Management- und Technologieberatung AG

Pharmacovigilance Services

Business Area Drug Safety

Version 04
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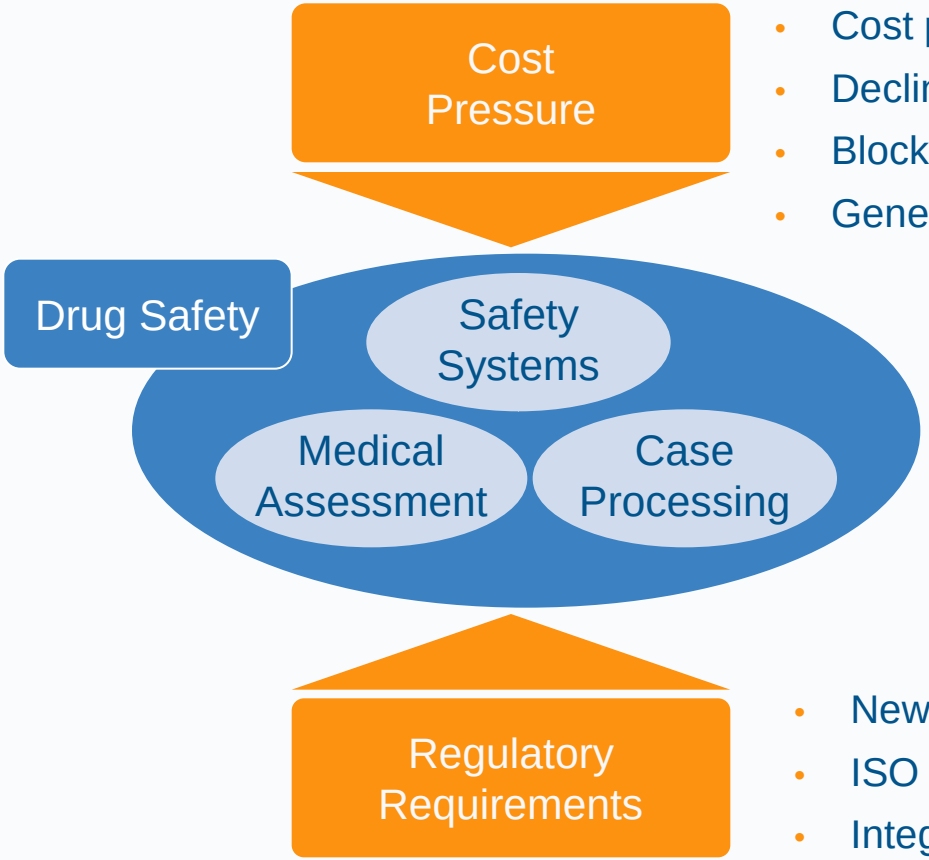
Need for Action
Challenges for Drug Safety

Drug Safety is in the pincer grip of cost pressure and regulatory requirements



- Cost pressure in life science sector
- Declining R&D productivity
- Blockbuster model is broken
- Generic / biosimiliar competition …

- New E2B (R3) standard for ICSR transmission
- ISO IDMP implementation
- Integration of Emerging Countries …

Need for Action
Cost Pressure & Regulatory Requirements

New regulatory requirements and increasing cost pressure translate directly into changes of related business processes and safety systems

- Upcoming new E2B standard (E2B R3)
- ISO IDMP implementation (Identification of Medicinal Products)
- Increasing importance of emerging countries with a broad diversity and frequent changes in local regulations
- Increasing cost pressure in life science sector

- Integrate E2B R3 readiness project into internal roadmap considering IT projects as well as business impact
- Prepare for IDMP requirements by ensuring a cleaned and standardized drug dictionary
- Setup strategy for integration of specific requirements of emerging countries into global processes
- Strive for standardization of system setup to reduce maintenance costs
- Implement lean processes within pharmacovigilance operation teams

JSC Services
Business Support (1)

Deep pharmacovigilance business knowledge enables JSC to provide significant benefit to respective business units

- Review, streamlining and design of business processes incl. standardization of local and global processes and tools
- Accompanying change management for smooth roll-out of new processes and tools into the organization
- Bringing business processes to the operational layer by providing standard operating procedures, work instructions, training materials, and user manuals
- Translation of generalized business expectations into precise IT project requirements
- Support of industry standardization programs (e.g. ArisGlobal Industry Standard Platform ISP) including incorporation of company needs *

* subject to acceptance of the program owner

JSC Services
Business Support (2)

With respect to change management JSC recommends a 3-step approach giving affected staff substantial time for positive re-orientation

Endings	Neutral Zone	Beginnings
• Selling the why • Anticipate / acknowledge losses • Define what is ending and what is not • Treat the past with respect • Open communication channels • Build commitment to change	• Use opportunities to try out new things • Set short-term milestones • Communication is vital: what do people need to know • Create new experiences • Monitor the transition • Provide support to staff	• Re-define performance measures • Ensure some quick successes • Engage people in defining and practicing new behaviors • Create symbols of the new beginning • Build on commitment and enthusiasm

Consistent, complete, convincing, open, and timely communication

JSC Services
Upgrade and Integration Projects (1)

In general, JSC offers a broad range of services covering the entire life cycle of IT projects in Drug Safety

Plan	Build	Run
• Conceptual design • User requirement collection • Feasibility study • Business benefit calculation • Software selection support • Project planning	• Project management • Functional specification • Interface management • Validation management • Implementation support	• User manual and training • Hand-over from project to operation • Lifecycle management • Operational support • Streamlining of maintenance processes

JSC Services
Upgrade and Integration Projects (2)

JSC has several years in-depth experience in upgrade and integration projects related to ARISg/j safety database systems

2003 … 2006	2007 … 2011	2012 … 2014
Product evaluation and decision support		Product evaluation (recommended)
ARISg v3	ARISg v5	ARISg v7
• Integration of legacy data • Version upgrade • **eReporting** implementation • eReporting roll-out • Automated case distribution to affiliates and partners	• Version upgrade • **Merge** of two Safety Databases • Call Center integration • eReporting FDA • **ARISj** implementation and eReporting PMDA • Drug Dictionary **data cleaning**	• **E2B R3** Readiness Study • **IRT** implementation (Inbound, Receipt, Triage) • **OST** evaluation (Outbound Submissions Tracking) • Evaluation of external hosting options • Version upgrade

JSC Services
Japan Integration

JSC has also in-depth knowledge for integration of Japanese affiliates into safety processes and systems

Process integration

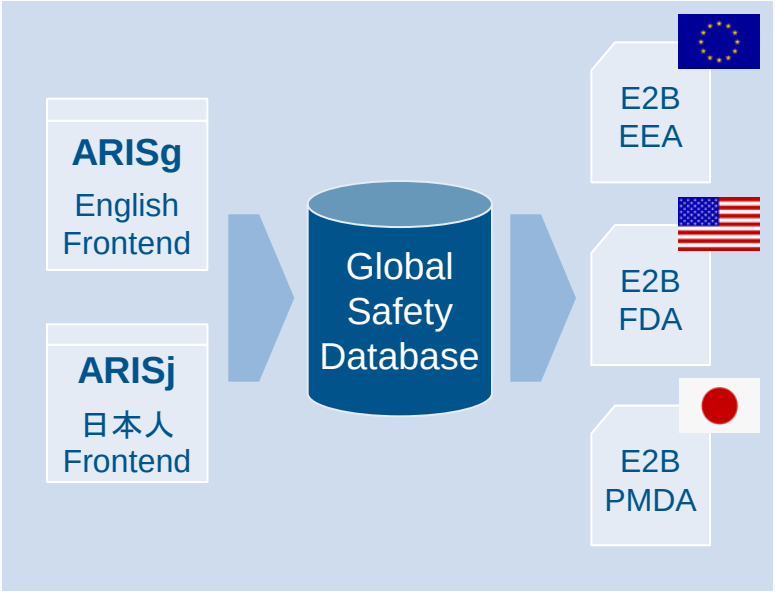
- Unification of data entry and medical assessment processes
- Integration of local assessment capabilities

Safety System integration

- Implementation of a fully integrated solution with one single global safety DB
- Integration of legacy data and decommissioning of local legacy system

Reporting to Health Authority

- Electronic reporting to Japanese Health Authority PMDA
- Cumulative reporting via JPSUR, CSUJ and customer specific Japanese reports



JSC Services
Reporting and Signal Detection

JSC has a proven track record regarding successful projects in the reporting and signal detection area which are of sensitive importance

Design and setup of a business intelligence environment incl. …

- standardized and human readable all purpose report templates for regulatory and company specific reporting requirements
- stand-alone modules for periodic and recurring reporting tasks for e.g. PSUR / DSUR, PSUSAR and for safety data exchange with partners

Implementation of a compliance tracking system incl. …

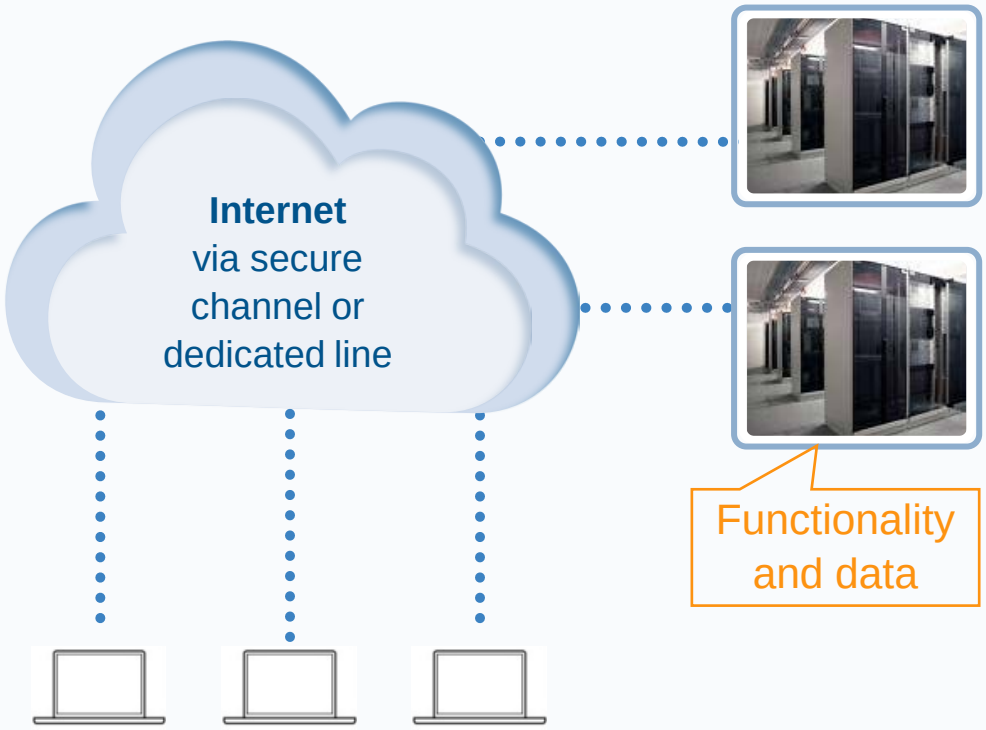
- capturing of local reporting information, identification of delays and CAPA handling
- generation of corporate compliance reports

Implementation of a signal detection environment based on agSignals incl. …

- integration of signal detection processes covering latest regulatory requirements (GVP Module VII)
- close collaboration with vendor to cover regulatory needs and client's processes

JSC Services
Evaluation of Cloud Solutions (1)

Software as a Service (SaaS) in the cloud becomes more and more attractive – its benefits are impressive …



+ Consumption is billed on utility subscription or flat rate
+ Customer can participate in EoS benefits of the cloud provider
+ High scalability via dynamic resource provision – nearly real-time
+ High flexibility with regard to locations – Internet is the common platform
+ Avoids own extensive CapEx in hardware and software

JSC Services
Evaluation of Cloud Solutions (2)

JSC is the professional partner for successful SaaS implementation since we can act on both sides: business and IT

Drug safety / pharmacovigilance

- Keep knowledge in-house for business critical processes *
- Precisely define and allocate tasks to business units, own IT and external service provider
- Timely adjust own organization / capacity according to new service provisioning model
- Prepare own organization for less “functional freedom”
- Build-up professional provider management

IT

- Consider different cloud solutions in the evaluation phase
- Safeguard control of information – check legal restrictions
- Consider impact on satellite systems ** and sensitive interfaces ***
- Precisely specify expected performance and reliability service levels
- Prefer pre-validated infrastructure environment

* e.g. product safety profiles, product risk assessment, ** e.g. reporting, signal detection,
*** e.g. clinical development: data validation and reconciliation (DVR)

JSC AG
Contact – Pharmacovigilance Services

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