

Qlik Sense in Pharmacovigilance

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What is pharmacovigilance?

Pharmacovigilance (PV or PhV), also known as **Drug Safety**, is the **pharmacological science** related to the collection, detection, assessment, monitoring, and prevention of **adverse effects** with **pharmaceutical products**.

The main activity of Pharmacovigilance is **continuous monitoring** of the safe use of medicinal products **starting from drug development** to the drug approves for marketing and **throughout the life cycle** of the drug



Where does the data come from?

Safety data is collected from:

- Preclinical studies (animal studies)
- Clinical studies (pre-post marketing)
- Spontaneous reporting from Health Professionals or consumers
- Literature



So why develop a PV app in Qlik Sense?

Increased focus on and need for:

- Safety of pharmaceutical drugs from authorities and the general public.
- Tools to identify and monitor adverse events data and potential safety issues in the safety repositories in pharmaceutical companies.
- Compiling frequent and detailed safety reviews and reports.
- Quick responses to regulatory queries.
- Implementation of quantitative signal detection methods.

Current systems' reporting tools are outdated:

- **Static** reports
- Difficult to get **overview** of the data
- High level of **manual** work in Excel
- Lack of **signal detection** tools

Why use Qlik Sense?

Main benefits:

- Easily consolidates multiple data sources
- Fast performance
- Enables associative search and analysis
- Display data with state-of-the-art graphics
- Save on development costs (out of the box functionality)

All Your Data



Combine, load, and analyze all your data, from all your sources without leaving any data behind

Explore Without Boundaries



Freely explore visualizations and data, without boundaries or restrictions

Speed of Thought

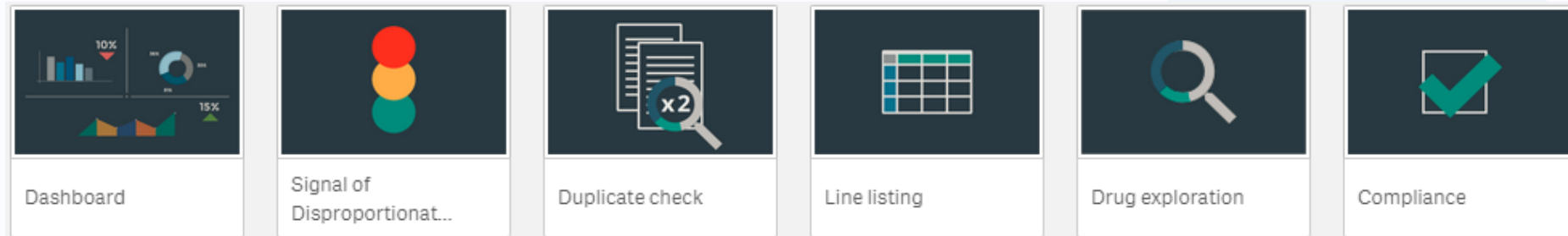


Provide instant response, for any questions, to support speed-of-thought analysis

Live demonstration

What does the Qlik Sense PV app gives the user?

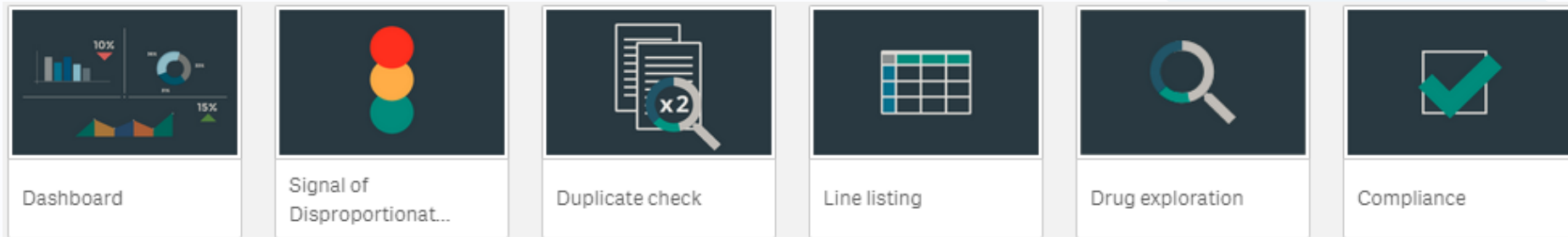
- Dashboard with metrics like # of cases, # of signals, reporting compliance
- Quantitative signal detection
- User-defined detection thresholds
- Data exploration module
- Compliance module
- Data quality check module
- Line listings and tabulations module



Live demonstration

What are the key benefits

- Interactive application enabling associative search and analysis
- Extensive exploration possibilities give you a unique window to your data
- Fast signal detection
- Intuitive and easy-to-use user interface
- Easy to share your analysis and findings
- Easy to extract data with fully customized filtering
- Short implementation time
- Easy to consolidate multiple data sources



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