Safety

cara LIFE SCIENCES PLATFORM

Integrated Safety

Predict, analyse, and react faster with a seamless platform for safety data

A comprehensive guide to Safety on the CARA Life Sciences Platform.

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INTEGRATED SAFETY
PREDICT, ANALYSE, AND REACT FASTER WITH A SEAMLESS PLATFORM FOR SAFETY DATA

Connectivity

Leverage a centralised system for all your global processes with a cloud-first solution.

Visibility

Gain true oversight with easy reporting, dashboard and a 'where-used' system.

Consistency

Take control of all your information with best practises across the board to reduce re-work and time wasted.

Proactivity

Automate work for your colleagues with collaboration and AI, ready for the challenges of tomorrow.

Safety

- **PV Case Management**
- **PSURs, Educational Materials & other Safety submissions and distributions**
- **Medical Inquiries**
- **PSMF**
- **Safety Data Exchange Agreements**
- **Risk Management**
- **MedDRA Integrations**

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PV Management

Automating pharmacovigilance with a modern cloud solution.

PV cases can be created in CARA from a number of input sources (XML input, emails, manual entry), and then processed to closure, including submission to the NCA using the ICH E2B R2/R3 standard.

Case Intake Flexibility

Information can come into the CARA case intake from a variety of sources, including: Email, XML files, API from another system, and manual entry, and a case will be created. Depending on the case information, notifications will be sent to the responsible parties based on the country, product, or other criteria. Additionally, CARA can create a data item / case in third party systems (e.g. SAP) or within 'Complaints' in the Quality workspace of the CARA Life Sciences Platform for example.

Save Time With Automated Case Processing

Cases can be automatically assigned to processors based on market, product, language, severity, or any other criteria that you need. As the case moves through its lifecycle, additional fields will become visible and/or mandatory. To maintain Data Privacy, some fields can be hidden from global processing trams and only available for the in-country teams.

Low-Effort Case Reporting

Once cases are ready to be reported, CARA can generate the required XML files using ICH E2B R3 format for submission to the Regulatory Authorities.

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PV System Master File (PSMF)

Simplifying a complex process

Managing the PSMF is a complex ongoing task, between updating sections owned by different parts of the business, and the challenge of creating the Annexes from information that comes from a variety of sources. CARA facilitates and streamlines the entire process, including automatically generating the Annexes.

Divide & Conquer – Separate the PSMF into Compartments

The PSMF main body chapters and annexes are separated in separate compartments within CARA, allowing for the flexibility of multiple data owners. Users can extract individual compartments from the PSMF for use as standalone documents, or for use in other items in the product development lifecycle. Workflows will be generated based on date triggers to the respective owners, and then finally to QPPV for review and approval.

Automated Annex Generation

CARA can automate the retrieval of data from various systems to automatically generate submission-ready PDF documents for each annex. The source systems for the data can be CARA (e.g. SDEA), MS Excel (exports from other systems), or direct integration with other systems. Any changes within the PSMF sections themselves are recorded in the CARA Audit Trail and can automatically generate an annex documenting the updates.

Quarterly and Annual Reviews

CARA manages periodic review workflows for sections of the PSMF that need reviewing quarterly or annually, and notifies relevant section owners of the required update. Versioning is used in CARA to produce the newly updated documents from older versions as well as to keep track of previous versions.

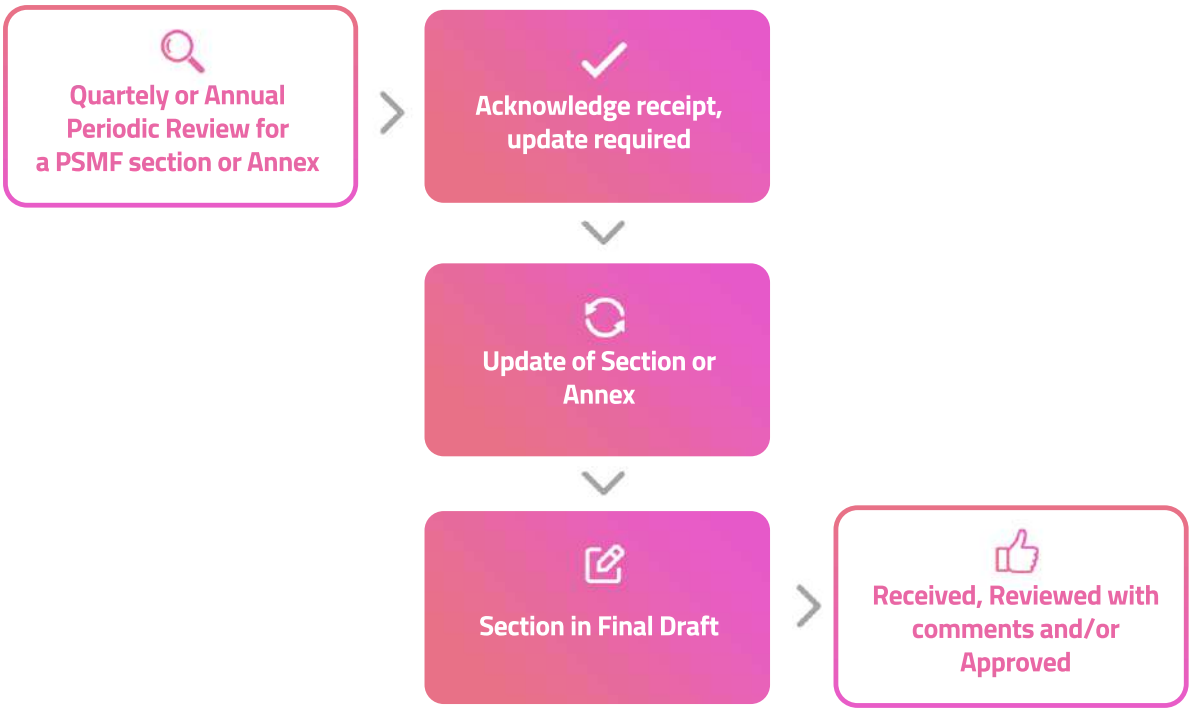
Concatenation

Once all relevant documents are up to date and approved, the different sections are concatenated, assembled, producing one MS Word or PDF document containing all updated sections ready for submission.

Global vs. Local

The sections of the Global PSMF can be used for the Local PSMF or adapted. Through property inheritance, CARA allows an automation for the generation of local sections from global sections. Local PSMFs per country/market are also handled and stored in CARA with the same functionality as a Global PSMF.

Example PSMF Section Update Workflow



SDEA Management Features

Creation

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

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 / externals

Tracking & 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 including 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

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PSURs, Educational Materials & other Safety submissions and distributions

The CARA Life Sciences Platform supports the 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 interactions.

Risk Management

Risk Management Plans and associated documents need to be created and distributed to Affiliates and Distributors. Traditionally those tools involve external systems for sharing content and a separate system for registering and reporting on implementation status. This can all be done in a unified and traceable way in the CARA Life Sciences Platform, with Affiliates / Distributors logging in to a user-friendly platform to perform to collaborate.

Medical Inquiries & Information

Deal with incoming Medical Inquiries and Information requests via call centres, emails, and more. Real-time searching for answers, including automatic sending, and full per-country data privacy handling. CARA has a simple and secure portal for third-party access for direct contribution to case information and automated response package preparation for reduced turnaround time.

Integrations with external databases including MedDRA and WHODrug

Ensure the data in your CARA Life Science Platform meets the standards and norms of dictionaries like MedDRA and WHODrug. By integrating the CARA platform with governed and regulated dictionaries including MedDRA and WHODrug, CARA provides internationally standardised terms in the regulated industry. These terms would be used in registration, documentation and safety monitoring of medical products both before and after a product has been authorised for sale.

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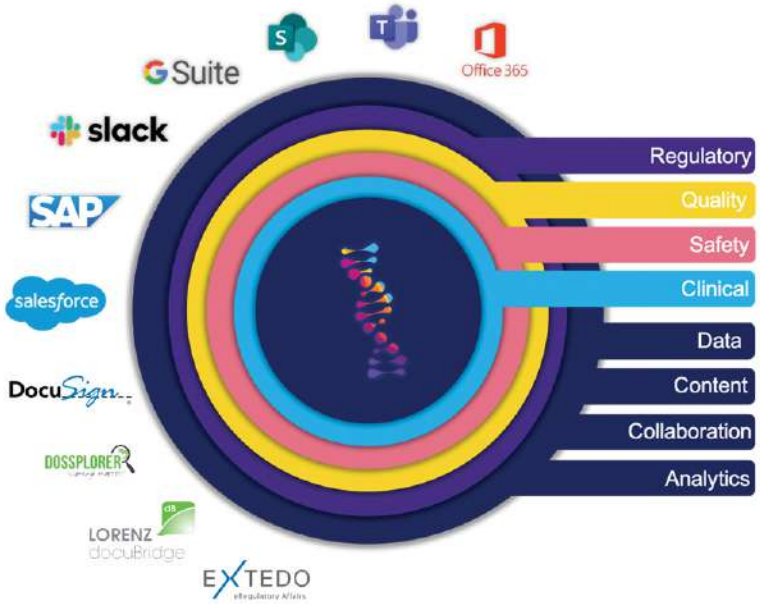
What is the CARA Life Sciences Platform?

The CARA Life Sciences Platform is an enterprise cloud for managing the content, data, and business processes throughout the whole R&D landscape.

The CARA Life Sciences Platform removes the technological, operational and financial drawbacks of a network of individual systems – instead, our customers can consolidate their processes, data and content onto a single platform of best of breed apps. Users can then create, locate, and re-use information instantly in any process across the organisation, leading to accelerated work with greater accuracy of information.

We provide standardised apps for Regulatory, Quality, Safety, Clinical and Enterprise processes powered by a single information lake that gives users instant access to cross-functional data and enables powerful process optimisation.



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