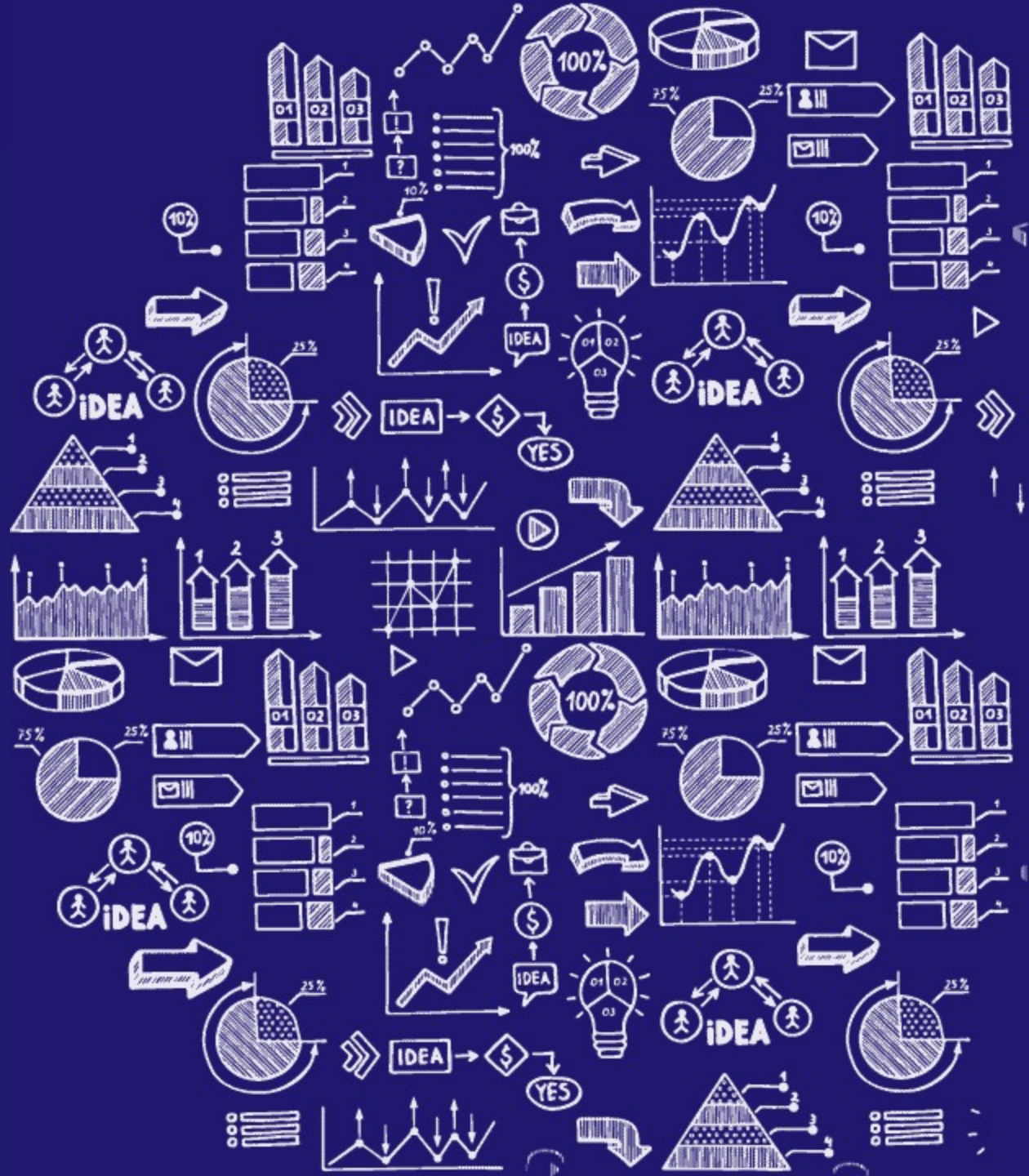
Gramener

Insights as Stories

Data Redaction Solution

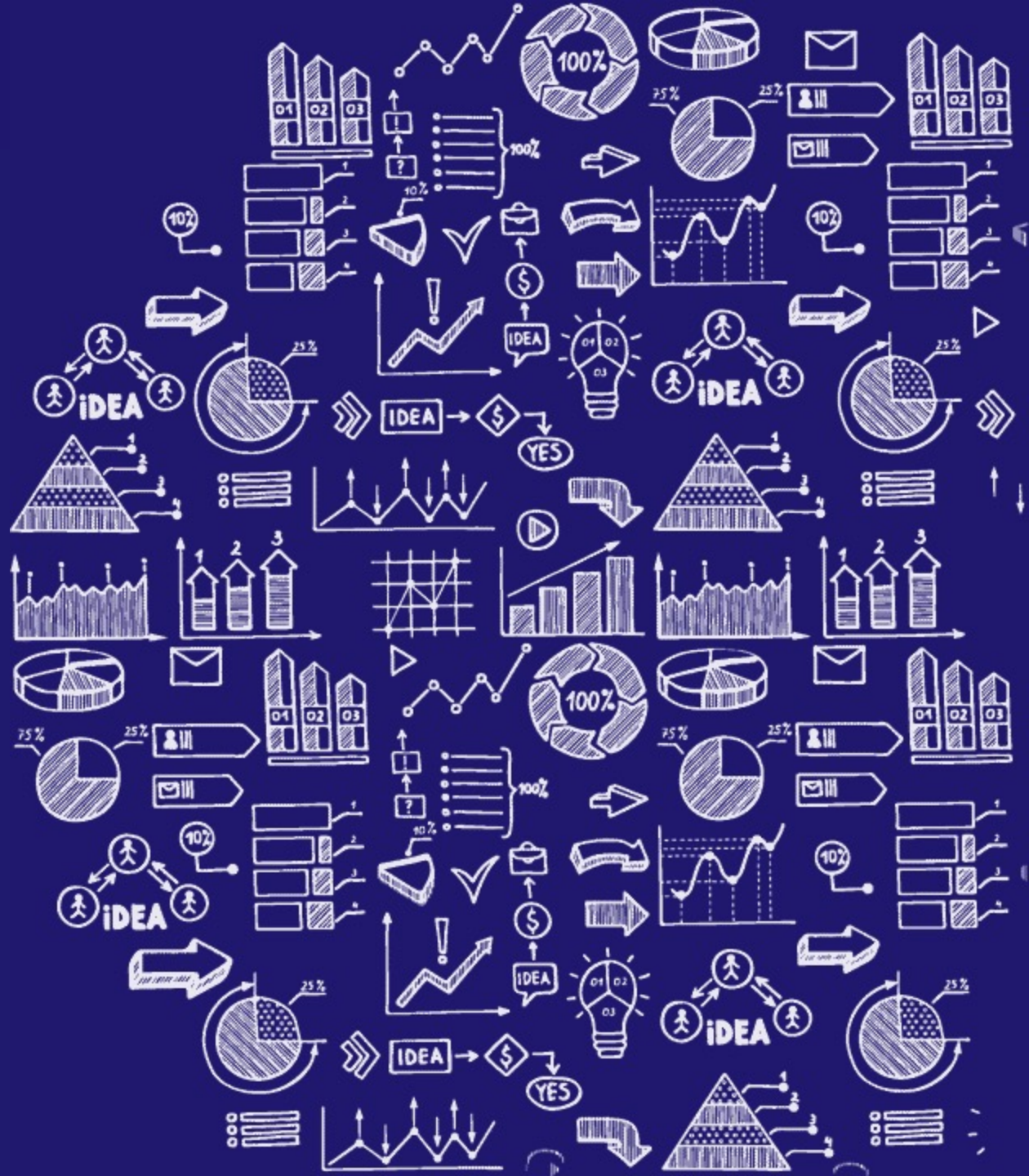


Gramener

Insights as Stories

Book a Free Demo at

gramener.com/demorequest



Clinical Trials Transparency: Redaction & Anonmyzation of patient personal information and company confidential information

Problem

- Client had a need to protect content such as intellectual property and personally identifiable information in clinical trial documents that are shared with third parties including health authorities and partners
- Anonymization of clinical summary reports is a regulatory requirement for EMA and health Canada
- Regulatory requirements have been growing over the recent years and other country health authorities are expected to follow suit leading to an increased demand for reduction and anonymization solutions

Approach

- The standard approach was to outsource to vendors the anonymization and redaction of patient personally identifiable information
- 3rd party vendors were taking longer time, were expensive and yet not delivering good accuracy of the documents
- Also 3rd party vendors were not delivering an assessment of risk of re-identification of data

Outcome

- Gramener developed a custom platform for redaction and anonymization for the client, leveraging NLP and other AI/ ML technologies
- The relevant PharmaCo personnel can now cater to requests for clinical trial information from outside quickly and more accurately and with the option for a Human to quickly validate the results from the AI/ ML enabled platform
- This has resulted in 97% time savings in submission process and expected to deliver savings of $1mn pa

Case Study: We delivered for a Big PharmaCo, their internal platform for Analytics driven automation of Risk Anonymization, with significant time & cost savings

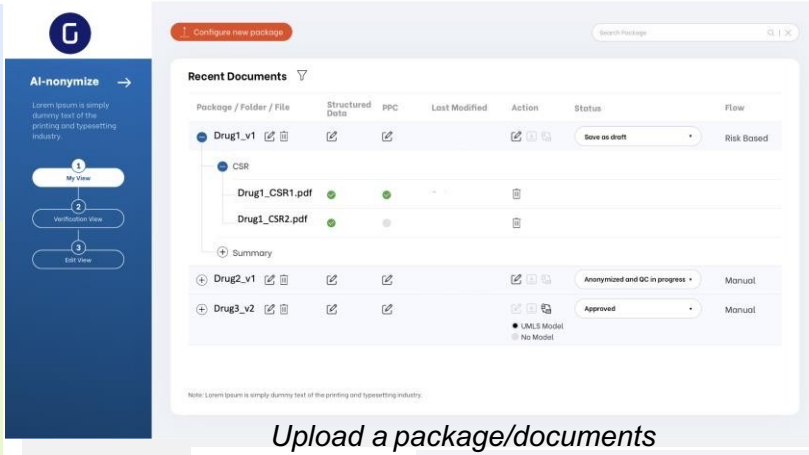
Redaction & Risk based anonymization are manual and high TAT activities which require iterative risk computation to be in compliance with EMA & HC norms. This delays regulatory submissions and increases the time to market

Privacy AI combines key elements of

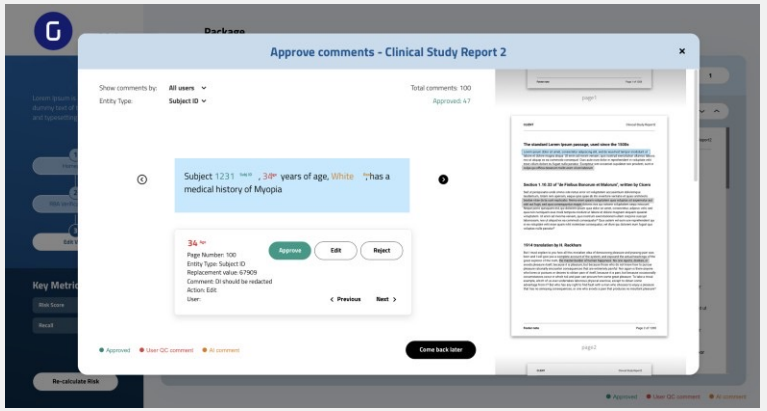
- *AI algorithms to identify required entities*
- *Risk computation algorithms*
- *Human in the loop interface to allow users to control the process*

Solution cuts down process turn around times and still ensures risk of patient reidentification is under the regulatory thresholds of 0.09

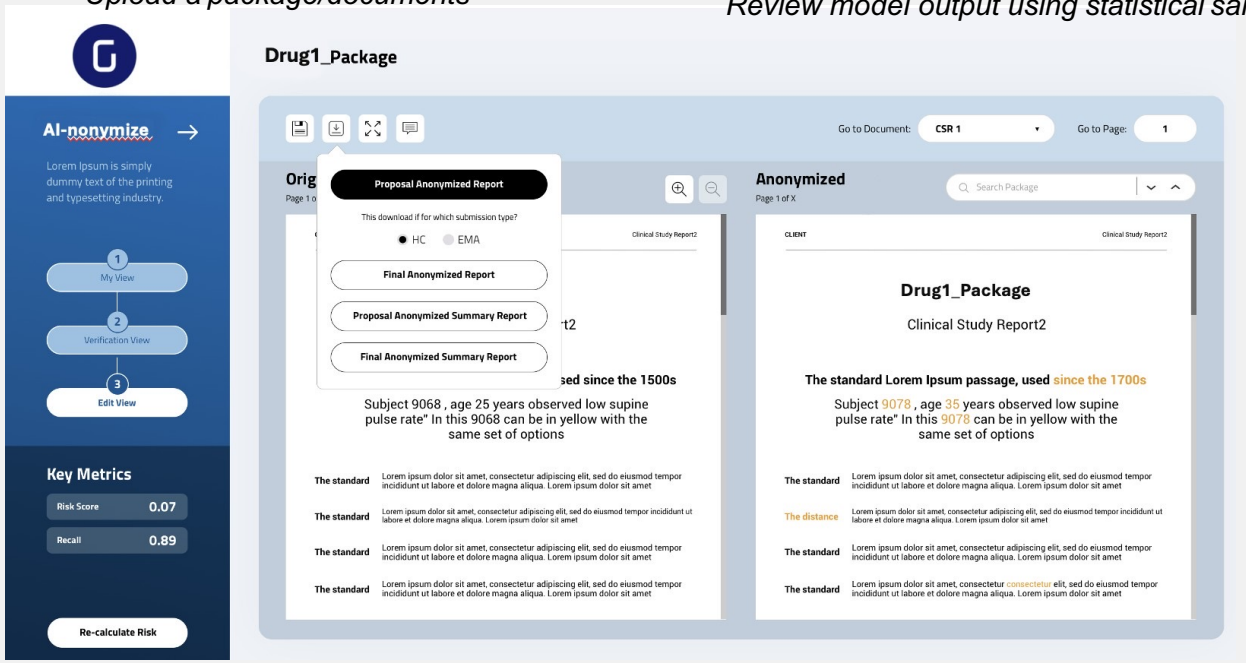
~97%	$1M/year
Time Savings in submission process	Cost Savings for only 1 use-case



Upload a package/documents



Review model output using statistical sampling



Compare original and anonymized files, download submission ready packages

Clinical trials transparency regulation implies that Pharma companies face the prospect of millions of dollars in risks and costs from any lapses in compliance

Regulatory changes relevant for Pharma Industry

The regulatory framework is evolving…

… to support better, faster, cheaper innovation in medicines for patients…

…while protecting privacy of patients and confidential data

US FDA, Europe's EMA, 'Health Canada' have mandated clinical trial data transparency

(as it is a lever to reduce ecosystem level R&D costs)

GDPR for data protection requires that patient related and other confidential data needs to be protected

Implication for Pharma companies

High penalties for non-compliance or for errors

Default methods to hide patient data are…

…manual, time-consuming, error-prone, non-standard & expensive

Currently available softwares are expensive, provide low accuracy and **do not** enable End-to-end automation

Financial Impact

Errors could result in law-suits with liabilities running into **millions of dollars**

Delays could risk penalties of **$0.3 mn monthly**

Depending on scale, spend of **$2-3 mn pa** in external vendor costs are incurred in addition to internal Org costs

To avoid and minimize financial risk of clinical trial transparency non-compliance, Gramex-4-Health Offers the most promising new technology for pharma companies

Options for Pharma Companies

Use of Tools & Technology	Maintain inhouse teams to carry out redaction	Leverage services from CROs and other regulatory service providers	Consider Gramex-4-Health (G4H)
Use Adobe or similar tool	This is the most common tool for manual redaction efforts		
Leverage available AI/ML enabled software	Currently available tools in the market are unable to maximize end-to-end automation		Significantly more powerful than available tools
Create internal AI/ ML based platform	Potential option for companies spending >1mn pa with external service providers for redaction & anonymization		Expertise to help you cost effectively build & maintain inhouse platform or redact as a service

Gramex-4-Health (G4H) 'Redaction & Anonymization' Platform is custom built for each client's needs

Problem solved by G4H Tool	**Automate the masking/ redaction/ anonymization of private, sensitive & confidential information in several large business critical documents, before sharing with 3rd parties** ***(e.g. clinical trial results sharing with 3rd parties as mandated by regulators in US, Europe, Canada)***

Input

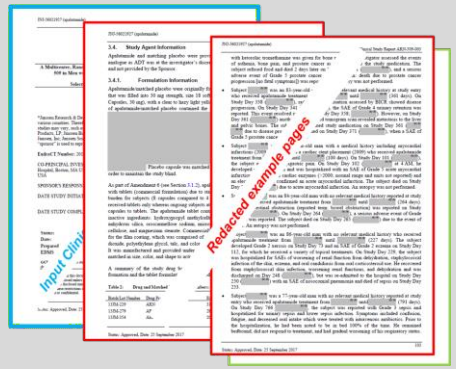
Document containing private/ confidential information

G4H Platform

Software for automated Redaction & Anonymization

Output

Machine generated redacted/ anonymized document



Most accurate, fast, cost-effective and automated approach to protect against regulatory penalties running into millions of dollars

G4H Custom Platform for redaction & Anonymization is targeted to offer significant benefits over other options

Detailed list of G4H Platform Features

1. Automated deidentification
2. Integrated re-identification risk measurement and reporting
3. PHI leak rate calculation
4. Full submission package
5. Automated compliance report generation
6. Active learning module
7. Management Portal
8. User centered UI
9. Deep Learning,NLP Module
10. Integration & Automation within the pipeline
11. Auditable logs
12. Submission Status
13. Deployable on-prem or in the cloud
14. Human in the loop Validation
15. Data-identification APIs
16. Reusable Template
17. Guidable Process workflow
18. Single Platform for all the services

G4H Differentiators compared with competitors

Accuracy	90%+ accuracy (10-20% points better than alternatives)
Speed	90% faster
End-to-end automation	70% more automation
Cost	40% of cost of alternatives
Continuous Improvement	Human in the Loop