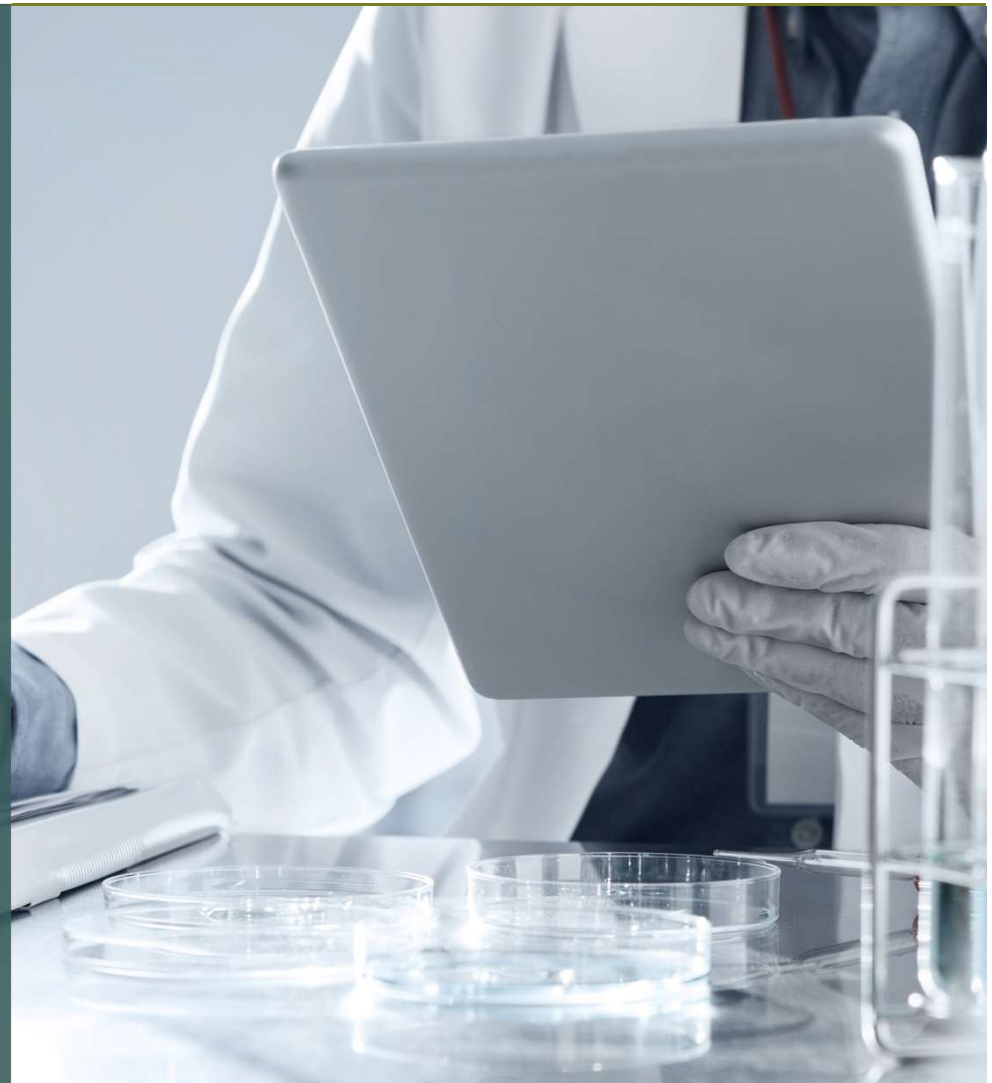


Improving pharmacovigilance: Regulatory outlook and Argus Safety

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,
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**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

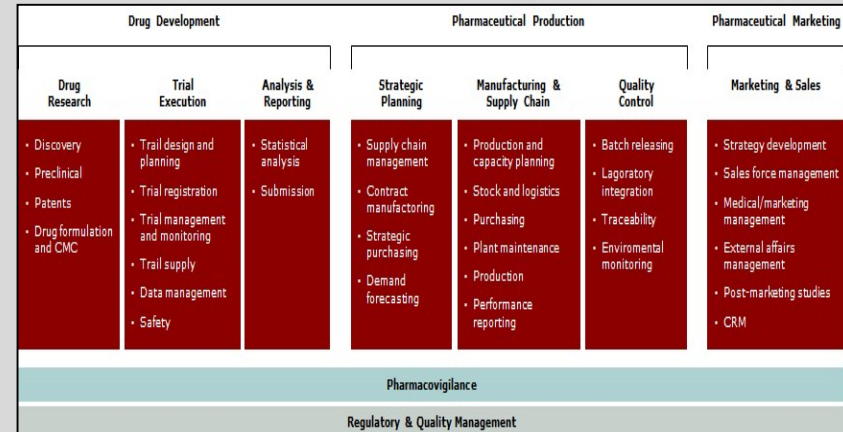
- A wide range of IT services for Life Sciences



- Delivered with integrated global teams...




- Across all key functional areas of Life Sciences



- NNIT references in Life Sciences





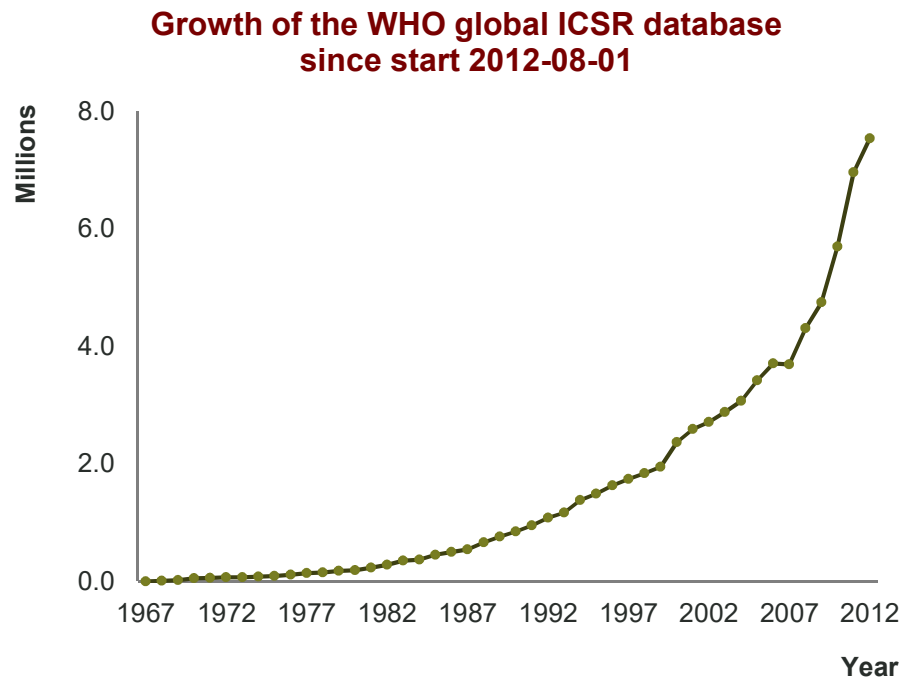
Pharmacovigilance in today's digital world

Poll:

How many safety cases does
your company have (yearly)?

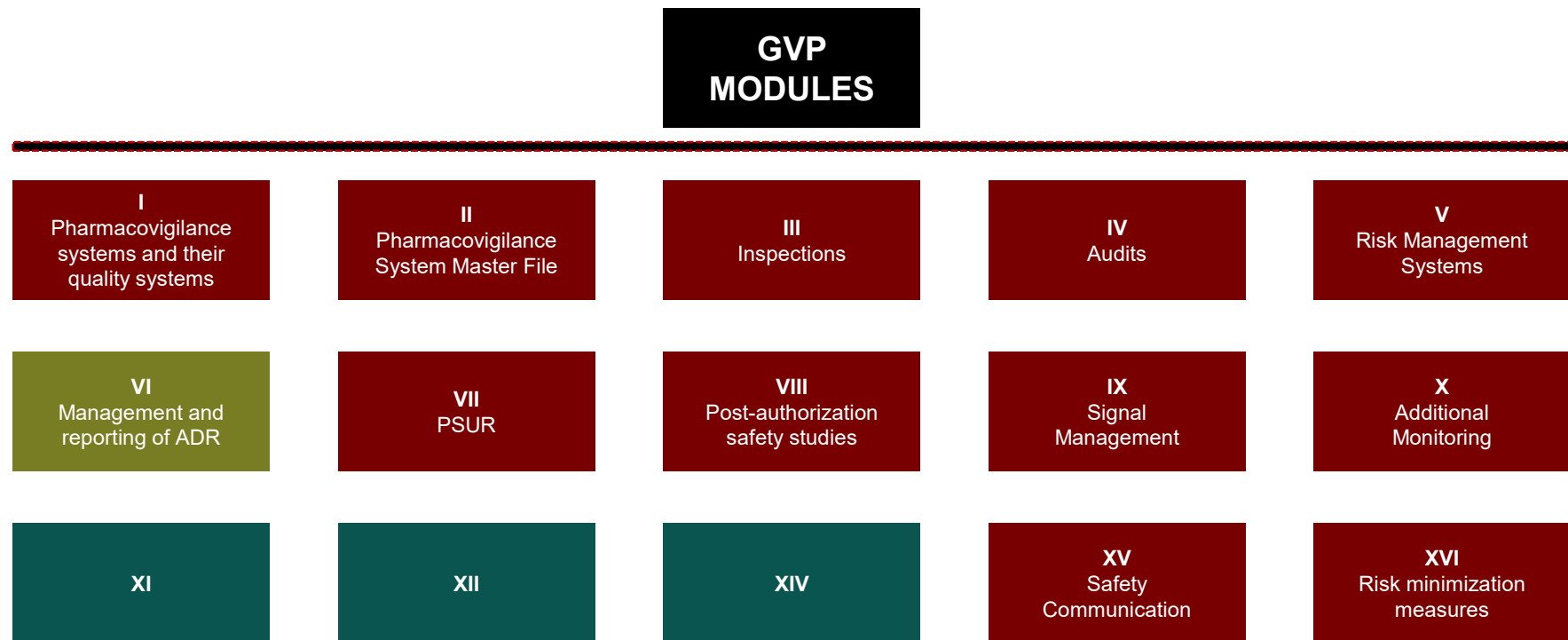
- A. Less than 50
- B. 50-500
- C. 500-10000
- D. Above 10000

The importance of pharmacovigilance

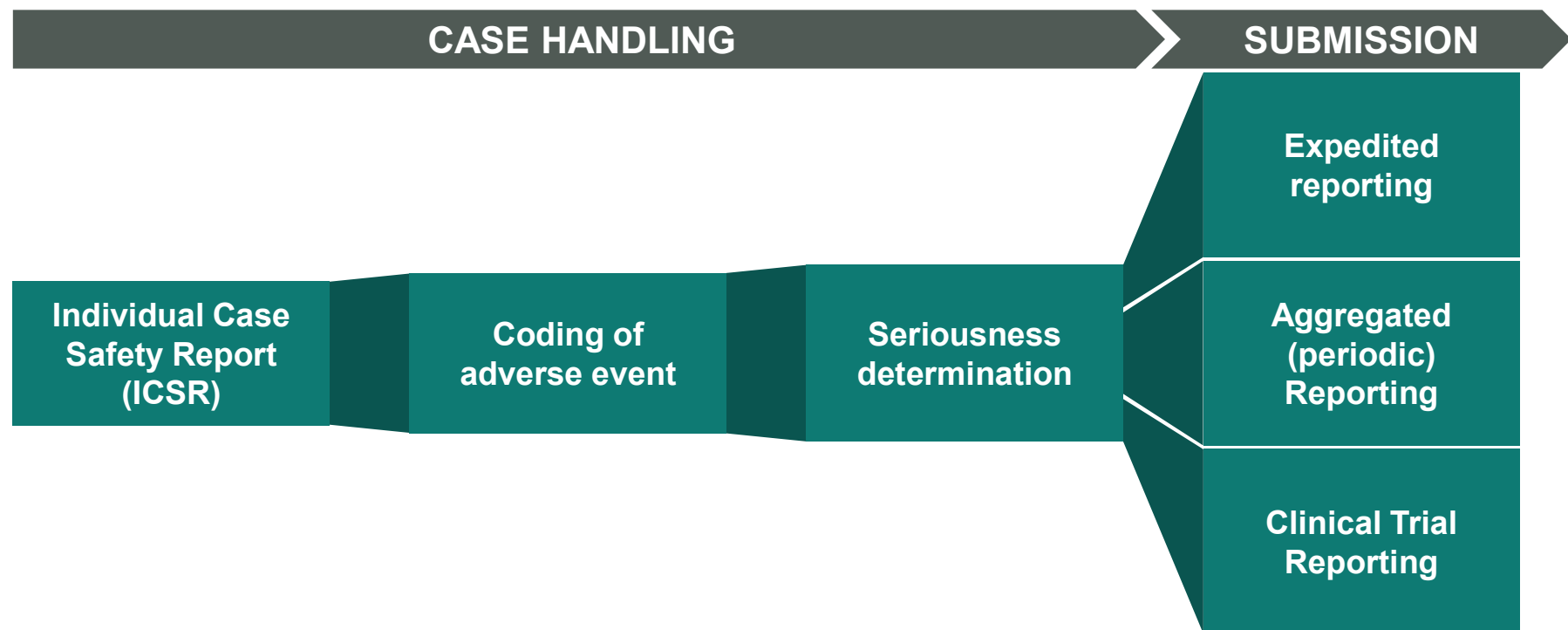


- The challenge of maximizing drug safety and maintaining public confidence has become increasingly complex.
- Pharmaceutical and biotechnology companies must not only monitor, but also proactively assess and manage drug risk throughout a product's lifecycle, from development to post market.

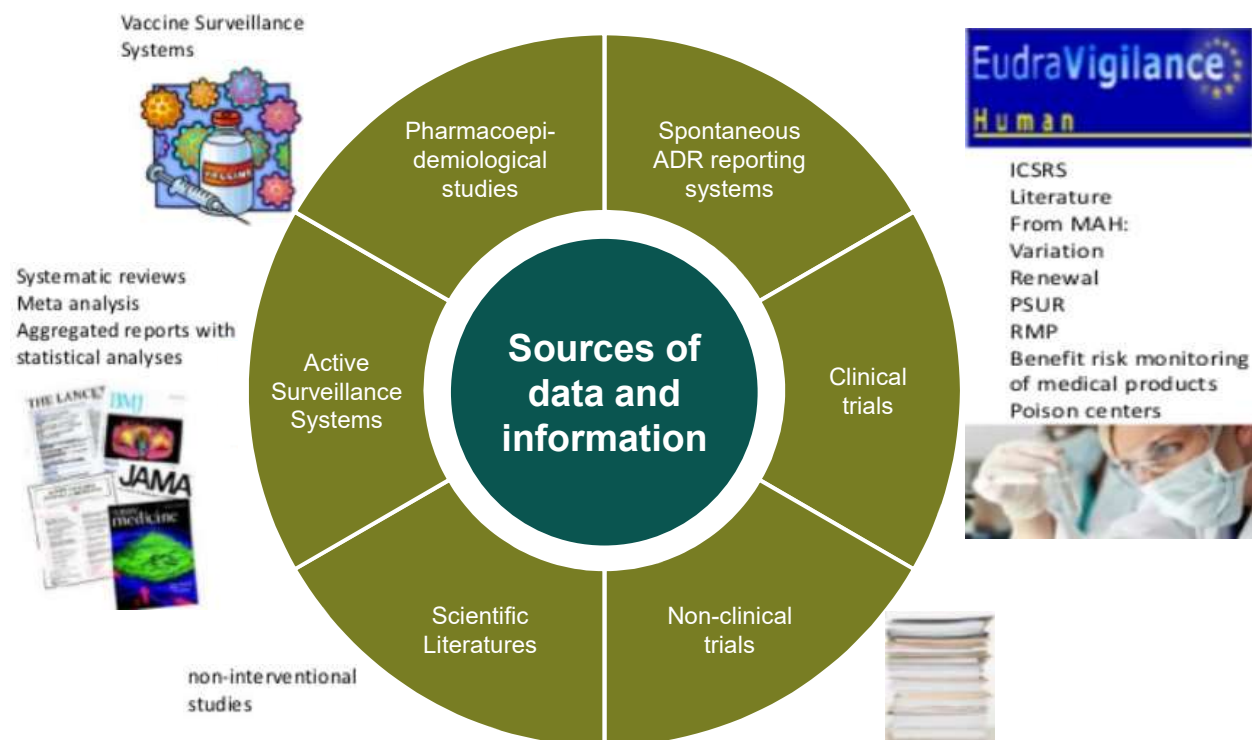
Overview of Good Pharmacovigilance Practice



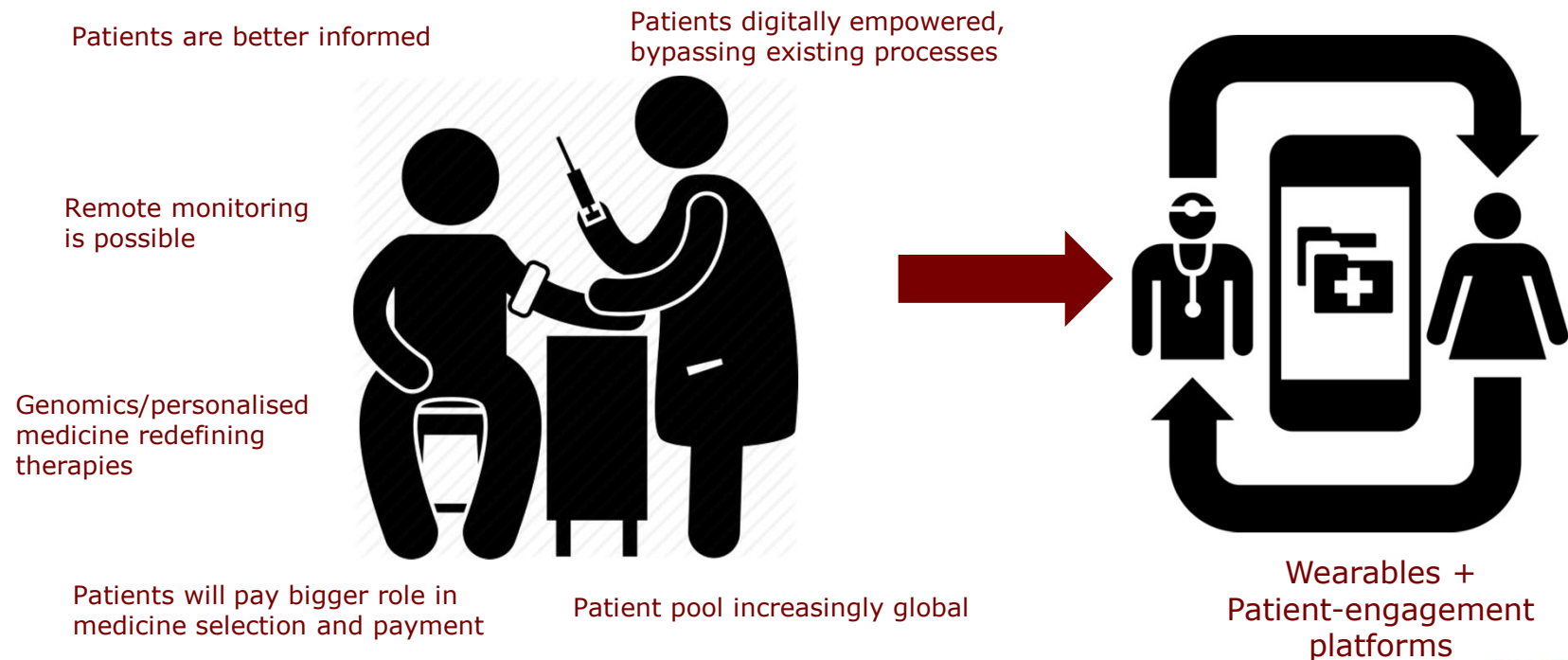
Elements of pharmacovigilance – module VI + (VII)



Sources of signals – GVP Module IX

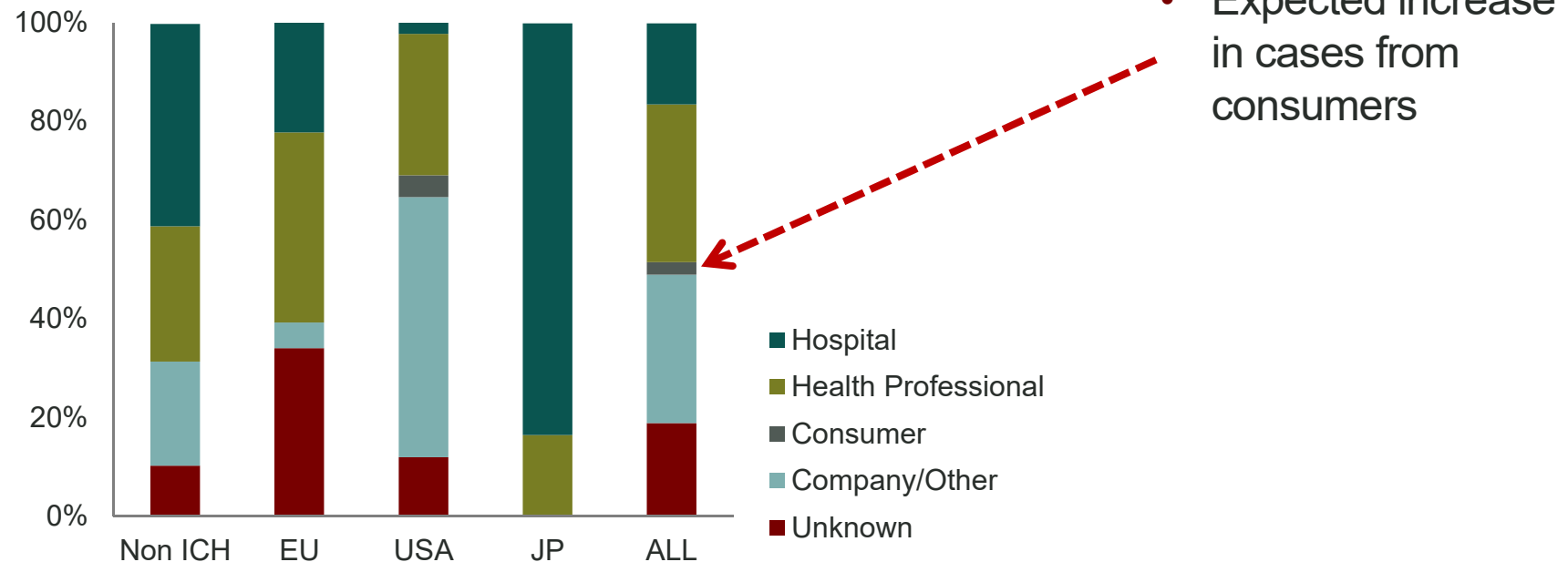


Trend: Patient empowerment is changing the conditions for pharmacovigilance



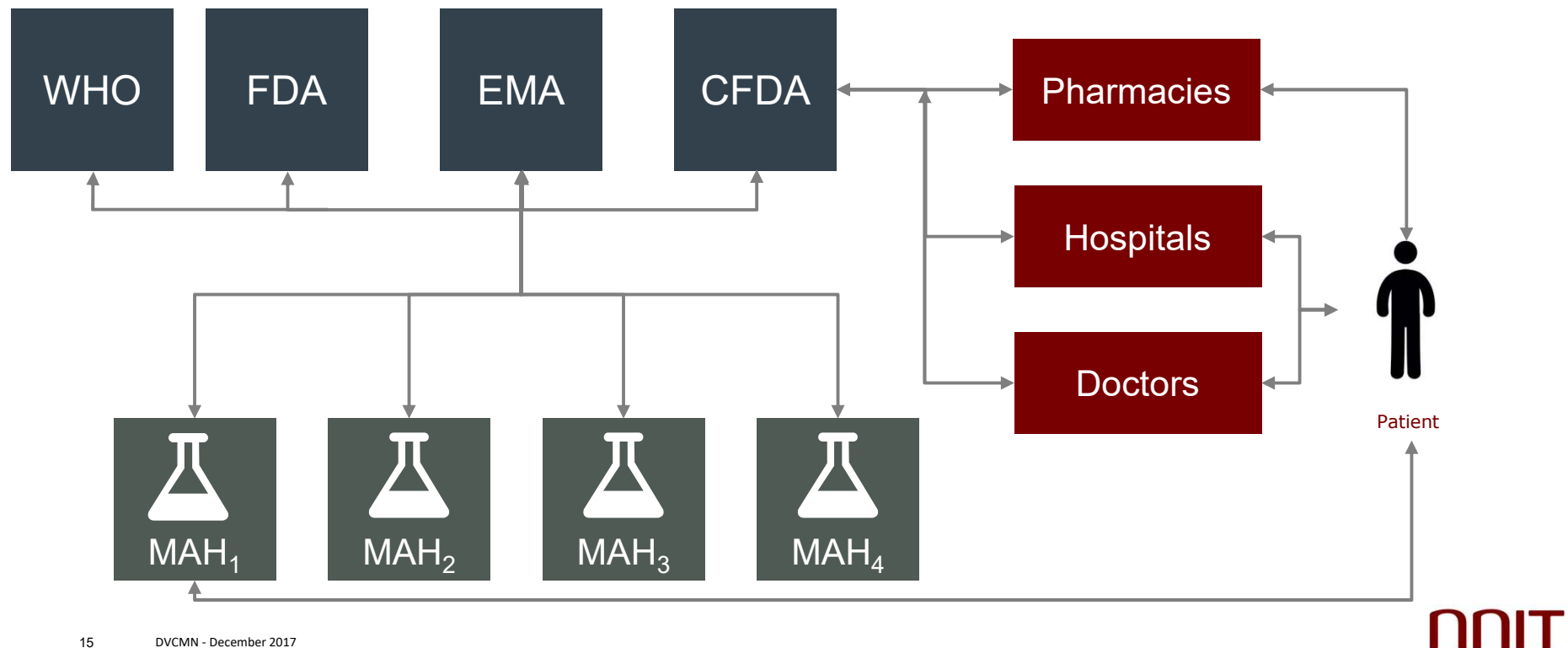
Trend: Patient empowerment is changing the conditions for pharmacovigilance

Sources of safety cases



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:

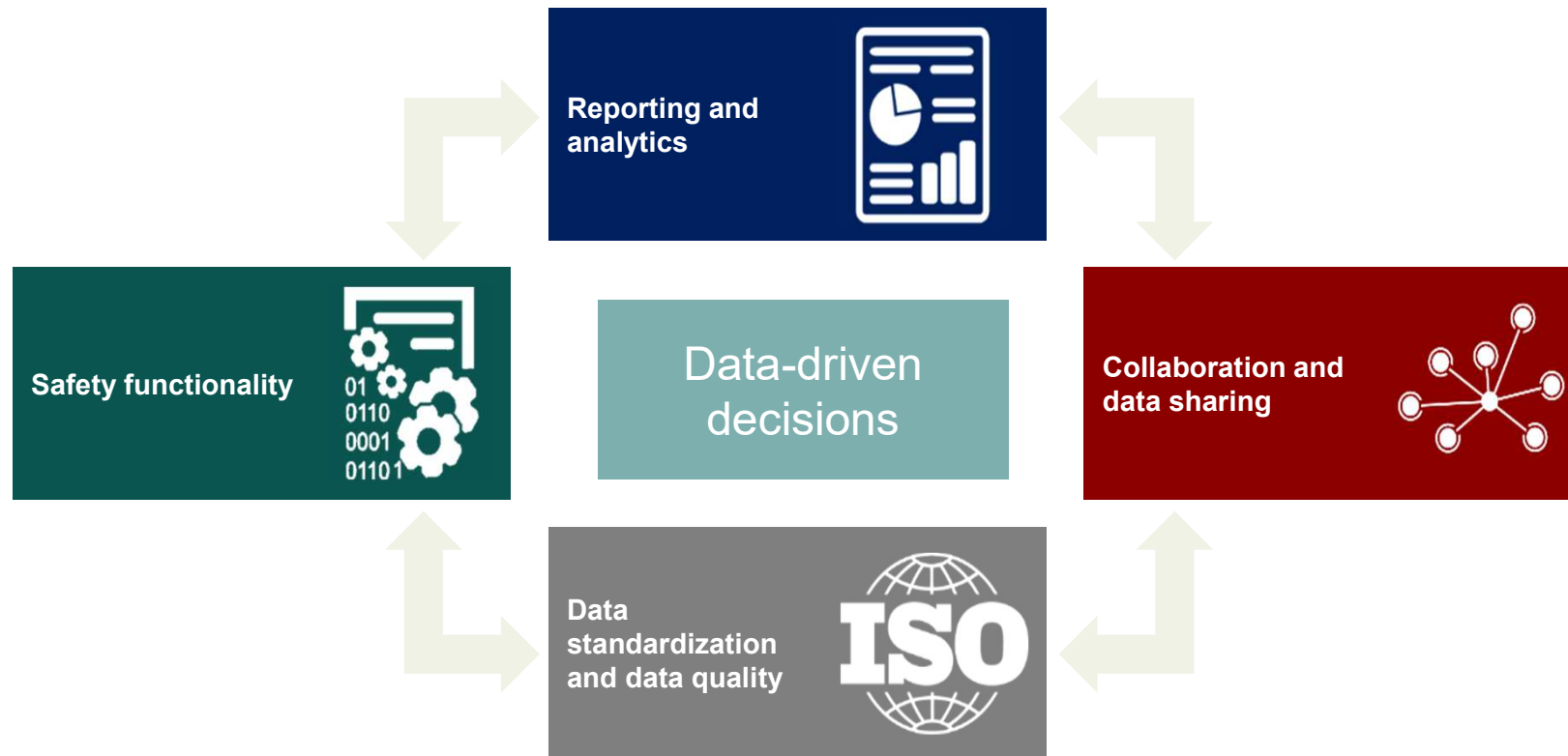
- Area dominated by Oracle Safety, followed by Aris Global ArisG.
- Traditional Safety vendors will be challenged by R&D suite vendors such as Veeva and Amplexor

ORACLE®

 **ArisGlobal**
We Bring the Future to Life™

nnit

The benefits of Safety databases



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

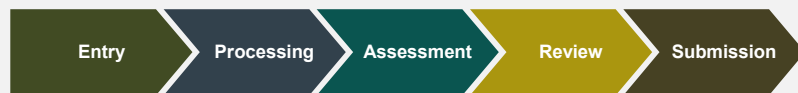


Safety data consolidated in one system supporting all PV processes

4 considerations when moving from Excel to System based approach

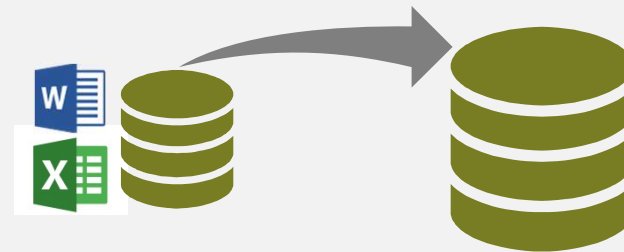
01 Overview of existing Pharmacovigilance processes and Metrics

- 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

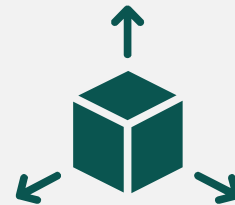
03 Users & Training

- 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?



#1



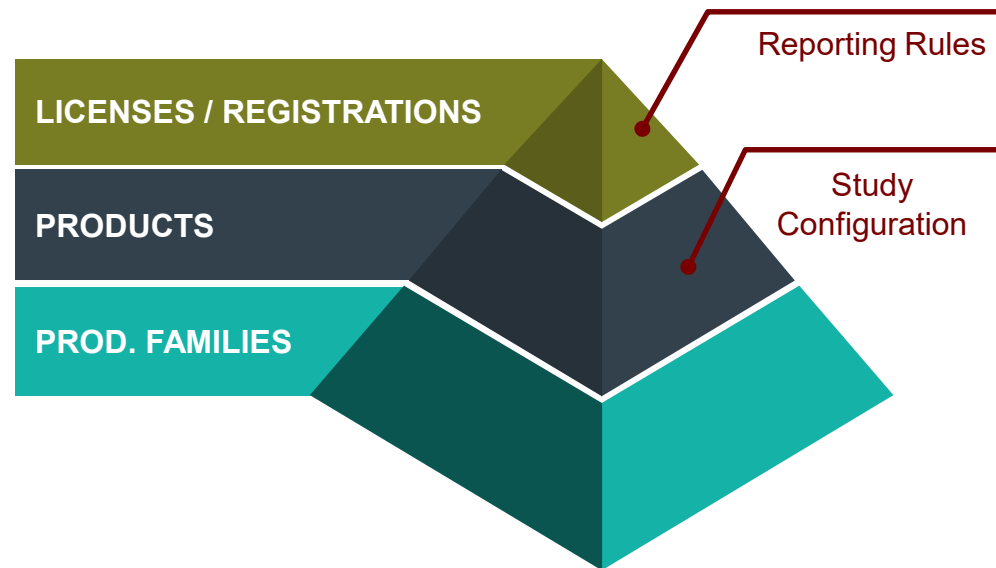
Argus is a standard software solution that is kept up to date with the latest global regulations while at the same time being configurable to allow adaption to specific business processes

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

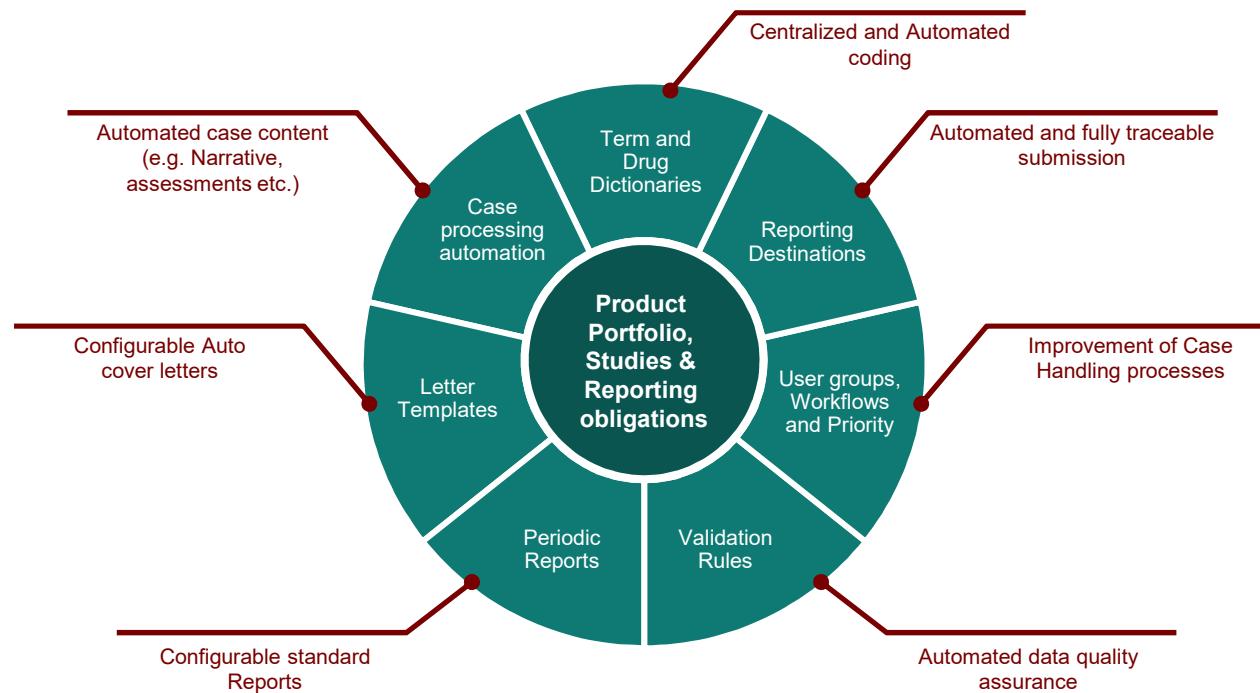
With NNIT hosting the cloud solution, you do not have to worry about (or validate) the infrastructure, software maintenance and the core application configuration

Argus Configuration overview

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



Main Features of Argus



Modules

- Japanese/Chinese
- Empirica
- Dossier
- Affiliate
- BIP Reports
- Insight
- Documentum

Argus Safety Introduction

- Typical Argus Safety workflow



Argus Safety Bookin & Intake

Initial Case Entry

Case Search Criteria

☐ Initial Receipt Date
 ☐ Receipt Range Limits 06-OCT-2017 - 03-FEB-2018

General

Initial Receipt Date

05-DEC-2017

Project ID

Product Name

AlaniOne

Description as Reported

headache

Central Receipt Date

05-DEC-2017

Study ID

Country

DENMARK

Center ID

Generic Name

ALANINE

Onset Date/Time

05-DEC-2017 07:17

Report Type

Initial Justification

Reporter

Sal.

First Name

Middle Name

Last Name

Suffix

Institution

Institution ID

Department

Mr

Peter

Pallesen

Country

State

Postal Code

Intermediary

DENMARK

Patient

First/Last Name or Initials

Pat. ID

Date of Birth

Age

Units

Gender

Jd

02-MAY-2001

16

Years

Male

Literature Reference

ID

Keywords

Journal

Title

☐ Full Search (Like, soundex)

Search

Continue

Cancel

Bookin

Seriousness Criteria

☐ Death
 ☐ Hospitalized

☐ Congenital Anomaly
 ☒ Life-threatening

☐ Disability
 ☐ Intervention Required

☐ Medically Significant
 ☐ Other:

Reported Causality

Possible

☐ Case is Non-Serious
 ☐ Unable to Determine

Attachments and References

#

Classification

Description

Add

Delete

Product Browser - Webpage Entry

http://52.244.253.226/8531/lookup/Product/lookup.asp?SP111455-BSearch drug_code=Bsearch_name=dalmaneBsearch_country=46-576-0CAT56-42792654

Product Browser

☐ Full Search

Drug Code	Country	Trade Name	Ingredient
ALANINE	AbenOne	AbenOne Injection, 200 microgram, heparins	AbenOne (DENMARK)

Family:

Ingredient:

Product Name:

Trade Name:

Coding of Products & Events

Duplicate search

Worklists example (New case)

ORACLE Argus Safety

Welcome GuestAccess1, Tuesday, December 5, 2017 (ARGCLD) Home

Active Case Worklist Case Actions Reports Utilities Dashboards Version Control

Worklist > New

NEW

Search Case

Filter Value

Case Number Search

☐ Only view locked Cases requiring Follow-up

Open

View ☒ Individual ☐ Group ☐ All

Total Number of Rows (9) Displaying Rows 1-9 Page Size 100

Lock State	Priority SUSAR	Receipt Date Aware Date	Days Open/ Remaining	Case Number Workflow State / Group	Product Name Generic Name	Event PT Event Verbatim	S/U/R F, LT or H	Case Type Study ID	Reporter Type Country	Assigned To Owner
<input type="checkbox"/> Initial	4	30-Nov-2017 30-Nov-2017	5 0	17DK000011 Data Entry /ArgusUser	Allergic WonderOne Product One	Loss of consciousness Fainted	Y/Y/Y H	Spontaneous	Physician US	(Unassigned) (Unassigned)
<input type="checkbox"/> Initial	4	01-Dec-2017 01-Dec-2017	4 1	17DK000012 Submission /ArgusUser	AlaniOne ALANINE		Y/N/Y No	Spontaneous	Physician DENMARK	(Unassigned) GuestAccess1
<input type="checkbox"/> Initial	4	01-Dec-2017 01-Dec-2017	4 6	17DK000013 Data Entry /ArgusUser	Allergic WonderOne Product One		Y/Y/Y No	Spontaneous	DENMARK	(Unassigned) (Unassigned)
<input type="checkbox"/> Initial	4	05-Dec-2017 05-Dec-2017	0 10	17DK000014 Data Entry /ArgusUser	AlaniOne ALANINE		Y/N/Y No	Spontaneous	Physician DENMARK	(Unassigned) (Unassigned)
<input type="checkbox"/> Initial	4	05-Dec-2017 05-Dec-2017	0 10	17DK000015 Data Entry /ArgusUser	AlaniOne ALANINE		Y/N/Y No	Spontaneous	Physician DENMARK	(Unassigned) (Unassigned)

Routing Details

Case Locked: testing

Print List

Worklist Case Actions

- New
- Open
- Action Items
- Contacts
- Reports
- Bulk Transmit
- Bulk Print
- Bulk ICSR Transmit
- Local Labeling
- Letters
- Intake

Worklists provides overview and assists with case assignment

Argus Safety Case Processing - General

Oracle Argus Safety
Welcome GuestAccess1, Tuesday, December 5, 2017 (ARGCLD) Home Help Logout

Active Cases Worklist Case Actions Reports Utilities Dashboards Argus Console

Case Form - 17DK000015 "PP" Case Priority : 4 Case Status : **Data Entry**

General Patient Products Events Analysis Activities Additional Information Regulatory Reports

General Information

Report Type: Spontaneous Country: DENMARK
Initial Receipt Date: 05-DEC-2017 Central Receipt Date: 05-DEC-2017 Medically Confirm: Yes Initial Justification:
Amendments / Follow-ups (0) Case Requires Follow-up:
Follow-up Received Safety Received Significant Data Clean Up Amendment Amendment / Follow up Justification

Reporter Information (1) Select

Sal: Mr First Name: Peter Middle Name: Last Name: Pallesen Suffix: Health Care Professional: Yes Occupation: Medical Assistant Report Sent to Regulatory Authority by Reporter?:
Address 1: Ostmarken 4 Institution: Institution ID: Department: City: Seborg
Address 2: State: Postal Code: 2860 County:
Phone Number: Alternate Phone: FAX Number: Reporter ID: Reporter's Reference #:
Email Address: Reporter Type: Physician Report Media: Intermediary:
P PALLESEN, Peter (Physic... (New)

Classification

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

Case Form - 17DK000015 "PP" Case Priority : 4 Case Status : Data Entry

General Patient Products Events Analysis Activities Additional Information Regulatory Reports

Patient Parent

Patient Information

Title First Name MI Last Name Initials
Address 1 City Country
Address 2 State Postal Code Phone Number Email Address

Patient Details

Date of Birth Age Units Age Group Height Weight
Gender Pregnant Date of LMP
Occupation Age at Vaccination Units (at Vaccination) Ethnic Group Military Status

Event Death Details

Other Relevant History (1)

#	Start / Stop Date / Ongoing / Age / Units	Condition Type / Verbatim / Product Identifier Type / Product Identifier / Version / Indication / Reaction	Coded PT / Description of condition LLT / Substance Information / Product Name Parts Information / Indication PT / Reaction PT	Notes
	01-JAN-2016 ??-??-0000	Current Condition allergy	Hypersensitivity Allergy	

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

Coding against MedDRA

Argus Safety Case Processing - Vaccines

Case Form - 17DK000015 "PP"

Case Priority : 4 Case Status : Data Entry

General

Patient

Products

Events

Analysis

Activities

Additional Information

Regulatory Reports

05d 07h 21m 23s

10d 14h 48m 26s

05d 07h 21m 23s

10d 14h 48m 26s

AlaniOne

VC

(New)

Vaccine

Product Information

Product Name

Select

Encode

AlaniOne

Generic Name

ALANINE

Product Identifier Type

Product Identifier

Version

Company Drug Code

Obtain Drug Country

Drug Code

WHO Medicinal Product ID

Formulation

Injection

Manufacturer

Concentration

Units

Interaction?

Contraindicated?

of Siblings

Birth Weight

lbs/ozs

grams

Drug Not Administered

Substance Information (1)

#

Substance Name

Substance Term ID

Version

Strength

Unit

1.

ALANINE

Product Name Parts Information (0)

#

Name Part Type

Name Part

Product Indication (1)

#

Reported Indication

Coded Indication

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

Case Form - 17DK000015 "PP" Case Priority : 4 Case Status : Data Entry

General Patient Products Events Analysis Activities Additional Information Regulatory Reports

Event Event Assessment

Headache (New)

Event Information

Description as Reported: Headache

Original Language: English

Diagnosis: ☒ Diagnosis ☐ Symptom

Medical Confirmation by HCP: ☒ Yes ☐ No

Description to be Coded: headache

Onset Date/Time: 05-DEC-2017 07:17

Onset Latency: NF

Onset From Last Dose:

Receipt Date: 00-MMM-0000

Stop Date/Time: ??-??-0000 00:00

Intensity:

Frequency:

Patient Has Prior History?:

Country in which Event Occurred:

Outcome of Event: Recovered

Event Coding

System Organ Class (SOC) (Code): Nervous system disorders (10029205)

High Level Group Term (Code): Headaches (10019231)

High Level Term (Code): Headaches NEC (10019233)

Preferred Term (Code): Headache (10019211)

Lower Level Term (Code): Headache (10019211)

Synonym (Code):

Seriousness Criteria

☐ Death ☒ Medically Significant

☐ Hospitalized ☐ Life-threatening

☐ Disability ☐ Intervention Required

☐ Other: ☐ Congenital Anomaly

Details

Possible

MedDRA Browser - Webpage Dialog

MedDRA Browser

Current Coding Version: Draft 17.1

Search All Levels

Full Search

Include Non-current terms

SOC: Nervous system disorders

HLGT: Headaches

HLT: Headaches NEC

LLT: Headache

Synonyms: Headache (concept), Migraine (aggravated), Headache (not migraine), Aggravated, Headache aggravated, Headache drug withdrawal, Headache dull, Headache fulminant, Headache fulminant, Headache H2S, Headache H2S aggravated, Headache occurring, Headache post-traumatic, Headache postoperative, Headache recurrent, Headache severe, Headache temporal

Coding of Events

Argus Safety Case Processing - Assessments

Case Form - 17DK000015 "PP" Case Priority : 4 Case Status : Data Entry

General Patient Products **Events** Analysis Activities Additional Information Regulatory Reports

Event **Event Assessment** 05d 07h 20m 38s 10d 14h 47m 41s

Recalculate

Product	Causality as Reported Source / Method / Result Causality as Determined Source / Method / Result Other Causality Source / Method / Result	D/S	Seriousness Severity Duration	Data Sheet	License	As Determined Listedness
--All--	Event PT (Description) / LLT --All--	--All--		--Assigned--	--Assigned--	
VC UK US AlaniOne ALANINE	Health Care profession MAH Headache (Headache) Headache	Global Introspection Global Introspection 	Possible Possible 	D	MS	DataSheet Main
					DK (Mkt.) US (Mkt.)	Listed Labeled Labeled

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 screenshot displays the 'Analysis' tab of the Argus Safety Case Processing interface. The window title is 'Case Form - 17DK000015 "PP"'. The top navigation bar includes tabs for General, Patient, Products, Events, Analysis (selected), Activities, Additional Information, and Regulatory Reports. The Analysis tab is further divided into sub-tabs: Analysis, MedWatch Info, BfARM Info, and AFSSaPS Info. The main content area is titled 'Case Analysis' and contains several text input fields: 'Narrative', 'Case Comment', 'Local Evaluator Comment', 'Abbreviated Narrative', 'Company Comment', and 'Evaluation in light of similar events in the past'. Each field has a 'Generate' button with a flag icon. Below the text fields is a 'Case Summary' section with a table of dropdown menus and notes.

Case Summary		
Case Serious	Yes	Notes:
Company Agent Causal	Yes	Notes: Not specified
Listedness Determination	Listed	Notes: Not specified
Case Outcome	Recovered	

The Analysis tab contains narratives and overall case assessments.

Often these are auto-generated.

Argus Safety Case Processing - Activities

The screenshot shows the Argus Safety Case Form for Case 17DK000015 'PP'. The 'Activities' tab is selected, showing a list of activities with columns for Date, Code, Description, and Group User. The 'Contact Log' section shows one entry for 'Letter to primary source' dated 05-DEC-2017. The 'Action Items' section shows one entry for 'Retrieve sample of vaccine' dated 10-DEC-2017. The 'Routing Comments' section shows one comment dated 05-DEC-2017 09:05 stating 'Automated initial case routing set responsible group to "ArgusUser".'

#	Date	Code	Description	Group User
1.	05-DEC-2017		Letter to primary source	ArgusUser
2.	00-MMM-0000			GuestAccess1

#	Date Open / Due / Completed	Code	Description	Group User
1.	05-DEC-2017 / 10-DEC-2017 / 00-MMM-0000		Retrieve sample of vaccine	ArgusUser
2.	00-MMM-0000 / 00-MMM-0000 / 00-MMM-0000			GuestAccess1

#	Date	User	Comment
1.	05-DEC-2017 09:05	GuestAccess1	Automated initial case routing set responsible group to "ArgusUser".

This tab contains actions, letters and routing details

Argus Safety Case Processing - Additional

Case Form - 17DK000015 "PP" Case Priority : 4 Case Status : Data Entry

General Patient Products Events Analysis Activities Additional Information Regulatory Reports

05d 06h 06m 04s 10d 13h 33m 07s

Notes and Attachments (1)

Attach File Add Delete

#	Classification Date / Incl. Reg. Sub	Keywords Description	
1.	Photograph 05-DEC-2017	Photograph of patient injection site reaction	Select
2.	00-MMM-0000		Select
3.	00-MMM-0000		Select

References (2)

Select Add Delete

#	Type	ID	Notes
1.	E2B Company Number	DK-NNIT-17DK000014	
2.	Source Case	17DK000014	Original Case : 17DK000014
3.			
4.			

Additional
information
contains
Attachments
and other
references

Argus Safety – Regulatory Reports

Case Form - 17DK000015 "PP" Case Priority : 4 Case Status : Data Entry

General Patient Products Events Analysis Activities Additional Information Regulatory Reports 05d 06h 03m 46s 10d 13h 30m 49s

Regulatory Reports Organized by Report Type / Submit Category / Reporting Destination

Reports (2)

- Expedited (2)
 - Pending (2) by Destination
 - FDA_R2 (1)
 - FDA_eVAERS (1)
 - Submitted (0) by Destination
 - Marked as Non Submit (0) by Destination
 - Periodic (0)
 - Pending (0) by Destination
 - Submitted (0) by Destination

Total Number of Rows (2)

Status	Destination	License Type	Generated Local Comment	Submitted	Due	Responsible
Seq	Report Type	License #		Notes		
Initial	Draft FDA_R2	Marketed			15-DEC-2017	
Final	E2B		N	Auto-scheduled; FDA - 10d E2B R2 Spon Marketed; AlaniOne(Alanik		
Initial	Draft FDA_eVAERS	Marketed			15-DEC-2017	
Final	eVAERS		N	Auto-scheduled; FDA - 10d E2B R3 Spon Marketed; AlaniOne(Alanik		

Auto Schedule Schedule New Report Auto Schedule Later Schedule Local Reports Only

Argus Safety 3.3 Argus Web ICSR Viewer

Report Type: Initial Sender's Case Number: 17DK000015 View Format: Decoded View

Report Identification Number: 17DK000015 DTG Version: 2.1

Field	Field Type	Description
A.1	Identification of the case safety report	
A.1.1	Safety Report Version Number	1
A.1.1.1	Sender's (Case) Safety Report Unique Identifier	DK-NNT-17DK000015
A.1.1.2	Identification of the country of the primary	DK (DENMARK)
A.1.1.3	Identification of the country where the reaction/event occurred	DK (DENMARK)
A.1.3a	Date of this transmission (format)	102 (CCYYMMDD)
A.1.3b	Date of this transmission	20171205 (5-DEC-2017)
A.1.4	Type of report	1 (SPONTANEOUS)
A.1.5.1	Serious	1 (YES)
A.1.5.2	Seriousness criteria-Results in death	2 (NO)
A.1.5.2	Seriousness criteria-Life threatening	2 (NO)
A.1.5.2	Seriousness criteria-Cause/prolonged hospitalization	2 (NO)
A.1.5.2	Seriousness criteria-Disabling/incapacitating	2 (NO)
A.1.5.2	Seriousness criteria-Congenital anomaly/birth defect	2 (NO)
A.1.5.2	Seriousness criteria-Other medically important condition	1 (YES)
A.1.6a	Date report was first received from source (format)	102 (CCYYMMDD)
A.1.6b	Date report was first received from source	20171205 (5-DEC-2017)
A.1.7a	Date of receipt of the most recent information (format)	102 (CCYYMMDD)
A.1.7b	Date of receipt of the most recent information	20171205 (5-DEC-2017)
A.1.8.1	Any additional documents available	2 (NO)
A.1.9	Does this case fulfill the local criteria for an expedited report?	1 (YES)

Manual and automated scheduling

Submission Worklist Example

BULK ICSR TRANSMIT

Reports Messages

Search Criteria

Report: E2B Case #: Message Type: All Periodic Report: Range: Custom Date Ra Start Date: 01-JAN-2017 End Date: 05-DEC-2017 Search

☐ Only show transmissions that have reached a failure state error ACK ☐ Show all transmissions (submitted and unsubmitted) having an error ACK View: ☒ Individual ☐ Group ☐ All

Total Number of Rows (1) Displaying Rows 1-1 Page Size 100

Lock State	Case Number Case Status	Date Created Date Transmitted	Due Date Submitted Date	Reporting Destination Local Company Name	Status Message Type	Transmit	EDI In	EDI Out	MDN Rec.	Ack Rec.
		??-??-0000	??-??-0000							
		??-??-0000	??-??-0000							
	17DK000012 Submission	01-Dec-2017	06-Dec-2017	FDA_R2 NNIT	Report Generation Successful ichlcr	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>

Status Details Stage Legend ● Pending ● Warning ● Success ● Failed

Tracking of
Expedited
report
submissions

Periodic Reports

ICH PSUR Line Listing Reports -- Webpage Dialog

Report Name: PSUR 20171130

Report Category: [Dropdown]

Report Sub Category: [Dropdown]

Subject of Report: [Dropdown]

Product Selection: [Dropdown]

Inclusion Criteria: [Selected]

Special Interest AE: [Dropdown]

Line Listing: [Dropdown]

Grouping: [Dropdown]

Summary Tabulations: [Dropdown]

UD Summaries: [Dropdown]

Scheduling: [Dropdown]

Security: [Dropdown]

Templates: [Dropdown]

☒ Case Creation Date ☐ Case Receipt Date ☐ Case Locked/Archived Date

From: 01-JAN-2017 To: 04-DEC-2017

☐ Age Groups

☐ Adolescent

☐ Adult

☐ Child

☐ Elderly

☐ Foetus

☐ Infant

☐ Neonate

☒ Use assessment in cases

☐ Re-assess cases against datasheet in effect at beginning

☐ Re-assess cases against datasheet in effect at end

☐ Expeditable Only

☐ Exclude Follow-up Cases

☐ Include unlocked cases

Advanced Condition: [Dropdown] [None] [Add] [Cancel]

☐ Use Datasheet Assessment for UDF Tabulations

☐ Add Cases not included in previous reporting period

Start Date: 00-MMM-0000

☐ Spontaneous

☒ Serious

☒ Fatal

☒ Listed

☒ Non-Serious

☒ Non-Fatal

☒ Unlisted

☒ Related

☒ HCP

☐ Primary Reporter Only

☒ Non-Related

☒ Non-HCP

Datasheet: <ALL>

OK Cancel

Periodic reports templates include commonly used, configurable formats

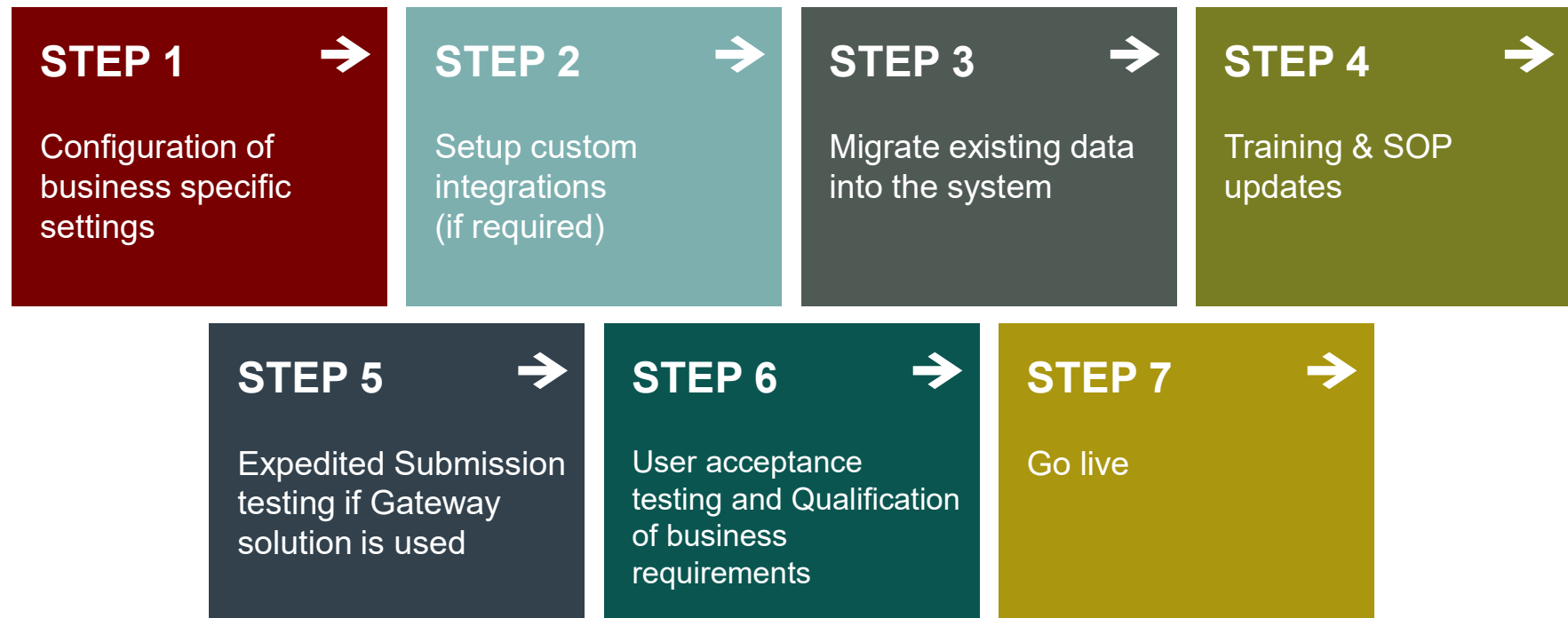
– e.g.:

- ICH PSUR
- CTPR
- IND
- NDA
- Case Data Analysis

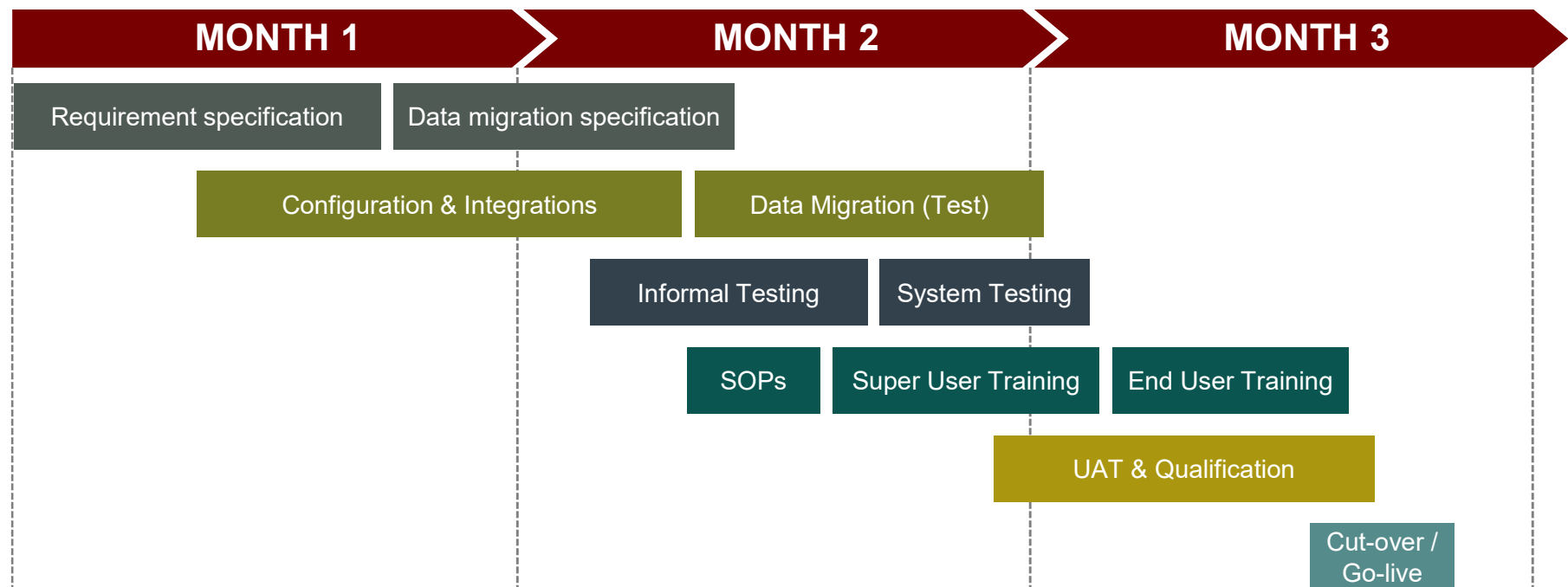
BI Publisher can be used for more advanced visual formatting

Configuration- and data inclusion options

Steps to use the system



Project Plan (Example)



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



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