CASE STUDY

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# Inside One Pharma Org's Successful Pharmacovigilance Literature Monitoring Process

Literature review is a core component of pharmacovigilance — but growing data sources and regulatory requirements can make the process a daunting task.

Here's a look inside one global pharmaceutical company's quest to improve their literature monitoring process — and the results they've seen since implementing RightFind®, CCC's content workflow solution.

## THE STATE OF PHARMACOVIGILANCE TODAY

Adverse events are reported in several different ways: from spontaneous reports by physicians, patients and manufacturers, to clinical trial data, regulatory reports, hospital records, scientific literature and more. The data sources that provide this type of information are expanding rapidly — and with 2.5 million articles being published a year (and growing), more information is available than ever before.

In addition to contending with more information, organizations must comply with frequently changing regulations, all of which vary across the globe.

The FDA received over 1.8 million adverse event and medication error reports associated with the use of drug or biologic products in 2017[1] — a 400% increase from ten years earlier. It's easy to see why many pharmacovigilance teams are struggling to manage this process effectively.

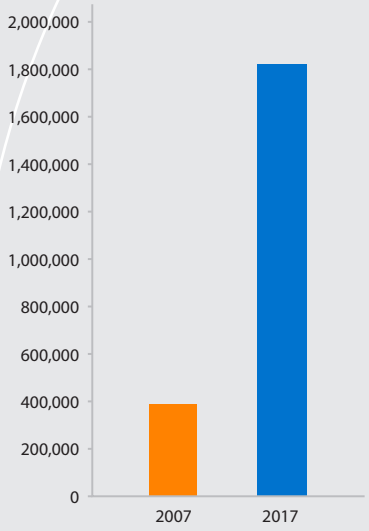
## INSIDE ONE PHARMA ORGANIZATION'S STORY

When a new head of information and knowledge management came on board at a leading global pharmaceutical organization, one of her first tasks was to assess how safety searches were being done in accordance with various regulatory bodies.

While she knew the information center was a key player in the pharmacovigilance search process, she quickly realized the information center and the pharmacovigilance department needed to act as a joint force in this initiative — and at the time, the two divisions were siloed.

"Pharmacovigilance teams are the experts in drug safety," she said. "We are the experts in documents and creating robust searches. We needed to work together to play to our strengths."

**ADVERSE EVENT AND MEDICATION ERROR REPORTS ASSOCIATED WITH THE USE OF DRUG OR BIOLOGIC PRODUCTS**

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Once the teams were meeting regularly to determine a plan, it was time to begin looking for a tool to more efficient and effectively monitor literature. Here were some of their requirements:

- An automated literature search process that would store and archive literature search results electronically.
- Simplified access to articles cited from search queries.
- A familiar and easily navigable interface.
- Minimal duplication of search results.
- Search results that would be automatically accessible for all members of the drug safety team.
- An established process to determine what had been reviewed by a safety team.
- A manageable audit trail.

## THE SOLUTION

The organization decided to implement CCC's RightFind, which allows for one, cloud-based library space for colleagues to monitor, review and automate the literature review process.

Utilizing RightFind was appealing because it was already engrained into the organization's daily information workflow. What they hadn't realized was how RightFind could be customized to fit the needs of pharmacovigilance tasks.

"We chose RightFind as our tool for managing literature, because everybody here is familiar with the process of ordering articles through RightFind," the head of information management explained. "They're used to the look and feel of RightFind and use the personal library feature within it very heavily."

Here's what the organization's literature monitoring workflow looks like today:

- Searches of the following four databases are run in ProQuest: Embase, Medline, International Pharmaceutical Abstracts, and BIOSIS.
- Searches are translated by Embase and automatically sent to RightFind.
- RightFind gathers and delivers the search results to each designated team member's mailbox. This weekly email provides links to abstracts and purchasing information for each of the search results.
- Once a user is inside RightFind's shared library, they can annotate each record and mark the review status, thus creating an audit trail.

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## MOVING FORWARD

Now ten months into the RightFind literature review process, both the information center and the pharmacovigilance departments are "delighted" by the ease of use. They admitted the work to coordinate the two databases was extensive, but it has made the pharmacovigilance review process more efficient and ensures all records are being reviewed.

"We'd recommend trying a soft launch before you convert your entire pharmacovigilance franchise," the head of information management said. "It's a great way to learn what to do better before you put it out there to the public."

## WHAT'S IN STORE FOR THE FUTURE?

"We are continuing to add new features in RightFind in frequent collaboration with our pharmacovigilance counterparts and CCC," she said. Monthly meetings have been set up with the pharmacovigilance teams for status updates, and to see if any additional items needed to be added to search.

## USING RIGHTFIND FOR PHARMACOVIGILANCE PURPOSES

RightFind®, the cloud-based content workflow solution from Copyright Clearance Center and its subsidiar y RightsDirect, provides pharmacovigilance teams a shared library space for colleagues to monitor, review and automate the literature review process. Users can rapidly identify adverse events, get quick access to content, and satisfy regulatory requirements.

[1] https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm070093.htm

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Copyright Clearance Center

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Learn more about RightFind for pharmacovigilance purposes.

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