

RLS PROTECT

Automating Personal Data Protection

Delivering scalable anonymization software and services based on proprietary Natural Language Processing (NLP)



RLS PROTECT is comprised of three validated software products that help pharma organizations comply with GDPR, EMA Policy 0070 and Health Canada PRCI

RLS PROTECT

*Definitive,
quantitative
measurements that
remove subjective,
non-compliant
approaches*

RLS PROTECT
RISK ASSESMENT
Disclosure risk and
data utility analytics

RLS PROTECT
DOCUMENTS
PDF document
redaction and
transformation

*Eliminate low-quality, repeatable and time-intensive
unstructured text anonymization tasks with automated NLP*

RLS PROTECT
WORKFLOW
Document/risk
tracking and management

*Monitor, measure, track and plan
resourcing across all
documents to manage
headcount and timelines*

The RLS Protect Platform: Overview of Features and Benefits

Our technology automates the identification and extraction of PPD¹ in unstructured data

RLS PROTECT is...

...an Automated Solution for Patient De-Identification



- Granular and customizable controls for automating identification and extraction of patient identifiers
- Works seamlessly across datasets and documents, across text and tables (and also images)
- Batch auto-anonymization features that supports complex masking of ad hoc files or entire databases at rest

...an Integrated, End-to-End, Off-the-Shelf Solution that Ensures Compliance



- Provides validated, peer-reviewed quantitative assessments/reports for measuring patient re-identification risk across documents and datasets
- Directly integrated with document management tools (e.g. Veeva) and brings all the anonymization, modeling and reporting required to meet policies e.g. GDPR and Policy 0070

...a Passive Document and Workflow Management Platform



- Each document run through RLS PROTECT that undergoes PPD metadata extraction can be tracked and measured passively
- Trending tools support resource forecasting and midcourse changes
- Users can instantly communicate, discuss and collaborate across teams within RLS PROTECT

...on-premise, desktop-ready and/or cloud deployable



- 'Live-in-five' – RLS PROTECT can be installed via weblinks by non-technical users and without extensive involvement from IT -keeping data within the sponsor environment
- PPD identification/extraction modules are pre-loaded and can be customized as required
- RLS PROTECT includes an interactive eTraining Suite to get users up and running independently

¹Personally Protected Data

^{*}[In partnership with ARX](#), an open-source risk assessment platform by F. Prasser and F. Kohlmayer at the Technical University of Munich Institute of Medical Statistics and Epidemiology

The RLS PROTECT Platform: Deep, Targeted Automation of PPD/CCI in Text

Using optimized/trained natural language processing and machine learning technology

RLS PROTECT

Automated
Document
Anonymization

Integrated Risk
Assessment
and Dataset
Anonymization

Submission and
Workflow
Management

Delivering rapid automation of redaction and transformation of PPD in unstructured data, with granular and customizable QC controls

- Taxonomies and semantic models **trained on millions of pages** deliver **rapid automation** of unstructured patient data
- Redaction and transformations are **automatically configured/applied** against the risk assessment outputs **ensuring risk thresholds are met**
- Users have **controls to manually intervene** at every point and can correct/customize automated outputs to **ensure accuracy**

Deep Automation with Granular Controls

Finalized Document

Transformed Document

Marked Document

Original Document

Clinical Review
Janssen, M.D.
NDA 202326
Initial (a)(4)(b)

Table 25: All Grade 5 Treatment-Emergent Adverse Events Excluding Disease Progression and Occurring Within 30 Days of Last Dose on the Active Arm

Patient ID	Grade 5 AAE Preferred Term	Last Dose Date	Onset Date	Death Date	Days from Last Dose to Death
1000001	Cardiovascular Accident	195	195	195	0
1000002	General Weakness	195	195	195	2
1000003	Cardiorespiratory Failure	252	252	252	4
1000004	Cardiorespiratory Failure	53	53	53	2
1000005	Diarrhea	215	215	215	1
1000006	Pulmonary Embolism	215	215	215	20
1000007	Septic Shock	141	141	141	2
1000008	GI Hemorrhage	252	252	252	2

Patient 1000001 was a 73 yo female with hypertension who previously had presented with transient symptoms of aphasia. She died suddenly of a CVA following acute onset of neurologic symptoms.

RLS PROTECT
DOCUMENTS

The RLS PROTECT Platform: Integrated Risk Assessment Tools

Automated risk assessment customized to global data privacy standards

RLS PROTECT

Automated
Document
Anonymization

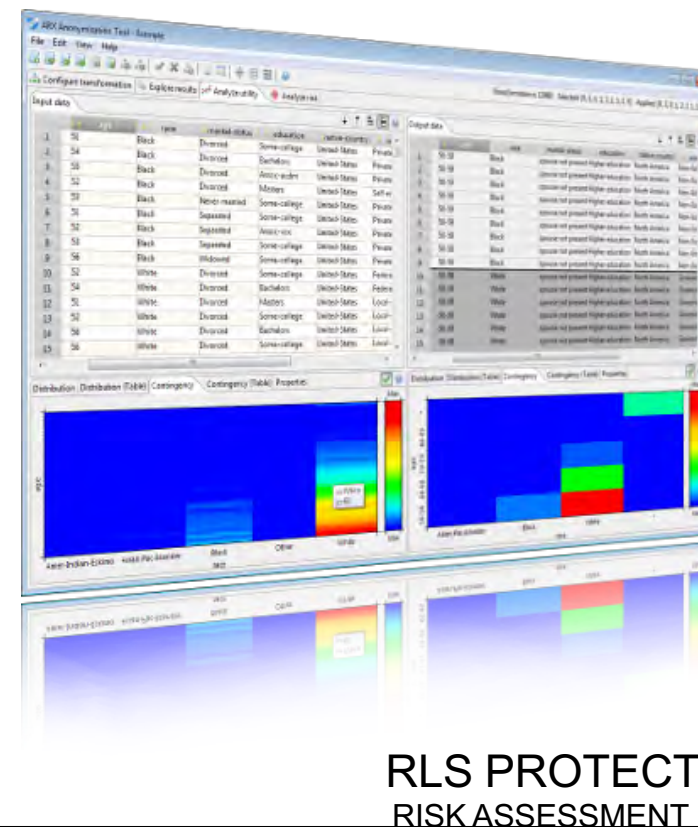
Integrated Risk
Assessment
and Dataset
Anonymization

Submission and
Workflow
Management

Standardized, quantitative and integrated risk assessment, complaint with data privacy standards/thresholds

- RLS PROTECT-RISK enables users to **quantitatively measure risk and data utility**, with batch processing, using **30+ peer-reviewed models**
- RLS PROTECT-RISK includes customizable templates that enable **near-instant, point-and-click risk assessment** and **outputs directly integrate** with RLS PROTECT-DOCS
- Templates are setup to **meet both mandatory and voluntary disclosure risk thresholds** and provide a **simplified/visual approach** to evaluate risk scenarios

Integrated Point-and-Click Risk Assessment



The RLS PROTECT Platform: Project/Workflow Management Tools

Passive tracking of progress allow us to rapidly report to you status of redaction

RLS PROTECT

Automated
Document
Anonymization

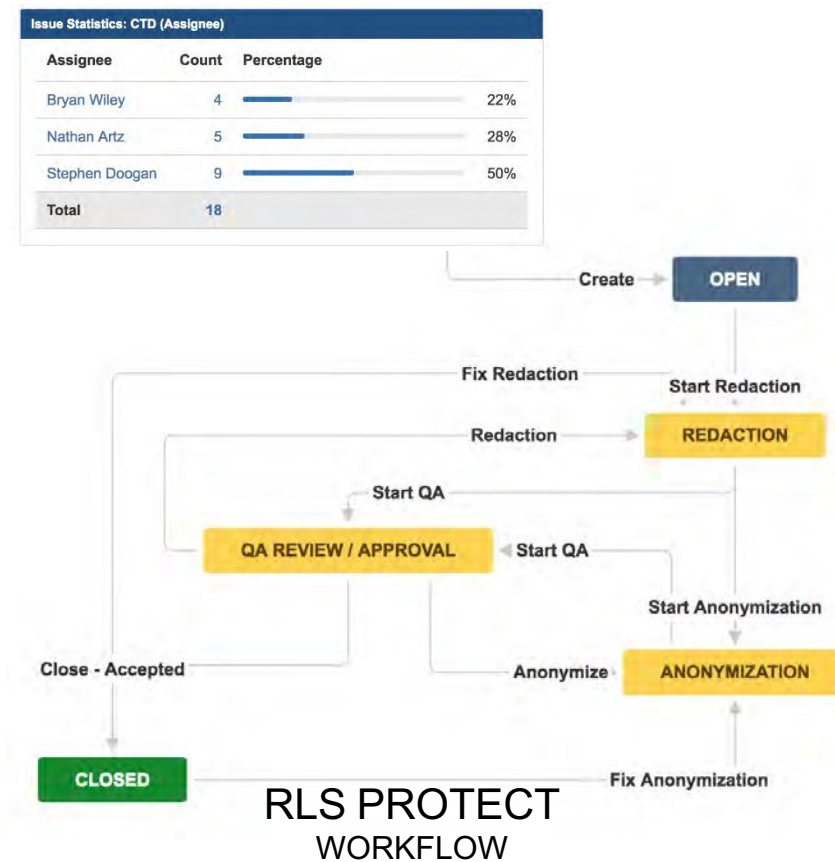
Integrated Risk
Assessment
and Dataset
Anonymization

Submission and
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Management

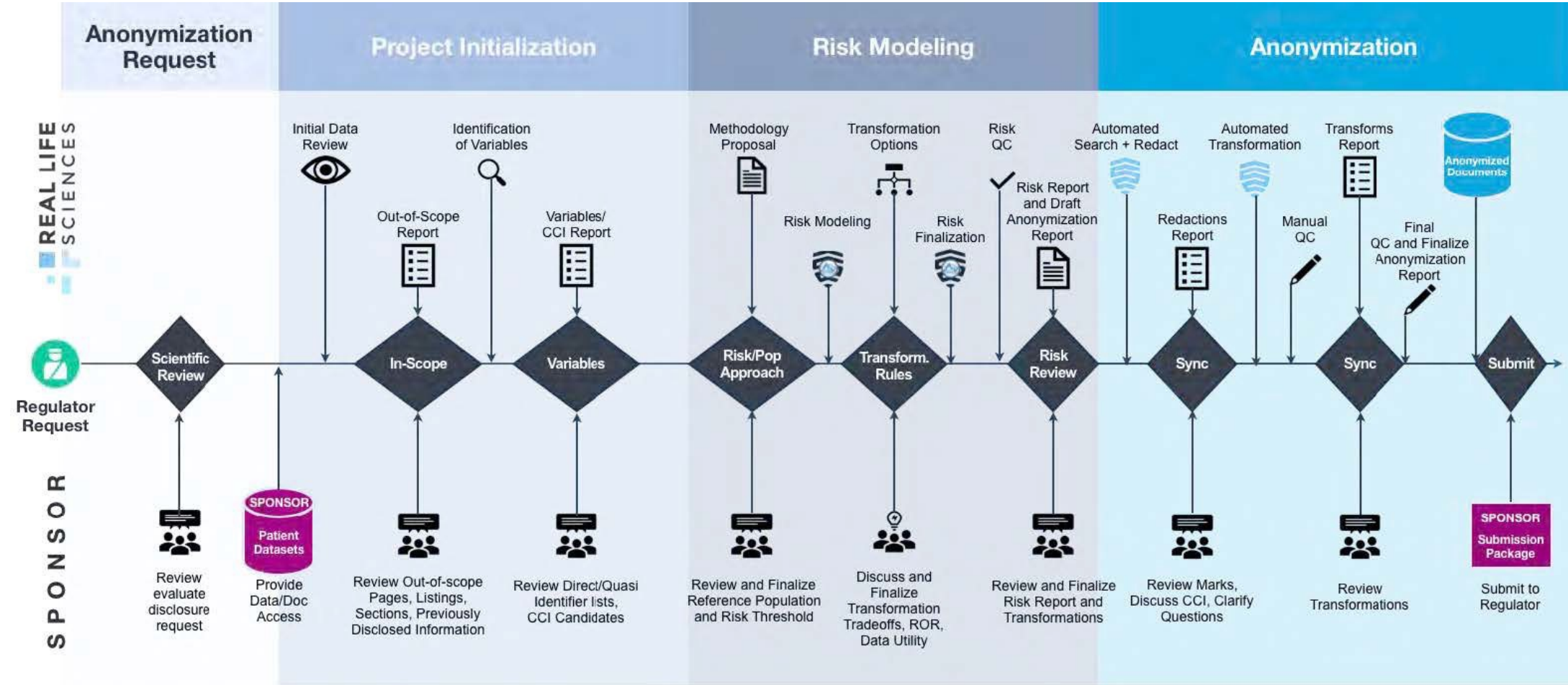
Passively manage/monitor data
extraction, expand internal knowledge
and reduce vendor communication issues

- Standardized templates enable **rapid de-identification setup**, **reduce time/effort** when publishing patient sensitive documents and **save cost**
- Document tracking data can be used to **measure performance**, **share knowledge with sponsors** and **optimize future resource planning and timelines**
- Passive tracking of data extraction activity **generates performance metrics** that can be **accessed on-demand**, reducing the need to setup time intensive meetings

Passive Tracking of Progress and Performance



RLS PROTECT supports the end-to-end anonymization process for clients to follow, that has been refined based on the best practices of meeting regulatory requirements (since 2014)



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