Hosted Pharmacovigilance Software Databases: The Emerging Solution

Dr J Vijay Venkatraman

MBBS, F. Diab., MBA

Managing Director & CEO

Oviya MedSafe

Coimbatore, India

London, United Kingdom

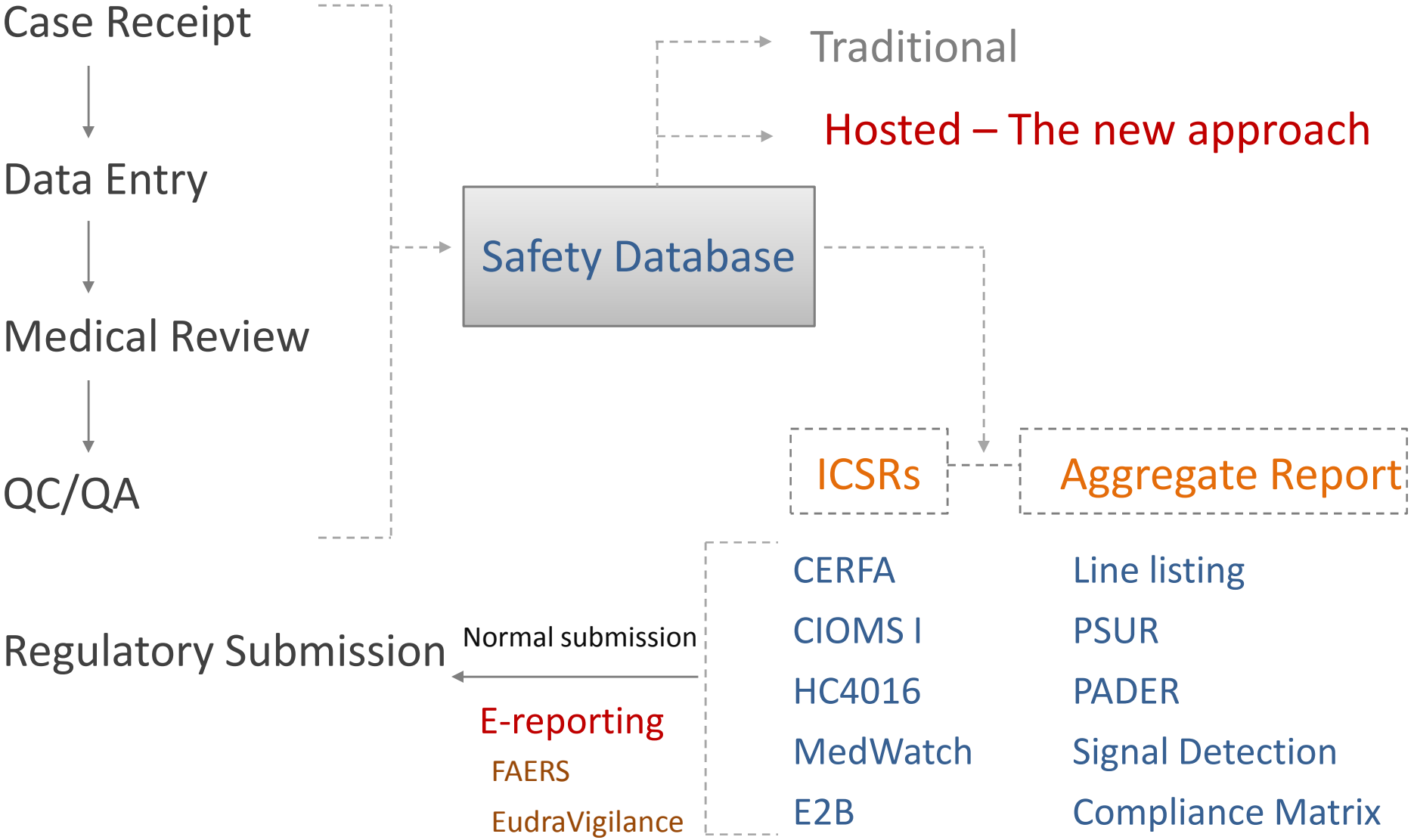
Introduction

Founded in the year 2012, **Oviya MedSafe** is a Pharmacovigilance Consulting & Drug Safety Services company based out of India and the UK, offering end-to-end global pharmacovigilance support.

Oviya MedSafe consults to emerging pharmaceutical companies to develop and maintain their drug safety systems, which includes advisory and operational support of safety databases.



AE Reporting



Mandatory E-Reporting

- An effort to improve efficiency of reporting
- Enhance the ability of reporting
- Better and timelier access to information
- Allows user/MAH to send secure messages and receive responses (acknowledgement)
- Timely exchange of information between MAHs and Competent Authorities



ICH-E2B(M)

Conventional Barriers

- Absence of a prompt to initiate reporting
- Considering that the reaction is already well known
- Time required to manually fill in adverse reaction forms
- Collecting and analyzing reports of ADR more challenging
- Different report with different reporting formats



E-Reporting

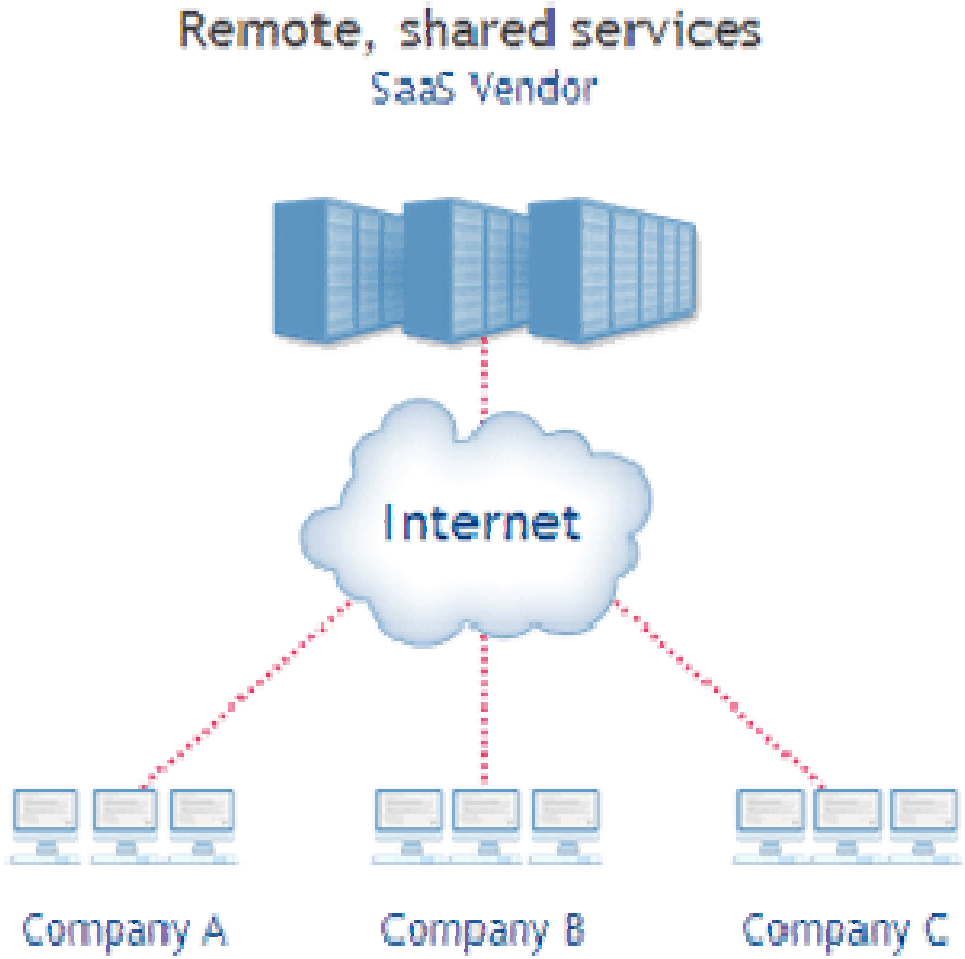
Traditional PV Database Barrier

- Expensive
  - Initial in-house implementations
  - Maintenance of a comprehensive PV system
  - Burden for smaller organizations
- Unavailability of competent support personnel
- Takes time and expertise to implement traditional drug safety database



Hosted Services

Software as a Service (SaaS) Model



Software as a Service (SaaS)



- Hosted system offers everything that a conventional PV database offers
  - Comprehensive data capture and reporting functionality
  - Data storage for later periodic reporting, trending and analysis
- Without the system overheads
  - Minimal setup costs
  - Minimal capital investment
  - Minimal local IT support requirements
  - Minimal on-going maintenance cost / resource requirements
- Advantage of secure access from anywhere over the Internet
- Boon for small and medium sized pharmaceutical companies

Limitation

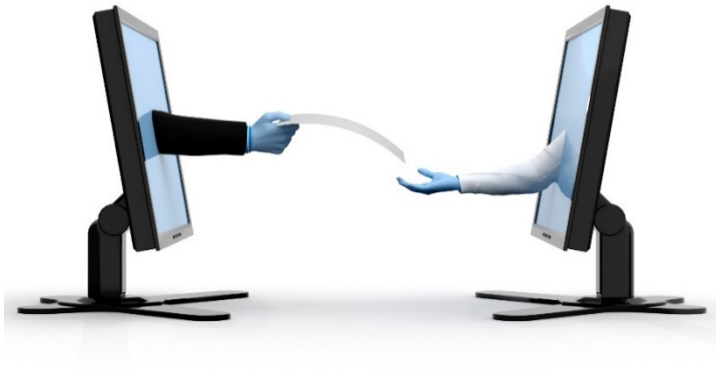
- Sensitive data is retained off-site
- Lesser degree of software configuration / customization
- Potential supplier failure



Choose the right service provider

Conclusion

- Hosted PV systems is the emerging, preferred, inexpensive, and robust solution
- No incurring huge fixed and recurring costs pertaining to the infrastructure
- No human resources needed to install and ensure the performance of a traditional pharmacovigilance software database.



Application

+

Support

+

Service

Contact Us

Global Delivery Centre (HQ):

Oviya MedSafe Pvt Ltd

2nd Floor, KTVR Gardens

220a-3, Marudha Konar Road

Velandipalayam

Coimbatore - 641 025

India.

Tel: +91-422-2444442

UK Office:

Oviya MedSafe UK Ltd

Suite LP25393

Lower Ground Floor

145-157, St John Street

London, EC1V 4PW

United Kingdom

Tel: +44-8452-733839

E-Mail: info@oviyamedsafe.com

Web: www.oviyamedsafe.com

Stay connected:

www.linkedin.com/company/oviya-medsafe

www.twitter.com/OviyaMedSafe

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Practising Safety

Our Home to Drug Safety



Thank You