Improving pharmacovigilance: Regulatory outlook and Argus Safety

Flemming Kjøller, Niels Buch Leander and Peter Stroyer Pallesen

NNIT

7th December 2017
NNIT presenters

Flemming Kjøller
Vice President
Life Sciences Sales

Niels Buch Leander
Consulting Director,
R&D consultancy

Peter Stroyer Pallesen
Senior Application Manager, Safety
AGENDA

1. NNIT overview - Flemming Kjøller
2. Pharmacovigilance in today’s digital world - Niels Buch Leander
3. Pharmacovigilance – Oracle Argus - Peter Stroyer Pallesen
4. Q&A
NNIT overview
IT for Life Sciences is our core business

- NNIT was created as the spin off of the Novo Nordisk IT organization in 1994
- ~3000 employees and one of Europe's leading consultancies in Life Sciences IT
- Clients served globally
- Life Sciences IT is our core business - practical experience within the entire pharmaceutical value chain
- Publically traded – Nasdaq Copenhagen
- 2016 results: $412M revenue, 10.6% operating margin, 8% growth
NNIT: What we do

• A wide range of IT services for Life Sciences

• Across all key functional areas of Life Sciences

• Delivered with integrated global teams...

• NNIT references in Life Sciences
Pharmacovigilance in today’s digital world
Poll:
How many safety cases does your company have (yearly)?

A. Less than 50
B. 50-500
C. 500-10000
D. Above 10000
The importance of pharmacovigilance

- The challenge of maximizing drug safety and maintaining public confidence has become increasingly complex.

- Pharmaceutical and biotechnology companies must not only monitor, but also proactively assess and manage drug risk throughout a product’s lifecycle, from development to post market.
Overview of Good Pharmacovigilance Practice

GVP MODULES

I Pharmacovigilance systems and their quality systems
II Pharmacovigilance System Master File
III Inspections
IV Audits
V Risk Management Systems
VI Management and reporting of ADR
VII PSUR
VIII Post-authorization safety studies
IX Signal Management
X Additional Monitoring
XI
XII
XIV
XV Safety Communication
XVI Risk minimization measures
Elements of pharmacovigilance – module VI + (VII)

CASE HANDLING

Individual Case Safety Report (ICSR) → Coding of adverse event → Seriousness determination

SUBMISSION

Expedited reporting

Aggregated (periodic) Reporting

Clinical Trial Reporting
Sources of signals – GVP Module IX

Sources of data and information

- Spontaneous ADR reporting systems
- Pharmacoepidemiological studies
- Active Surveillance Systems
- Scientific Literatures
- Clinical trials
- Non-clinical trials
- Non-interventional studies
- Systematic reviews
- Meta analysis
- Aggregated reports with statistical analyses
- Vaccine Surveillance Systems

EudraVigilance

ICRS
- Literature
- From MAH:
  - Variation
  - Renewal
  - PSUR
  - RMP
- Benefit risk monitoring of medical products
- Poison centers

NNIT
Trend: Patient empowerment is changing the conditions for pharmacovigilance

- Patients are better informed
- Patients digitally empowered, bypassing existing processes
- Remote monitoring is possible
- Genomics/personalised medicine redefining therapies
- Patients will pay bigger role in medicine selection and payment
- Patient pool increasingly global
- Wearables + Patient-engagement platforms
Trend: Patient empowerment is changing the conditions for pharmacovigilance

Sources of safety cases

- Expected increase in cases from consumers

Source: WHO 2008
Trend: A strengthening ecosystem of Pharma and Healthcare, based on data collaboration
Pharmacovigilance trends

**Business area focus:**
- Main focus is the move to new data model E2B(R3), which is being rolled out globally, FDA CBER Vaccines in E2B(R3) from Q1 2017, EMA from Q4 2017
- Centralization of safety reporting at EMA from Nov 2017
- PV is moving closer to Regulatory Affairs, organizationally and data-wise
- Increased focus on device safety (eMDR in US and upcoming medical device regulation in EU)

**Trends and new technologies**
- Safety databases are mature
- Next focus will be on BI, integration, planning tools and process automation
- Beginning inquiry into artificial intelligence and big data for better signal detection
- Future requirements on social media monitoring

**Safety vendors:**
- Area dominated by Oracle Safety, followed by Aris Global ArisG.
- Traditional Safety vendors will be challenged by R&D suite vendors such as Veeva and Amplexor
The benefits of Safety databases

- Reporting and analytics
- Safety functionality
- Data-driven decisions
- Collaboration and data sharing
- Data standardization and data quality

DVCMN - December 2017
Poll:

How are you managing pharmacovigilance today?

A. On paper documents
B. With Excel
C. With Excel + a simple database
D. With a Safety IT system
Moving from Excel to System sets a crossroad in the Safety strategy
Benefits of moving to a system based PV setup

Automation of data entry and case handling processes - adapted to specific business process

High compliance in Expedited Reporting based on standard reports, configured workflows and submission rules

Compliant Configurable Periodic Reports and line listings

Safety data consolidated in one system supporting all PV processes
4 considerations when moving from Excel to System based approach

01 Overview of existing Pharmacovigilance processes and Metrics

- Assess benefits (process and quality improvements) vs. effort – e.g. data sources, workflows, number of cases, product portfolio and reporting obligations

02 Migration of data and configuration for follow-up and periodic reporting in the new system

- Source and quality of existing data
4 considerations when moving from Excel to System based approach

03 Users & Training
- Accesses, privileges, responsibilities, SOPs

04 Technical Integrations
- Which existing integrations exist? E.g. Reporting tools, Case intake, Analytics etc.
- Do they become obsolete or should they be include in the new setup?
Why Oracle Argus?

Argus is a standard software solution that is kept up to date with the latest global regulations while at the same time being configurable to allow adaption to specific business processes.

Oracle Argus is the leading solution for handling of Pharmacovigilance processes. This makes it future proof.

With NNIT hosting the cloud solution, you do not have to worry about (or validate) the infrastructure, software maintenance and the core application configuration.
Argus Configuration overview

- The **Product** Portfolio, **Studies** and **Reporting rules** comprise the core Business configuration.

![Diagram showing the relationship between Licenses/Registrations, Products, and Prod. Families with Study Configuration and Reporting Rules highlighted.](image-url)
Main Features of Argus

- Centralized and Automated coding
- Automated and fully traceable submission
- Improvement of Case Handling processes
- Automated data quality assurance
- Configurable Auto cover letters
- Configurable standard Reports
- Periodic Reports
- Validation Rules
- User groups, Workflows and Priority
- Reporting Destinations
- Term and Drug Dictionaries
- Case processing automation
- Letter Templates
- Product Portfolio, Studies & Reporting obligations

Modules
- Japanese/Chinese
- Empirica
- Dossier
- Affiliate
- BIP Reports
- Insight
- Documentum
Argus Safety Introduction

• Typical Argus Safety workflow
Argus Safety Bookin & Intake

Coding of Products & Events

Duplicate search
Worklists example (New case)

Worklists provides overview and assists with case assignment.
Argus Safety Case Processing - General

Dynamic workflow status

The General tab contains core details of the case, the reporter of the case and any literature references.
Argus Safety Case Processing - Patient

This tab contains details on the patient including medical history and available lab data.

Coding against MedDRA.
The product tab contains details of the suspect vaccine(s) and concomitant product(s).

Products are selected from the Company (Argus) - and WhoDrug Dictionaries.
Argus Safety Case Processing - Events

Coding of Events
The Assessment tab contains the assessment of causality for all suspect product / event pairs and assessment of Listedness for all related Licenses/Registrations.
Argus Safety Case Processing - Analysis

The Analysis tab contains narratives and overall case assessments.

Often these are auto-generated.
This tab contains actions, letters and routing details
Argus Safety Case Processing - Additional

Additional information contains Attachments and other references
Argus Safety – Regulatory Reports

Manual and automated scheduling
Submission Worklist Example

Tracking of Expedited report submissions
Periodic reports templates include commonly used, configurable formats – e.g.:
- ICH PSUR
- CTPR
- IND
- NDA
- Case Data Analysis

BI Publisher can be used for more advanced visual formatting
Steps to use the system

**STEP 1**  ➔  **STEP 2**  ➔  **STEP 3**  ➔  **STEP 4**
Configuration of business specific settings
Setup custom integrations (if required)
Migrate existing data into the system
Training & SOP updates

**STEP 5**  ➔  **STEP 6**  ➔  **STEP 7**
Expedited Submission testing if Gateway solution is used
User acceptance testing and Qualification of business requirements
Go live
Project Plan (Example)

MONTH 1
- Requirement specification
- Configuration & Integrations

MONTH 2
- Data migration specification
- Data Migration (Test)
- Informal Testing
- System Testing
- SOPs
- Super User Training

MONTH 3
- End User Training
- UAT & Qualification
- Cut-over / Go-live
Key take-aways from this webinar

A Safety database increases compliance by centralizing and harmonizing safety information

Consider who else inside or outside your organization uses your pharmacovigilance data

Oracle Argus is the leading Argus Safety software, compliant with all regulations

Patients are being increasingly empowered and their data is being increasingly exchanged electronically

Monitor increasing global regulatory requirements, especially in pharmacovigilance

NNIT is a leading life sciences service partner, implementing, hosting and managing Oracle Argus.
Q&A

Flemming Kjøller
Vice President
Life Sciences Sales
feke@nnit.com

Niels Buch Leander
Consulting Director,
R&D consultancy
nbin@nnit.com

Peter Stroyer
Pallesen
Senior Application
Manager, Safety
pbnd@nnit.com