Regulatory Affairs Manager in each case below	CRI solutions
Compare the labelling and application procedures requirements across the regions .	Use comparison table Medical Device Labeling Requirements to compare the requirements. This table covers answers of 8 questions, and using the country / region filter, you can filter the information for required regions easily.
What is the overall process for registration/ clearance/ certification in the U.S. ?	For local regulatory practices, refer to country based regulatory summary Medical Devices Regulatory Framework (U.S.) . You can also refer to the section 7 for device approval / clearance / certification / conformity assessment / other mechanisms .
Explore the relevant Japanese combination product guidelines translated in English.	Use title or reference of specific guidelines and get this specific report with search and filters. English metadata is provided for all documents in local languages and for high profile of reports, CRI provides full expert translations.
Learn from regulatory precedence of Medical Devices in the EU .	Refer to intelligence report EU Parliament and Council Regulation 2017/745 on Medical Devices (MDR) highlights .

Table 2: Insights example 2.

How CRI helped the global pharmacovigilance manager	CRI solutions
Compare the post-marketing pharmacovigilance reporting requirements across the LATAM region.	Refer to comparison table Medical Device post-marketing procedures by filtering country/ region with LATAM countries.
How should expedited reports be submitted in Mexico .	Refer to the question, How should expedited reports associated to MDs be submitted (paper / electronic / webportal, etc.)? in comparison table Medical Device adverse incident reporting requirements by filtering country/region with Mexico.
Understand the PV obligations for compassionate use in Brazil .	Refer to section Device Vigilance and Recalls in regulatory summary Medical Devices regulatory framework . If more details are needed, click on the link pointing to source document: Resolution RDC 608: On the compassionate use of Medical Devices from this regulatory summary.
Set up alert notification .	Easily set up a personalized alert based on your areas of interest.
Ask the expert .	Gain quick access to get support from our content specialists.

Figure 2: Supporting your needs across the full lifecycle of device development.



RS: Regulatory summaries IR: Intelligence report CT: Comparison table

Outcome

Unburdening the regulatory team of cumbersome and manual aspects of their job significantly improved their ability to quickly reach key insights ultimately allowing the company to expedite the delivery of treatments and therapies to patients.

Notable improvements included:



The ability to effectively stay on top of the regulatory changes and guidelines and reach key insights more quickly.



Reduced the time to find current regulatory information from days to just a few minutes.



Empowered to make informed decisions, enabling the company to optimise a **proactive** regulatory strategy, driven by accurate and comprehensive regulatory insights.



Enhanced efficiency in submitting product applications to regulatory authorities.



Reduced time to market approval and improved success rates.

Improved their ability
to expedite the delivery
of treatments and
therapies to patients.



About Clarivate

Clarivate is a leading global information services provider. We connect people and organizations to intelligence they can trust to transform their perspective, their work and our world. Our subscription and technology-based solutions are coupled with deep domain expertise and cover the areas of Academia & Government, Life Sciences & Healthcare and Intellectual Property. For more information, please visit clarivate.com.

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