TATA ELXSI

DEMONSTRATION

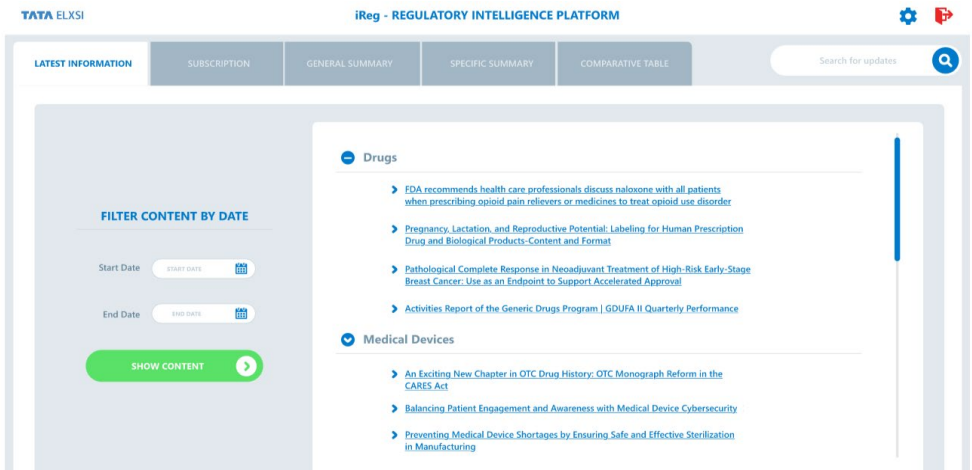
iREG: REGULATORY INTELLIGENCE PLATFORM

Demo Description

- Local, regional, and global Health authority updates report: weekly, monthly, ad-hoc from US FDA, EMEA, PMDA, Health Canada
- Tracking regulatory updates for drugs and medical devices
- Ready-to-use information on country-specific and regional compliance requirements
- Guideline line search and quick referencing when creating regulatory & safety submissions
- Search strings/ keywords to track specific events
- Insights on drug-drug interactions for monitoring compounds compared to competitor products, indications of interest, and therapeutic class

Scope

- Synthesis of regulations, guideline documents for developing timely strategies complying with regulations, guidelines, and policies
- Rule-based automated update alerts and notifications for competitor labels/ indications of interest
- Meticulous and regular monitoring of adverse event reporting and safety label changes on government-owned or sponsored websites across the globe



BENEFITS

- Auto-crawling reduces manual searching and monitoring efforts by 90%
- Assimilation of data in one single repository reduces information distribution cost by more than 70%
- Real-time information availability ensure speed of process that impact time to market by more than 20%
- Reduced localization expense can save OpEx cost by 40%
- Commercial models configured for subscription-based, demand-based, and functional service outsourcing