

An Optimal Solution for Pharmacovigilance Management for your Organization



JAZZ SAFETY is a fully-validated and web based Pharmacovigilance Database System which enables pharma organizations an “end-to-end” safety management during clinical development and post-marketing phases

JAZZ SAFETY enables management of safety reports associated with drugs, medical devices or biologic products and for any type of safety-related information (eg., adverse reactions, medication error)

Flexible to fit to the local and/or regional pharmacovigilance structure and processes of your organization

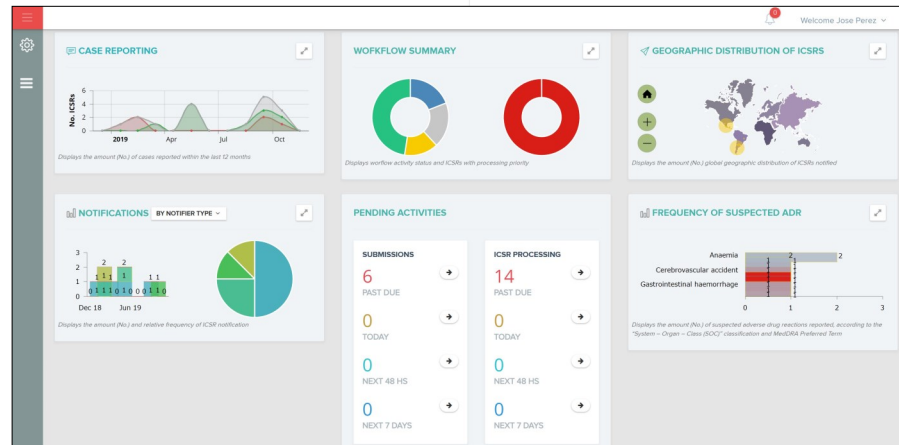
Helpdesk 24/7

The screenshot shows a detailed case report form. Key sections include:

- Description:** GI bleeding
- Native language:** English
- MedDRA:** Gastrointestinal bleeding (L1:3007936 V22.0)
- CTCAE:** Upper gastrointestinal hemorrhage
- Grade:** Grade 2 - Moderate symptoms; medical intervention or minor cauterization indicated
- Term highlighted by reporter:** Anemia
- Start date / time:** 2016 Dec 14 09:10
- End date / time:** 2016 Dec 19
- Duration of event:** 6 Days
- Severity:** Moderate
- Outcome:** Recovered / resolved
- Required treatment?** No
- Medically confirmed?** Yes
- Country (where the event occurred):** Mexico

**Complies with
21 CFR Part 11 and
ICH E2B**

**Multi-language inter-
face: Spanish - English
- Portuguese**



- Data collection**
 - ◇ Electronic AE forms (e.g., for Call Center, sales representatives, patients, health professionals)
- Data processing**
 - ◇ Processing of initial & follow up reports
 - ◇ Automated ICSR processing workflow with configurable timelines to optimize efficiency and effectively manage increasing case volume & complexity
 - ◇ Database architecture developed in line with ICH E2B (R3)
 - ◇ Extensive data validation, cross-field validation checks and use of pick lists
 - ◇ MedDRA browser and Organization’s Product Library integrated
 - ◇ e-storage of source documents
 - ◇ Auto-narrative tool
- Medical evaluation**
 - ◇ Medical evaluation module integrated
 - ◇ Exporting of customized data listings
 - ◇ Dynamic reporting trends per product & geolocation
- Regulatory notification**
 - ◇ Regulatory compliance module
 - ◇ Case exporting in harmonized formats (e.g., CIOMS, E2B xml) and local Authority forms
 - ◇ Standard line listings extraction for PSURs and custom reports library

