



PSURs / SABR / Educational Materials / Aggregate Reports

Managing Safety is an ongoing task of distributing safety information on a periodic basis to affiliates, distributors and other third parties responsible for safety reporting to NCAs, and tracking the registration / agency interactions. CARA facilitates the entire process.



DISTRIBUTION

Trigger workflows for distribution of safety data and documents to affiliates and distributors – manually, or automated via an API call from an external system.



DOCUMENTATION

Manage the creation, review and approval internally of PSURs, SABR Signals, Educational Tools, Aggregate reports and more.



PORTAL ACCESS

Distributors, affiliates and other third parties can access CARA via a simple portal to acknowledge, submit and confirm required actions with Agencies.



TRACKING

Central regulatory affairs has a real-time view per-product and per-country of the status of safety document receipt, submission and registration.

CARA for Safety Distribution – Example workflow



Complex Safety Workflow

- There are multiple documents (e.g. PSURs, Educational Tools, SABR Signals, etc) that are required to be distributed to Affiliates and Distributors for registration and process in their local markets
- Traditionally those tools involve external systems for sharing content AND some separate system for registering and reporting on submission status
- This can all be done through CARA, with Affiliates / Distributors logging in to a simple UI to perform their tasks
- Define complex workflows in CARA based on process rather than documents
- Distribute documents to Affiliates Distributors including Setting Service Level Agreements for each step of the process
- Defining default participants per country / product combination
- Allow Affiliates to login to a simplified CARA Portal and see / process just their workflows, including visibility of the associated documents
- Allow for automated notifications on each step, including overdue notifications and escalations
- All actions added to the dashboard so central Regulatory has a real time view of the status of each activity country product

Enterprise Central Source of Truth

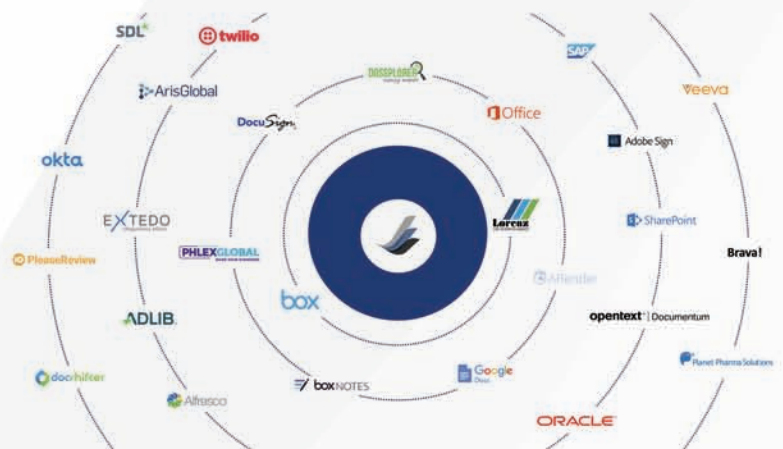
CARA is designed to serve as a seamless platform for all regulatory application requirements. However, we realise that there are other applications and many tools that your business relies on.

The concept of a central source of truth is to create a single place to access all that content and data regardless of where it is stored and managed.

While a particular business group may use a particular tool for their niche process, that content and data is available in CARA to be tracked, managed and re-used across your business.

CARA Benefits

- **Maximise the user experience**
simple to learn and use and personalised to each individual's requirements
- **Access and manage content from one place**
a single destination user interface, integrated seamlessly with multiple systems
- **Meet corporate and regulatory standards**
configure CARA to suit your exact requirements
- **Supports the full document lifecycle**
from creation to access, search, review, approval and publication
- **Automate manual processes**
with CARA workflows
- **Easily navigate and search content**
CARA provides multiple ways to access the information you need
- **Securely access content on the go**
our mobile apps give you the full CARA experience
- **Securely share information with external partners**
secure third-party access, watermarking and more



- Search & Report Across the Enterprise
- Prevent Content, Information, and Effort Duplication
- Provide a Central Authority