

SDEA and PV Contract Management

It is a legally mandated obligation for each pharmaceutical company to track pharmacovigilance agreements and contracts relating to pharmaceutical products and the exchange of Adverse Events.

Rather than being a requirement that can be met by a stand-alone contracts management system, this requirement is more complex. CARA allows for the interaction of these contracts with the Pharmacovigilance domain, ensuring consistency and accuracy of data, and reducing manual input and tracking.

Features

Creation

- Create contracts from templates.
- Push metadata into Word documents to populate the contract with e.g. automatically generated contract numbers, counterparty information, and more.
- Utilise the integrations with Brava or the internal CARA features to compare versions / documents.
- Create a contracts package of multiple documents, including a Publish to PDF built into CARA.
- Use the CARA Forms capability to create an input form for Business Partner Evaluations, QA questionnaires, and more.
- Dynamically render the form contents to PDF, including hyperlinks to attachments.

Tracing & Integration

- Build CARA Reports to show contracts or other information status by country, month, group, product, or other variables.
- Get automated alerts when contracts are due to expire and trigger automatic workflows.
- CARA Dashboards – show information from inside CARA and from external systems in single reports with graphing.
- Measure and track performance over time without need for separate reporting software.
- Output information directly into a PSMF or in a form ready for manual inclusion.
- Integrate with other systems e.g. Master Data Management, ARGUS, ARISg, Veeva CRM. No integration is required if you are using CARA for these functions as well.

Approval / Third Parties

- Share contracts with external counterparties through use of the email / portal to send.
- Receive back counterparty edits via manual or automated upload to the Staging Area (extracting from emails.)
- Utilise the CARA internal workflows for approval, including eSignature.
- Display signatures as added pages on the contract using the CARA DocSecure module.
- Use the CARA integrations with DocuSign / AdobeSign for digital signature, including individuals who are not system users, e.g. third parties or externals.

Benefits

Contract Approval and e-signature

Our eSignature capabilities apply user information into a signature page that can be added to documents automatically once contract approval workflows are completed.

Portal for third parties

CARA Portal enables third party viewing for simple and secure access by PV users and external contributors to contracts.

Integration with PV systems

Integrations with Pharmacovigilance (including ARISg and ARGUS) systems enabling the required information flow for managing PV contracts and SDEAs .

Advanced Reporting and Dashboards

Users are able to monitor statistical information such as upcoming contract expiration, contracts locations and processing time.

Enhanced Location-Based Contract Management

Implement intuitive map-based navigation to streamline and improve the efficiency of location-based contract management.

The screenshot displays the CARA interface. On the left, a map of Europe is shown with a blue pin over Switzerland. On the right, a table lists search results for 1333 documents. The table has columns for Product, Contract Approval Status, Country, and City. The row for 'Submitted' status in 'Lichtenstein' is highlighted in yellow.

Product	Contract Approval Status	Country	City
CARA	In Discussion	Kosovo	Shtime
CARA	In Discussion	Kosovo	Prizren
CARA	Approved	Kosovo	Kamenice
CARA	Approved	Kosovo	Kline
CARA	Rejected	Kosovo	Hani i Elezit
CARA	Approved	Kosovo	Partesh
CARA	Submitted	Kosovo	Novoberde
CARA	Submitted	Lichtenstein	Babers
CARA	Rejected	Luxembourg	Mersch
CARA	Submitted	Luxembourg	Capellen
CARA	Approved	Monaco	Monaco
CARA	Approved	Montenegro	Cotrlje
CARA	Submitted	Montenegro	Rozaje
CARA	Rejected	Macedonia	Gevgelija
CARA	Approved	Macedonia	Probitip
CARA	Approved	Macedonia	Novaci
CARA	Submitted	Malta	Attard
CARA	Approved	Malta	Cospicua

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