COLLABTRIAGE

DRUGS

AN AI-DRIVEN CASE TRIAGE AND REGULATORY ASSESSMENT

ABSTRACT

The increasing volume and complexity of product related cases, ranging from customer complaints to adverse event reports, have placed significant operational and compliance burdens on organisations. Traditional manual triage processes are often slow, inconsistent, and difficult to audit. This white paper introduces CollabTriage Drugs, an AI-based case triage system designed to automate the classification, seriousness assessment, and regulatory routing of product-related cases. By combining artificial intelligence, rule-based validation, and human oversight, CollabTriage Drugs delivers a scalable, consistent, and auditable solution aligned with global and regional regulatory requirements

1. Introduction

Organizations operating in regulated environments must process large volumes of product-related cases originating from diverse sources such as customer feedback, complaints, and adverse event reports. These cases frequently contain multiple issues, each of which may require independent evaluation and regulatory consideration.
Historically, initial case triage has relied heavily on manual review, resulting in extended processing timelines, subjective decision-making, and inconsistent outcomes. As regulatory expectations continue to rise, there is a growing need for automation that preserves compliance, transparency, and human accountability.
Collabtriage Drugs addresses this need by introducing an AI-enabled, rule-driven framework for standardized case triage and regulatory assessment.

2. Solution Overview

Collabtriage Drugs is an AI-based case triage system that automates the initial assessment of product-related cases received from the market. The system validates incoming data, classifies issues by seriousness, and routes cases to the appropriate regulatory workflows.
A key foundation of the solution is the enforcement of PREP validation - Patient, Reporter, Event, and Product, as a mandatory gating mechanism. Only cases meeting PREP requirements are eligible for automated regulatory assessment.
Cases are categorised into Global, Local, or MOCD, and each issue within a case is evaluated independently. If any issue is classified as serious, the system escalates the entire case as serious, ensuring timely regulatory action. Region- and product-specific regulatory checks, such as MOCD (US), TFI (EU), and TSCA (Fabric/Household products) are applied prior to final case routing.

3. Business Impact

The adoption of Collabtriage Drugs delivers measurable operational and compliance benefits:

- **Reduction in manual effort through automation of initial triage activities**
- **Improved consistency in case classification and seriousness determination**
- **Faster identification and escalation of serious cases**
- **Scalability to support increasing case volumes across regions and products**
- **Clear audit trails to support regulatory inspections and reviews**

By standardizing decision logic and embedding compliance checks early in the process, the system strengthens the organization's regulatory posture while improving efficiency.

4.Product Objectives

The primary objective of Collabtriage Drugs is to standardize and automate the initial triage of product-related cases while ensuring full regulatory compliance.

Key Objectives

- **Automate manual case triage using AI and predefined business rules**
- **Enforce PREP validation before regulatory assessment**
- **Identify and escalate serious cases without delay**
- **Apply region- and product-specific regulatory checks**
- **Maintain transparency and traceability for every decision**
- **Enable human review when automation confidence is uncertain**

5.Process Architecture and Flow

5.1 Case Intake / Data Ingestion

Cases are ingested in a structured data format, with each case potentially containing multiple issues requiring independent evaluation.

5.2 PREP Validation

Each case must include the following mandatory elements

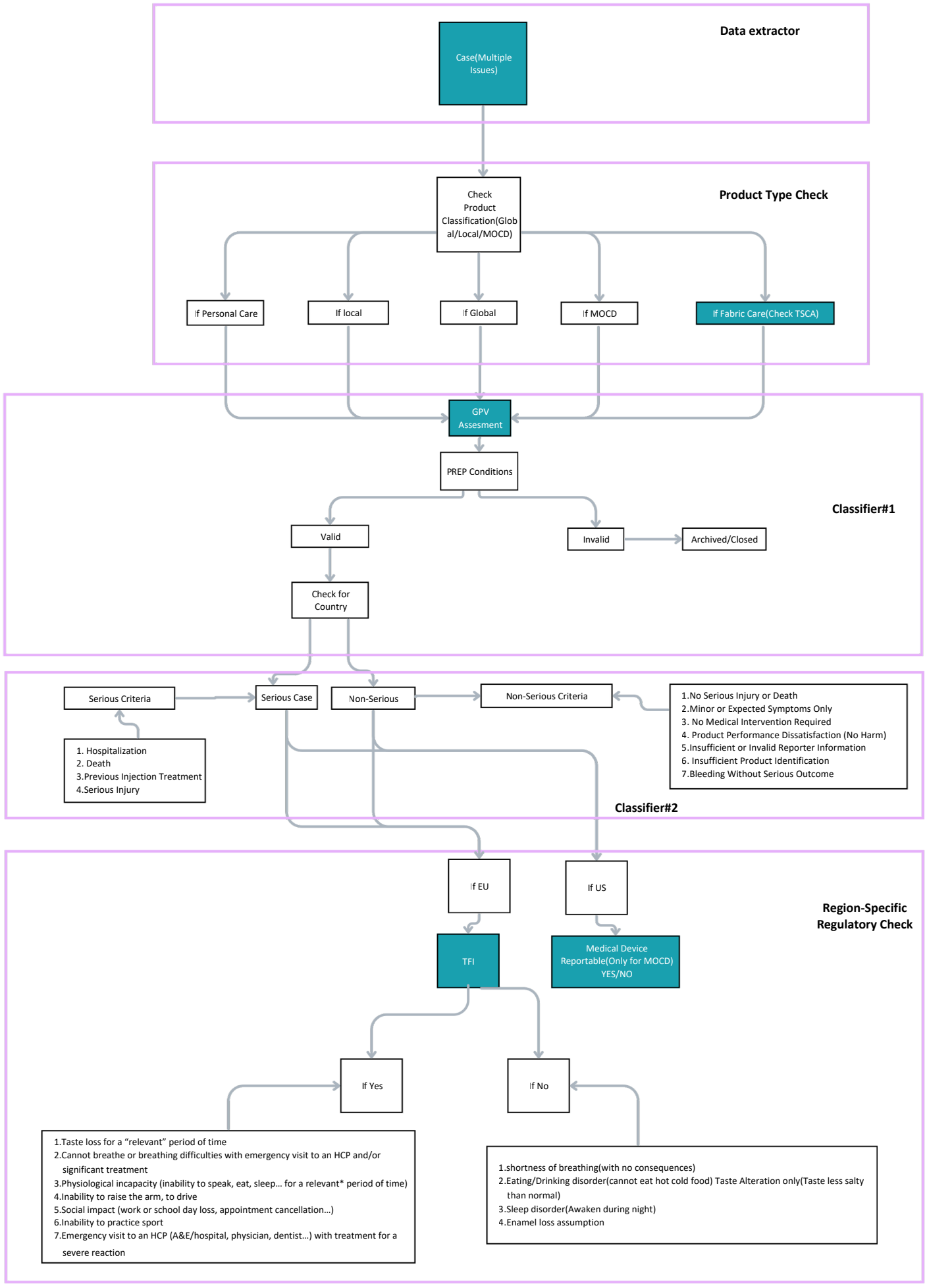
Cases missing any PREP component are marked as invalid or routed for manual review, ensuring data integrity prior to regulatory processing.

5.3 Issue and Case Classification

Each issue within a case is classified independently as:

- **Invalid**
- **Serious**
- **Non - Serious**

If at least one issue is identified as serious, the entire case is classified as serious, ensuring conservative and compliant escalation.


Data extractor
Case(Multiple Issues)
Product Type Check
Check Product Classification(Global/Local/MOCD)
If Personal Care
If local
If Global
If MOCD
If Fabric Care(Check TSCA)
GPV Assesment
PREP Conditions
Classifier#1
Valid
Invalid
Archived/Closed
Check for Country
Serious Criteria
Serious Case
Non-Serious
Non-Serious Criteria
1. Hospitalization
2. Death
3.Previous Injection Treatment
4.Serious Injury
1.No Serious Injury or Death
2.Minor or Expected Symptoms Only
3. No Medical Intervention Required
4. Product Performance Dissatisfaction (No Harm)
5.Insufficient or Invalid Reporter Information
6. Insufficient Product Identification
7.Bleeding Without Serious Outcome
Classifier#2
If EU
If US
Region-Specific Regulatory Check
TFI
Medical Device Reportable(Only for MOCD) YES/NO
If Yes
If No
1.Taste loss for a "relevant" period of time
2.Cannot breathe or breathing difficulties with emergency visit to an HCP and/or significant treatment
3.Physiological incapacity (inability to speak, eat, sleep… for a relevant* period of time)
4.Inability to raise the arm, to drive
5.Social impact (work or school day loss, appointment cancellation…)
6.Inability to practice sport
7.Emergency visit to an HCP (A&E/hospital, physician, dentist…) with treatment for a severe reaction
1.shortness of breathing(with no consequences)
2.Eating/Drinking disorder(cannot eat hot cold food) Taste Alteration only(Taste less salty than normal)
3.Sleep disorder(Awaken during night)
4.Enamel loss assumption

5.4 Regulatory Assessment and Routing

Based on product type and geographic region, additional regulatory logic is applied:

- **MOCD for US mechanical oral cleansing devices**
- **TFI for EU cases involving temporary functional incapacity**
- **TSCA for fabric and household products**

Following assessment, cases are routed to:

- Global Pharmacovigilance (GPV)
- Local regulatory workflows
- Archival
- Manual review queues

6. Technology Stack

Collabtriage Drugs is built on a secure and scalable technology foundation:

Python	**Backend services for orchestration, classification, and rule execution**
AI models	**NLP-based models for PREP extraction and validation**
Data Storage	**Secure relational databases for structured case management**
User Interface	**Reviewer dashboards for validation results and decision oversight**
Security	**Role-based access control, encryption, and comprehensive audit logging**

7. Decision Logic and Governance

The system implements clearly defined and auditable logic:

- **PREP Gate Logic:** All four PREP components must be present for processing
- **Issue-Level Logic:** Each issue is evaluated independently
- **Case-Level Logic:** Any serious issue escalates the entire case
- **Regulatory Logic:**

  MOCD for applicable US products

  TFI for applicable EU cases

  TSCA for fabric and household products