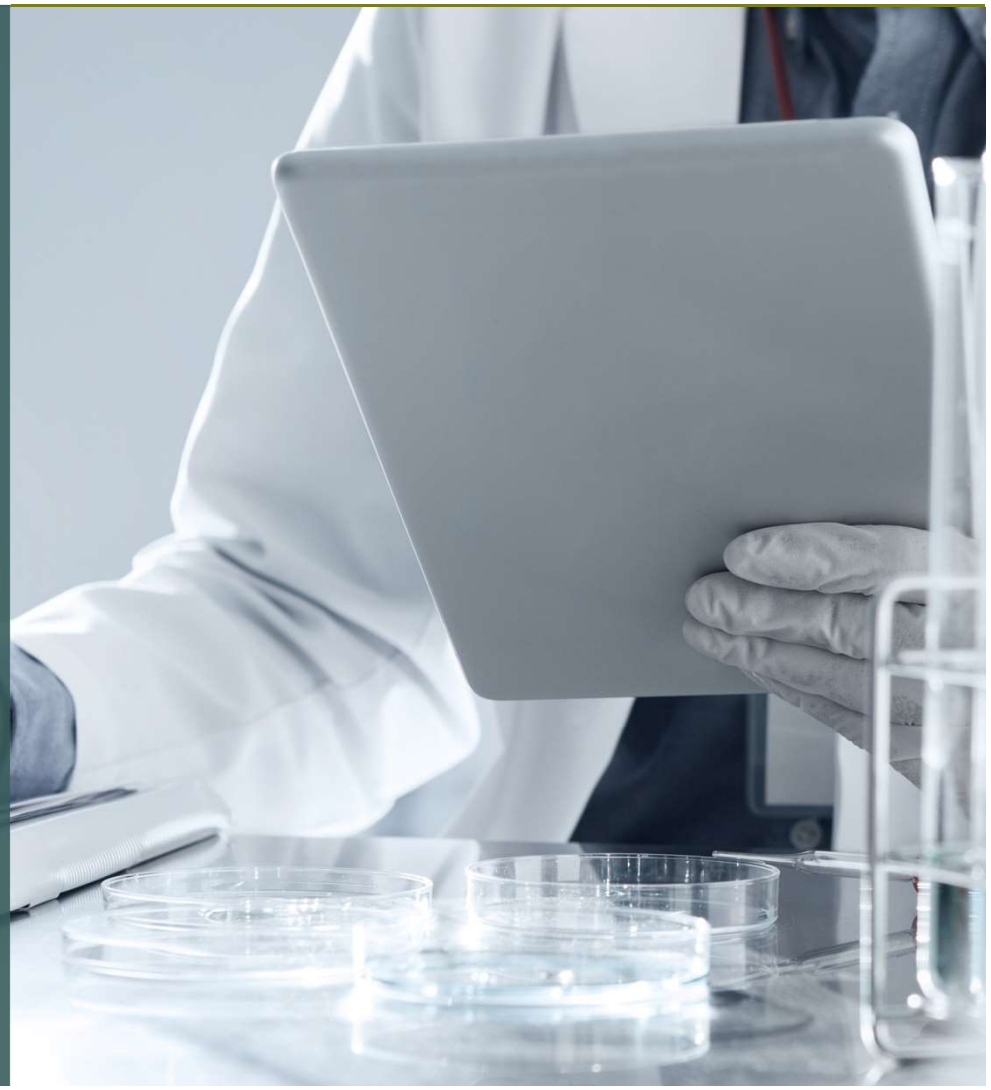
Improving pharmacovigilance: Regulatory outlook and Argus Safety

Flemming Kjøller, Niels Buch Leander and Peter Stroyer Pallesen

NNIT

7th December 2017



NNIT presenters

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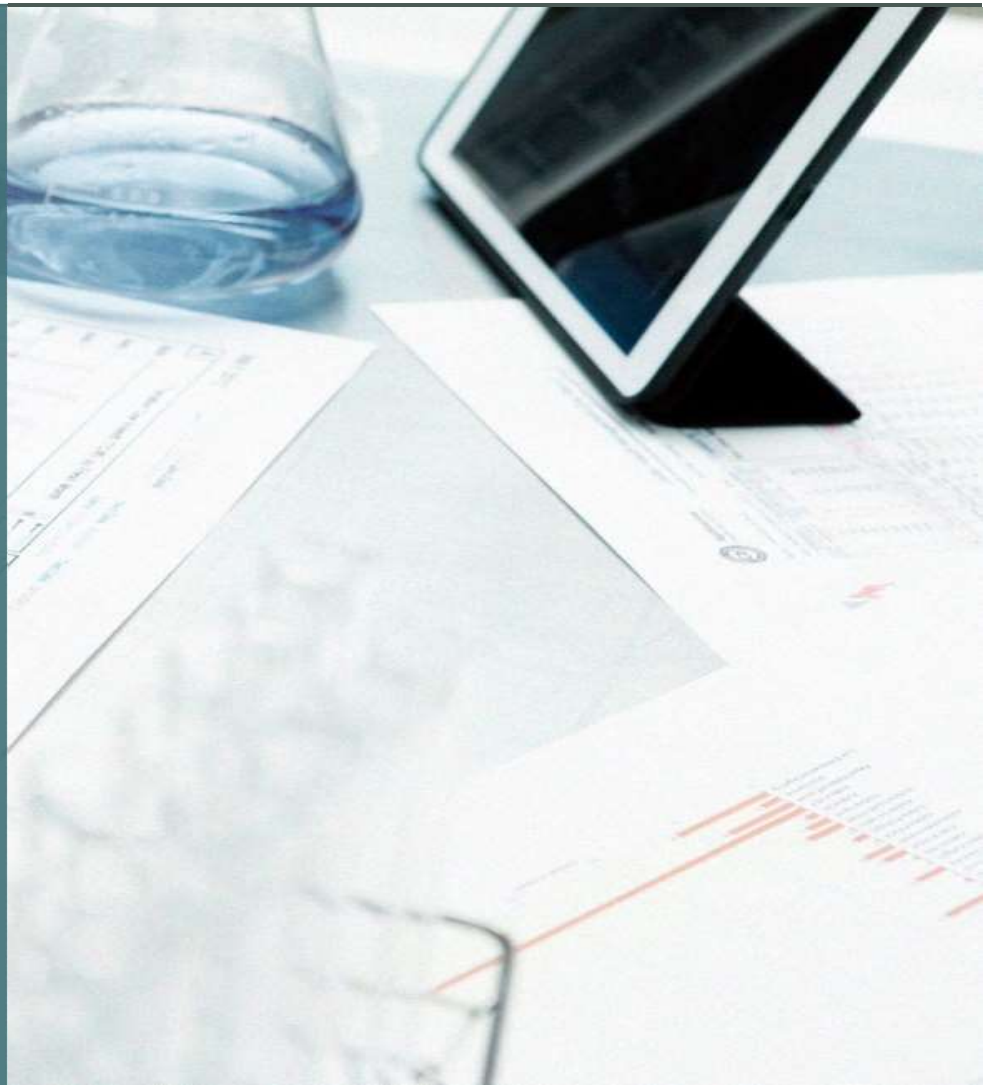
AGENDA

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

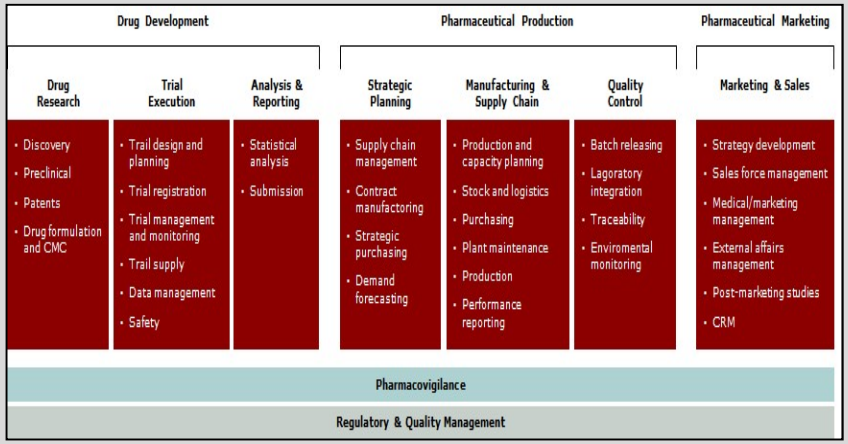
- NNIT was created as the spin off of the Novo Nordisk IT organization in 1994
- ~3000 employees and one of Europe's leading consultancies in Life Sciences IT
- Clients served globally
- Life Sciences IT is our core business - practical experience within the entire pharmaceutical value chain
- Publically 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

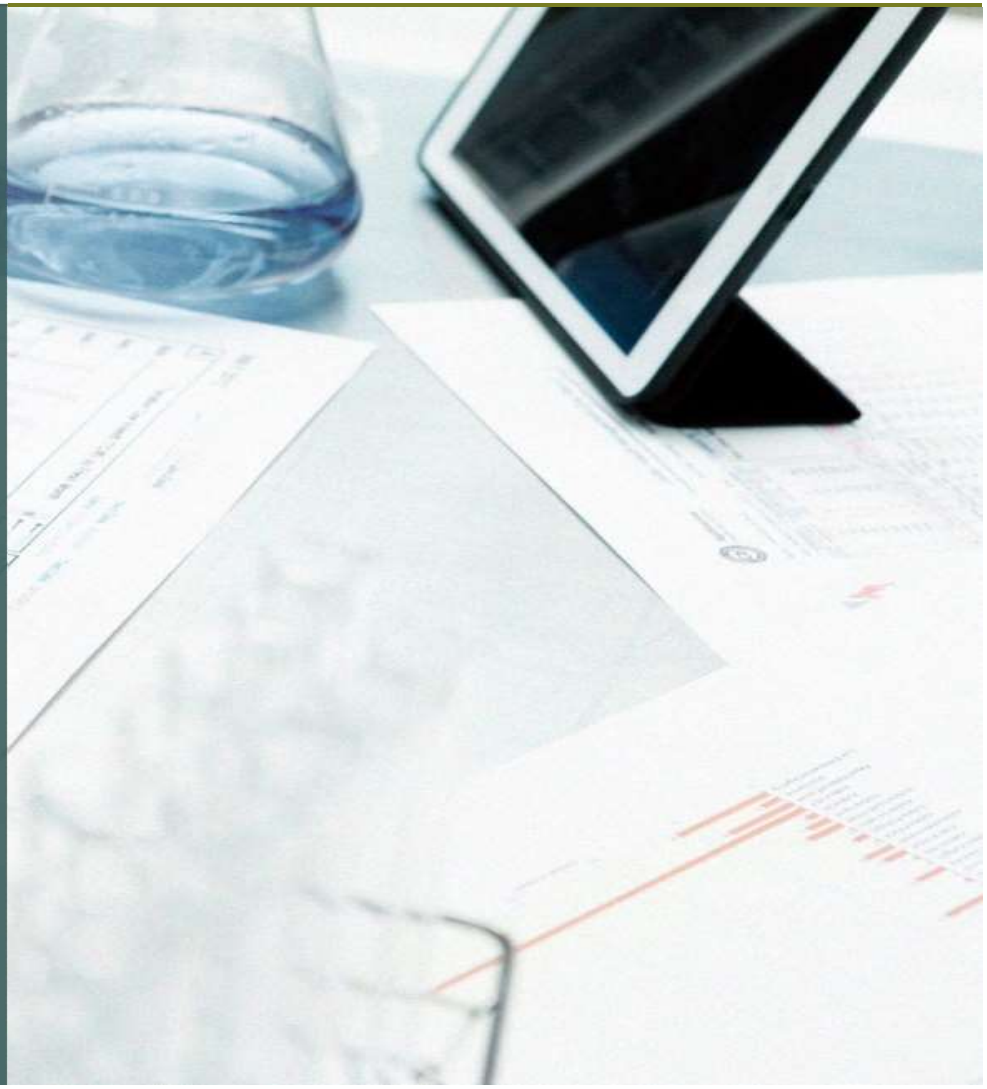
- Delivered with integrated global teams…

- Across all key functional areas of Life Sciences



- NNIT references in Life Sciences

Pharmacovigilance in today’s digital world

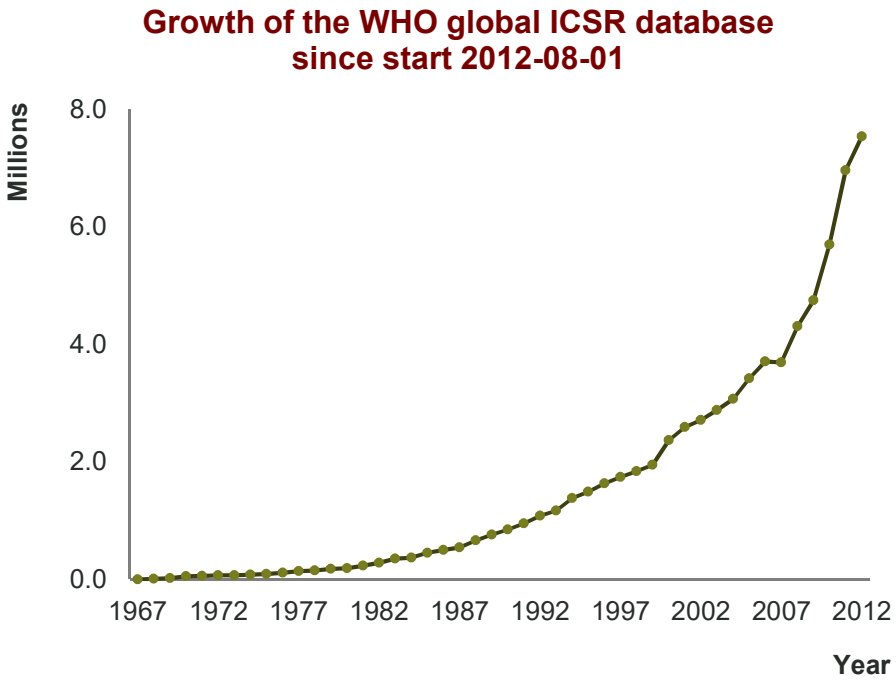


Poll:

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



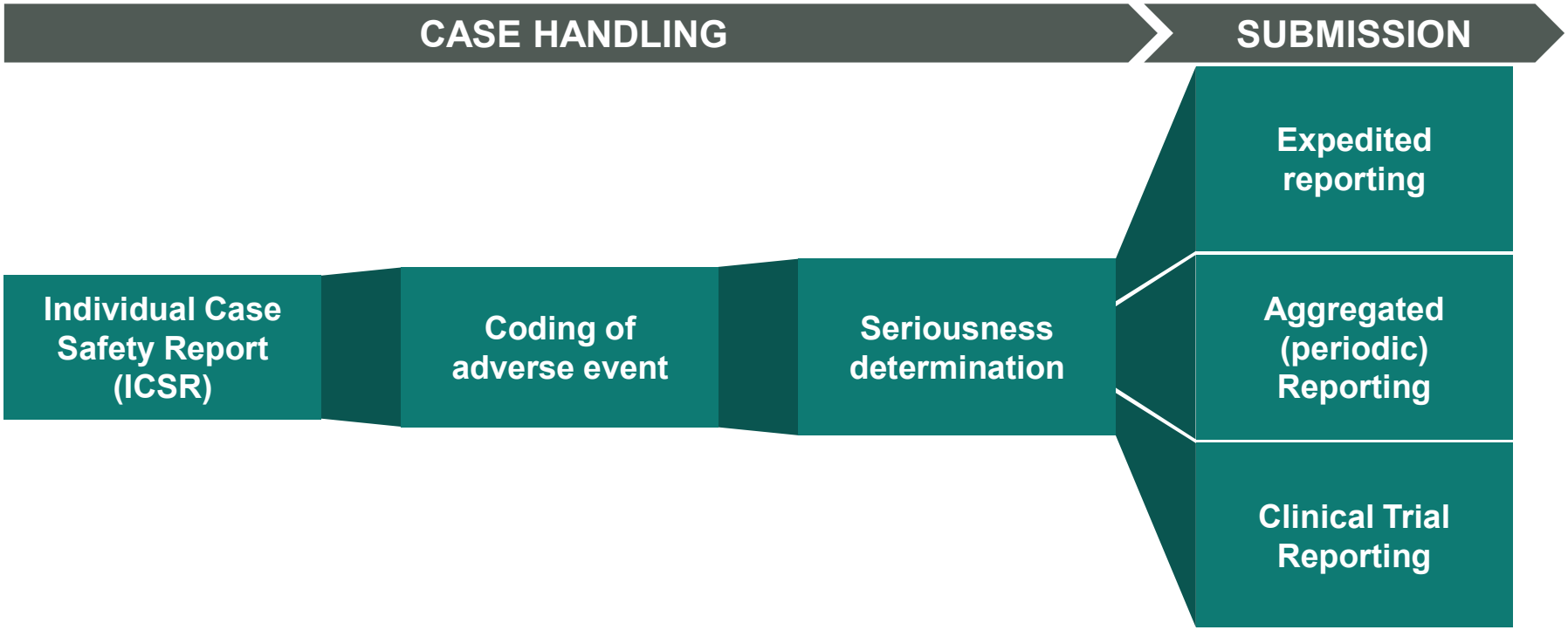
- The challenge of maximizing drug safety and maintaining public confidence has become increasingly complex.
- Pharmaceutical and biotechnology companies must not only monitor, but also proactively assess and manage drug risk throughout a product's lifecycle, from development to post market.

Overview of Good Pharmacovigilance Practice

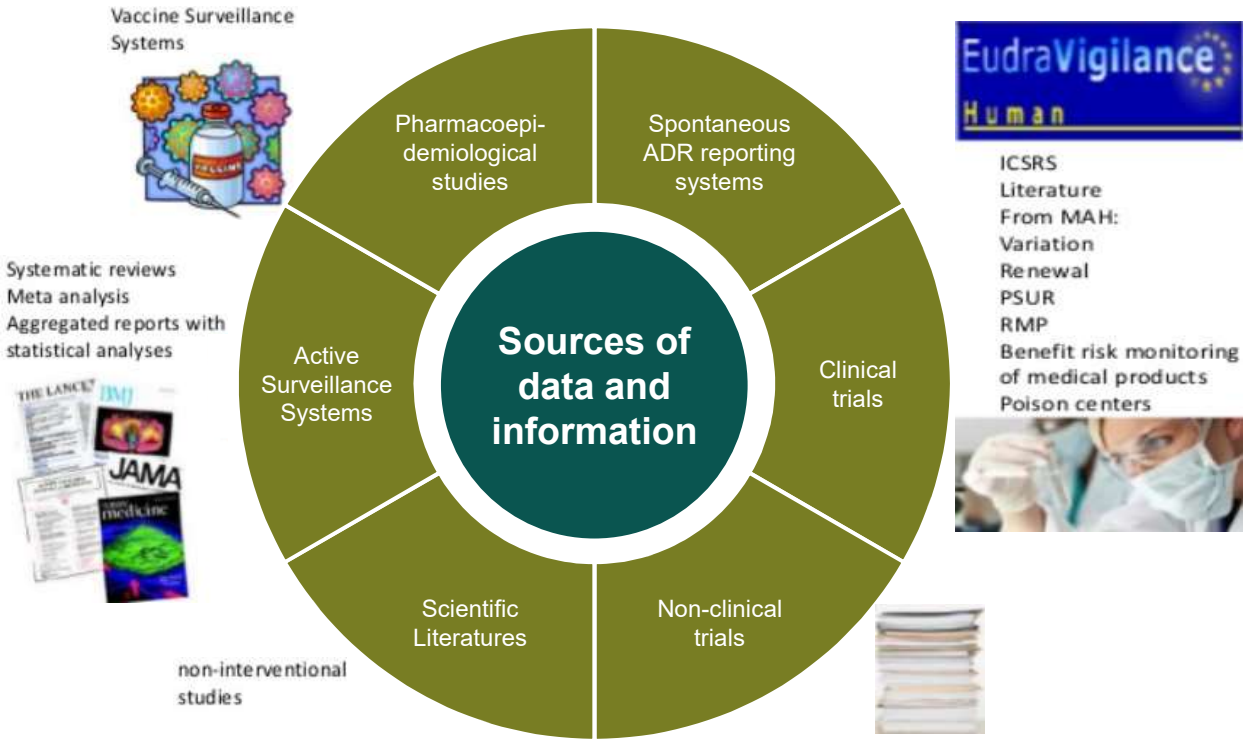
GVP MODULES

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)



Sources of signals – GVP Module IX



Trend: Patient empowerment is changing the conditions for pharmacovigilance

Patients are better informed

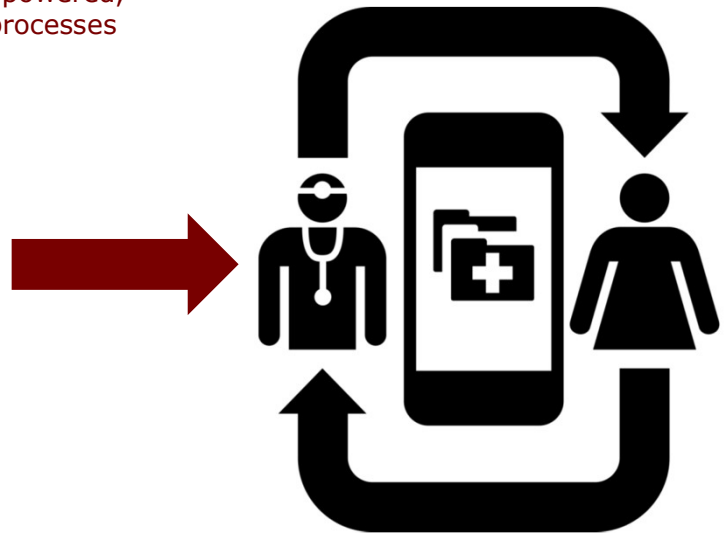
Patients digitally empowered, bypassing existing processes

Remote monitoring is possible

Genomics/personalised medicine redefining therapies

Patients will pay bigger role in medicine selection and payment

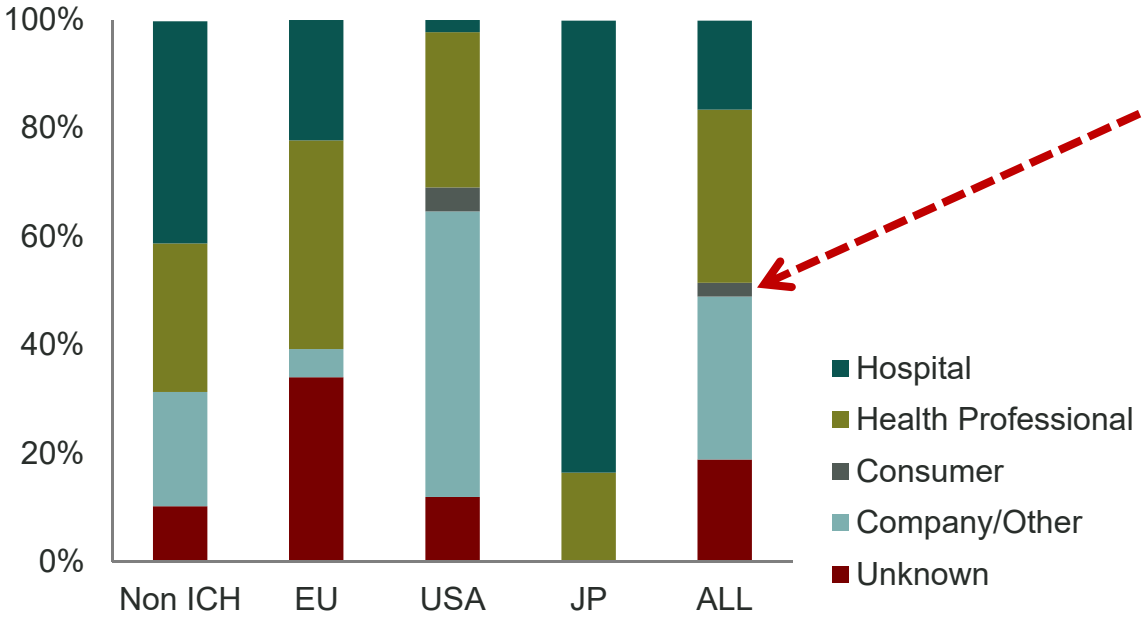
Patient pool increasingly global



Wearables + Patient-engagement platforms

Trend: Patient empowerment is changing the conditions for pharmacovigilance

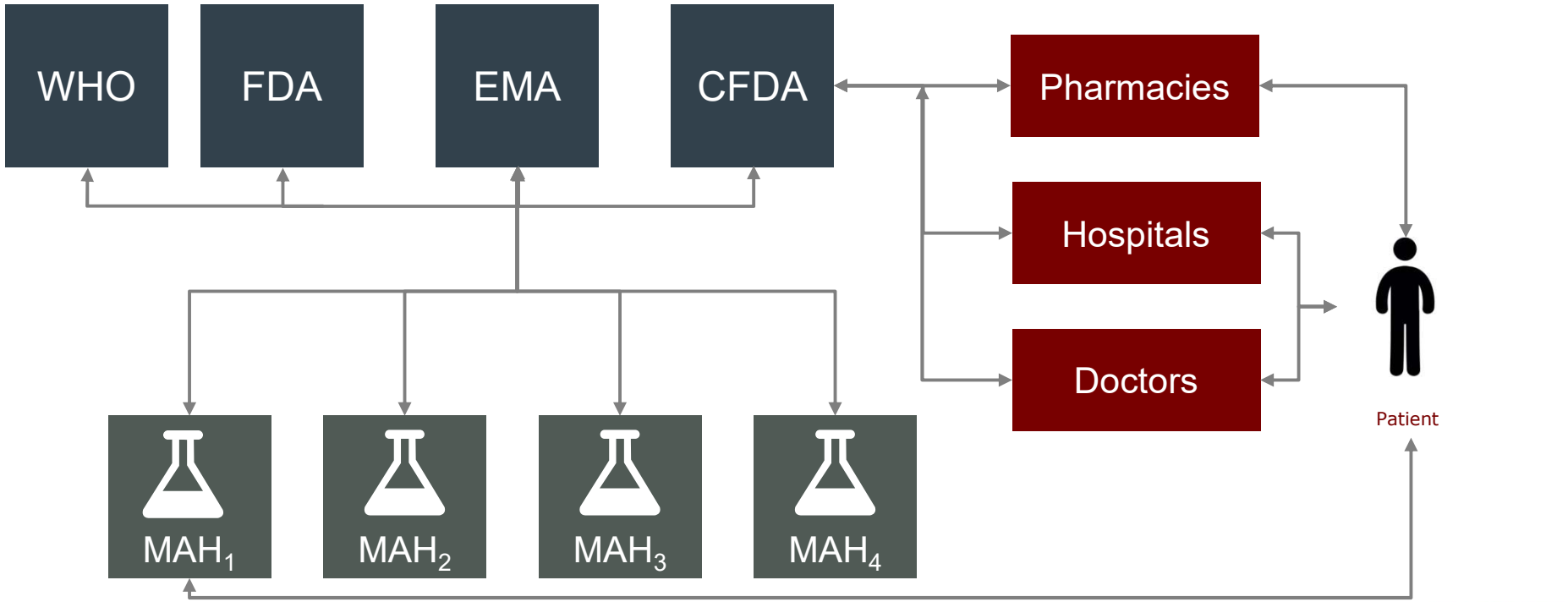
Sources of safety cases



- 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

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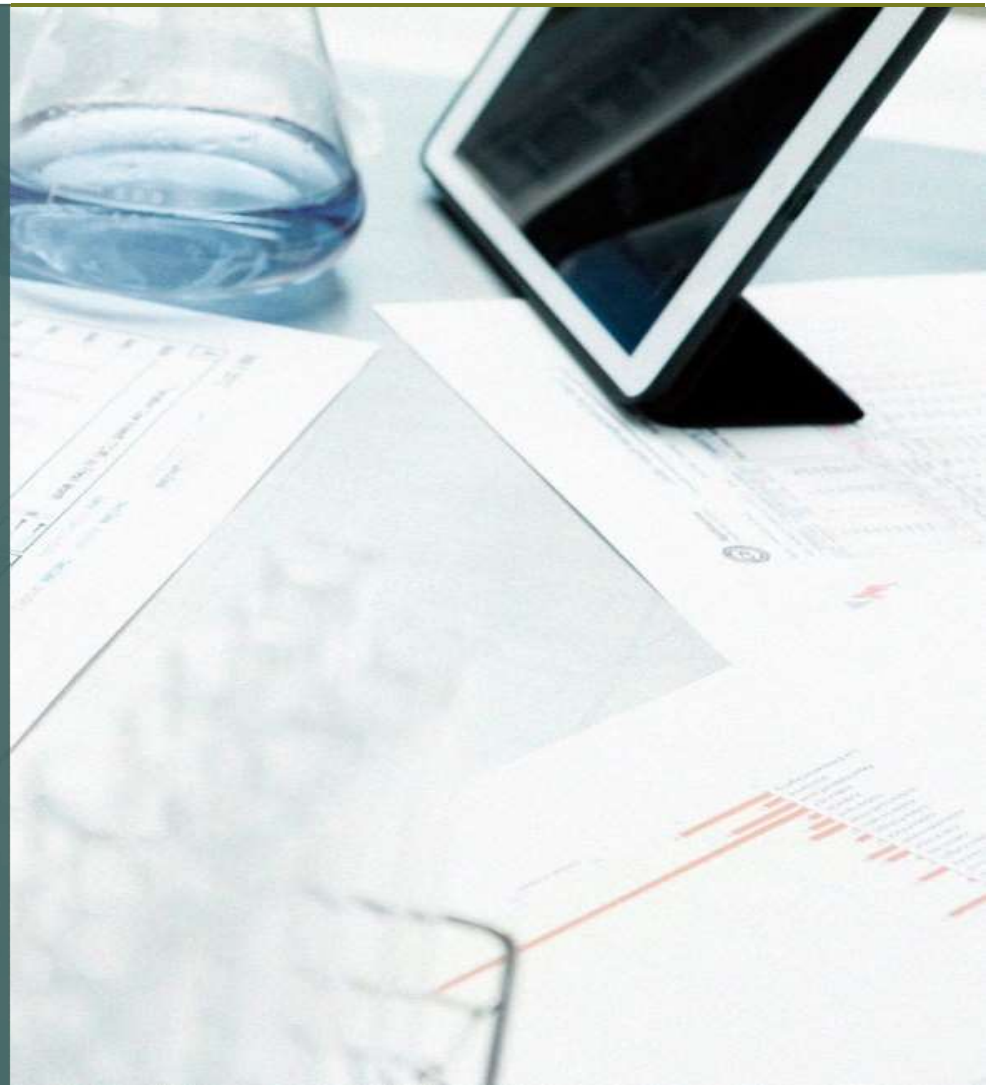
The benefits of Safety databases

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

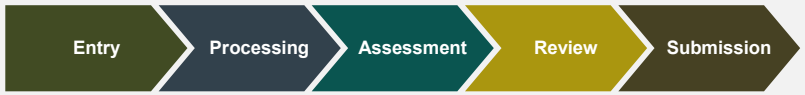
Compliant Configurable Periodic Reports and line listings

Safety data consolidated in one system supporting all PV processes

4 considerations when moving from Excel to System based approach

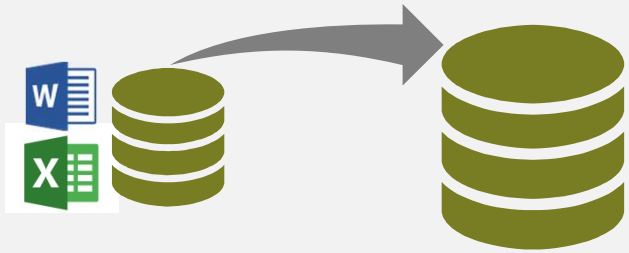
01 Overview of existing Pharmacovigilance processes and Metrics

- 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

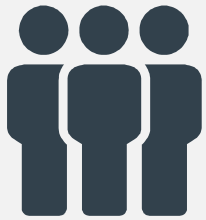
- Source and quality of existing data



4 considerations when moving from Excel to System based approach

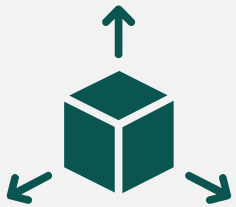
03 Users & Training

- 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?



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Why Oracle Argus?

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ORACLE ARGUS SAFETY

#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

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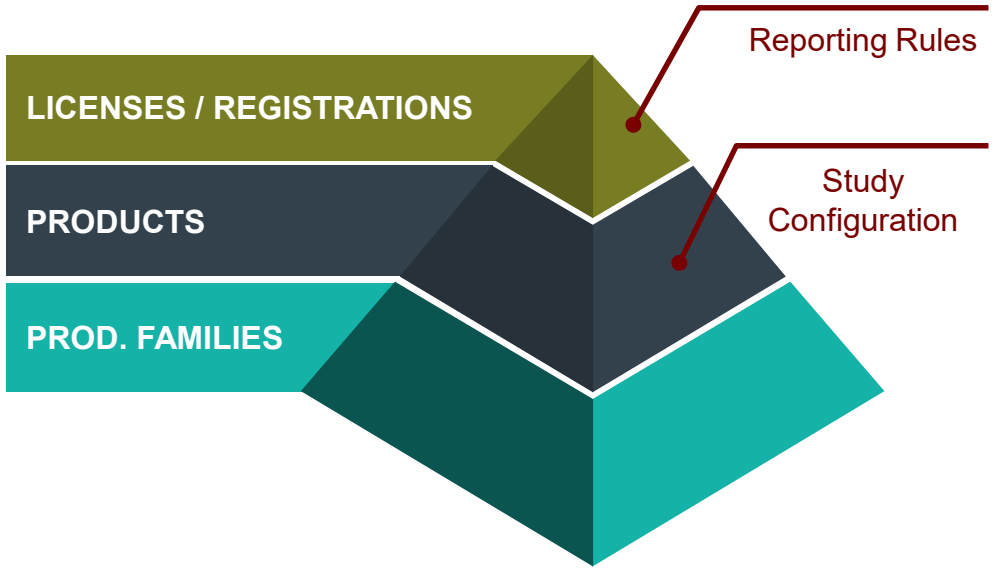
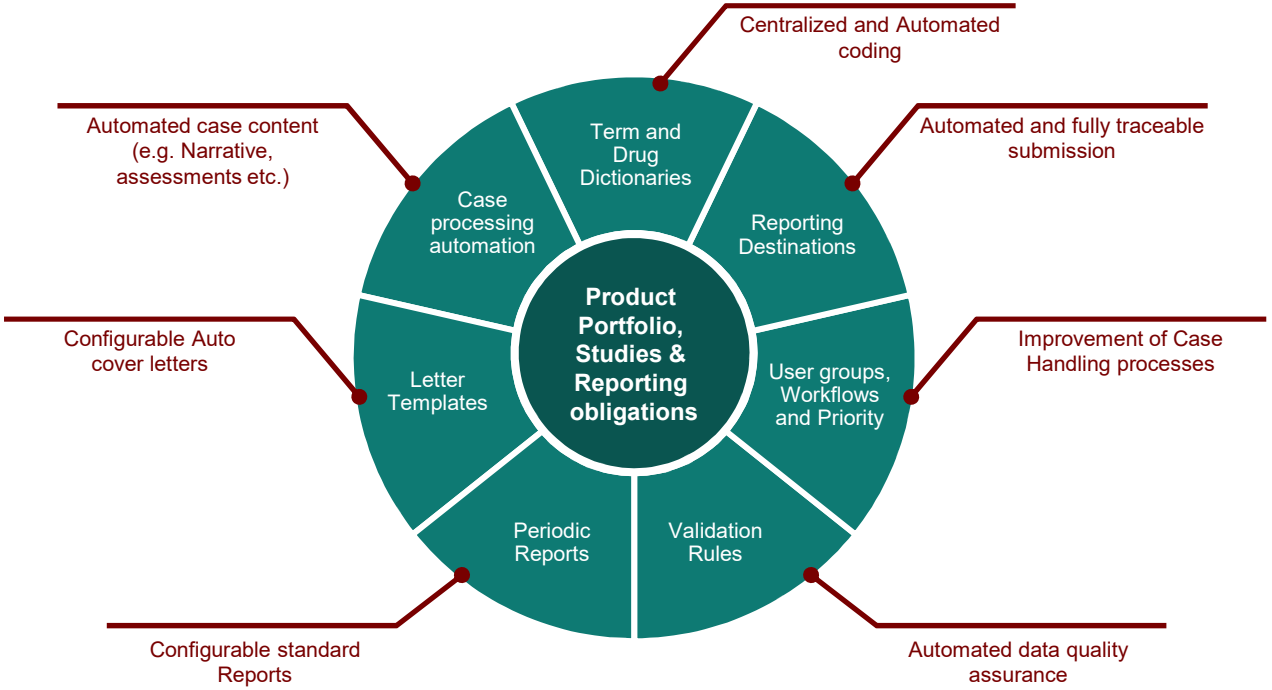
Argus Configuration overview

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



Main Features of Argus



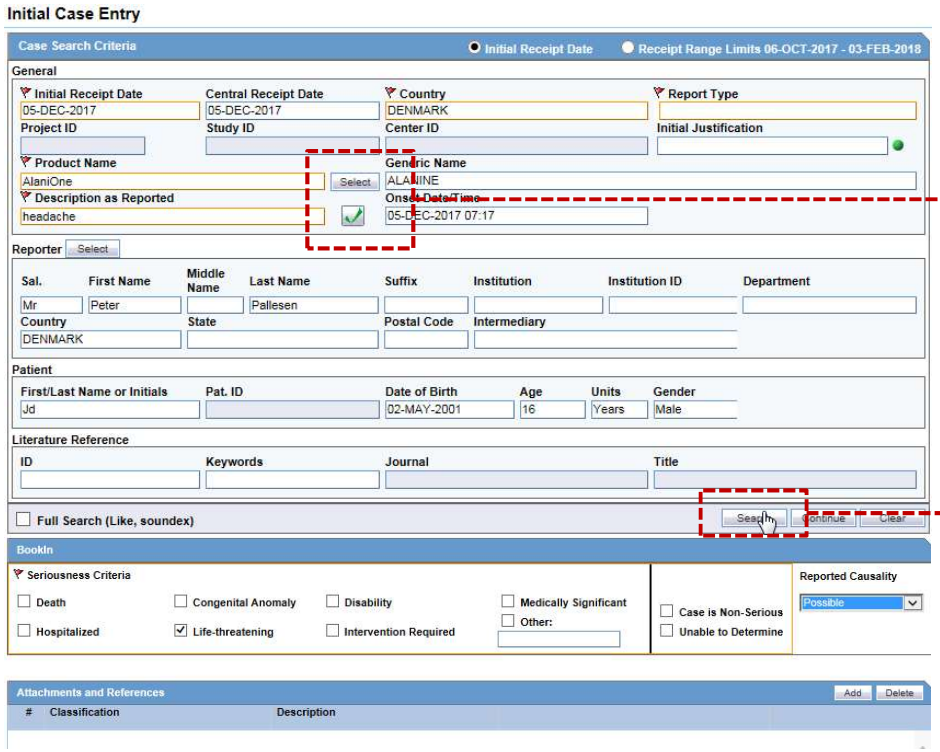
Modules

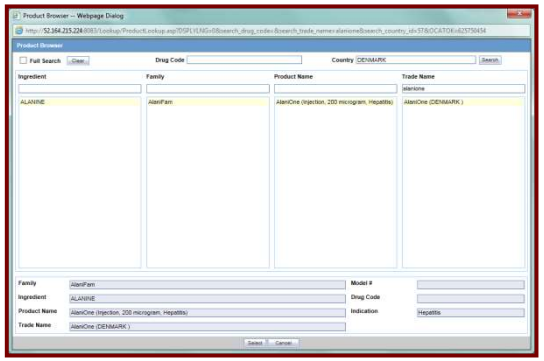
- Japanese/Chinese
- Empirica
- Dossier
- Affiliate
- BIP Reports
- Insight
- Documentum

Argus Safety Introduction

- **Typical Argus Safety workflow**

Argus Safety Bookin & Intake

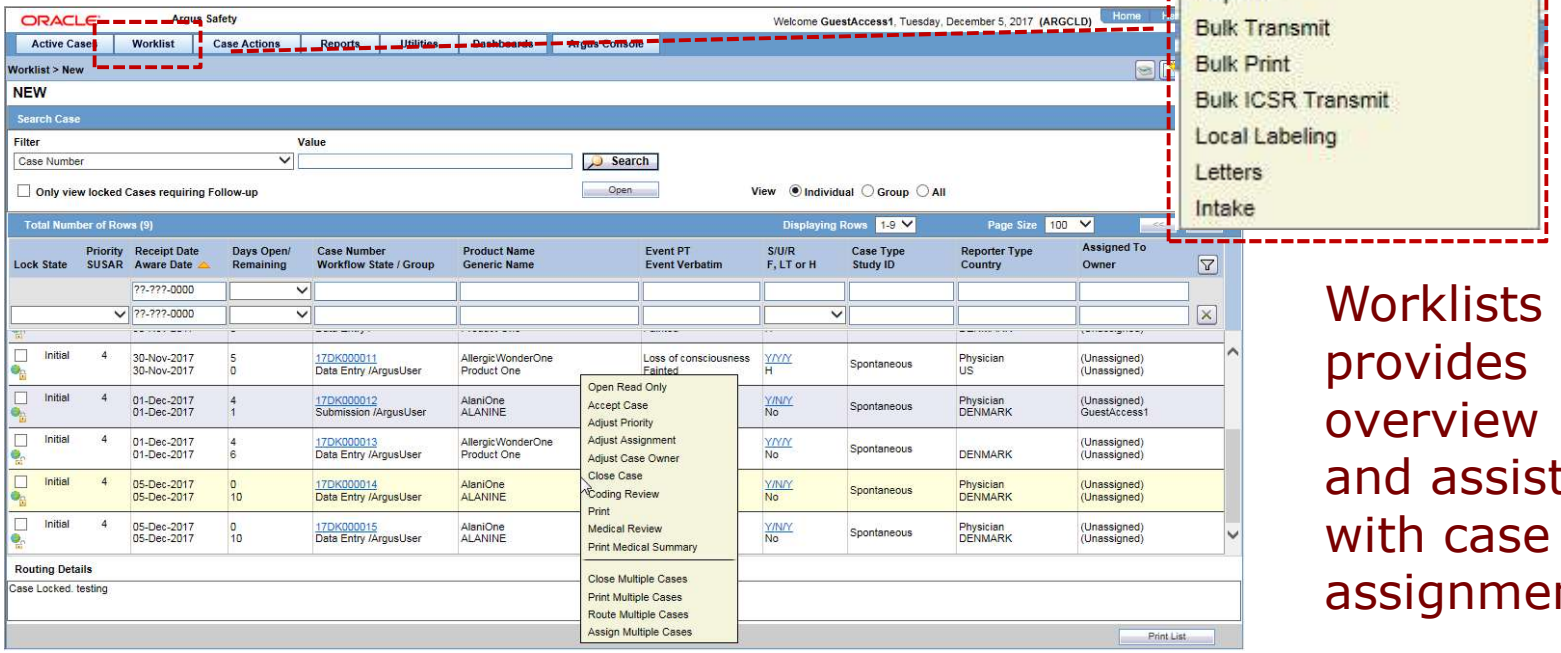




Coding of Products & Events

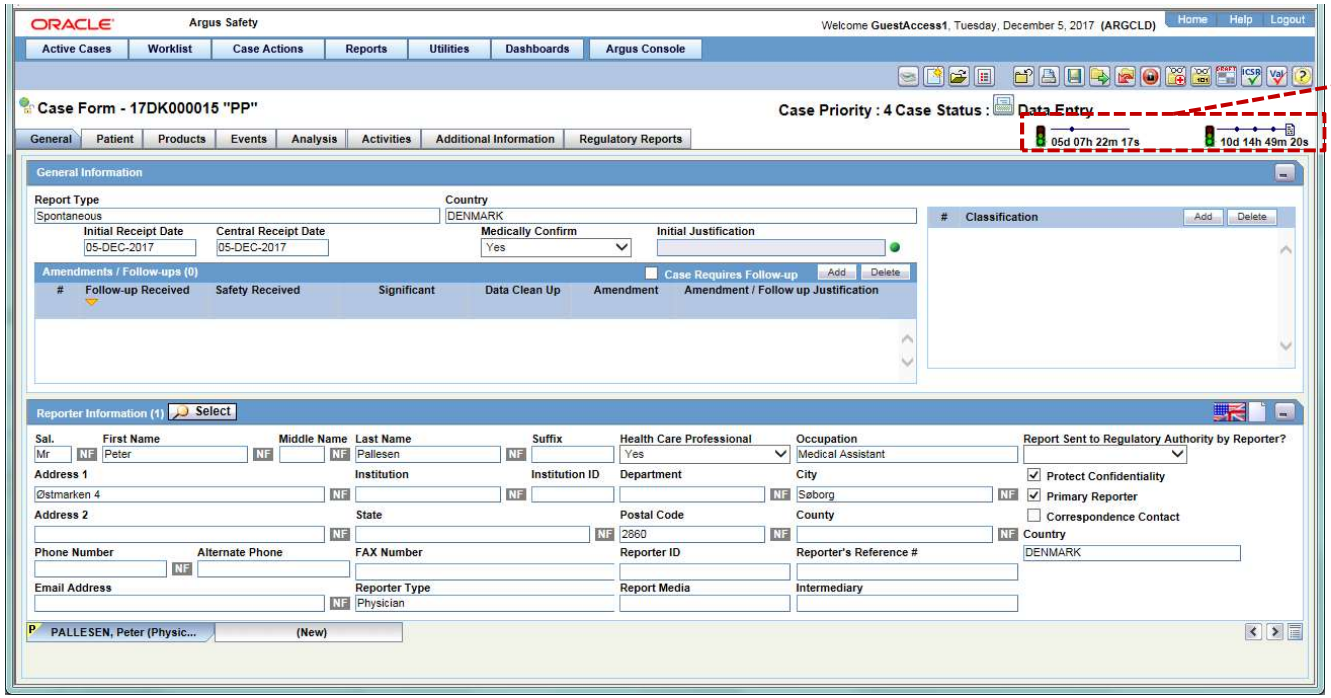
Duplicate search

Worklists example (New case)



Worklists provides overview and assists with case assignment

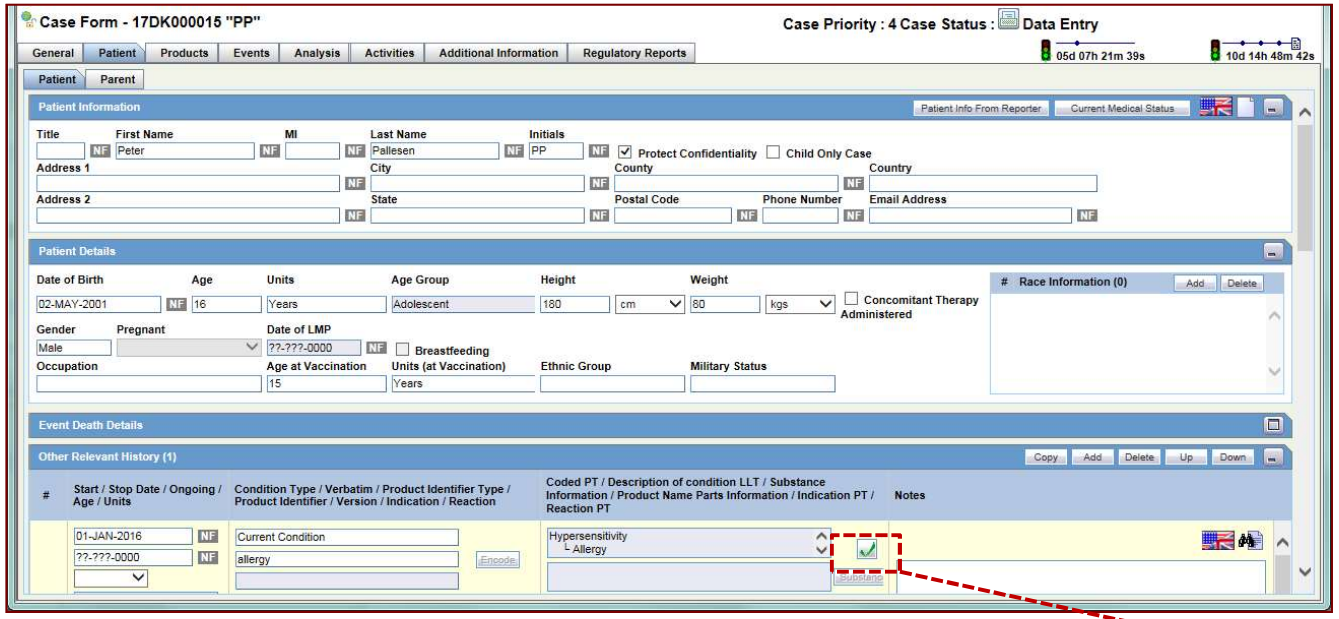
Argus Safety Case Processing - General



Dynamic workflow status

The General tab contains core details of the case, the reporter of the case and any literature references

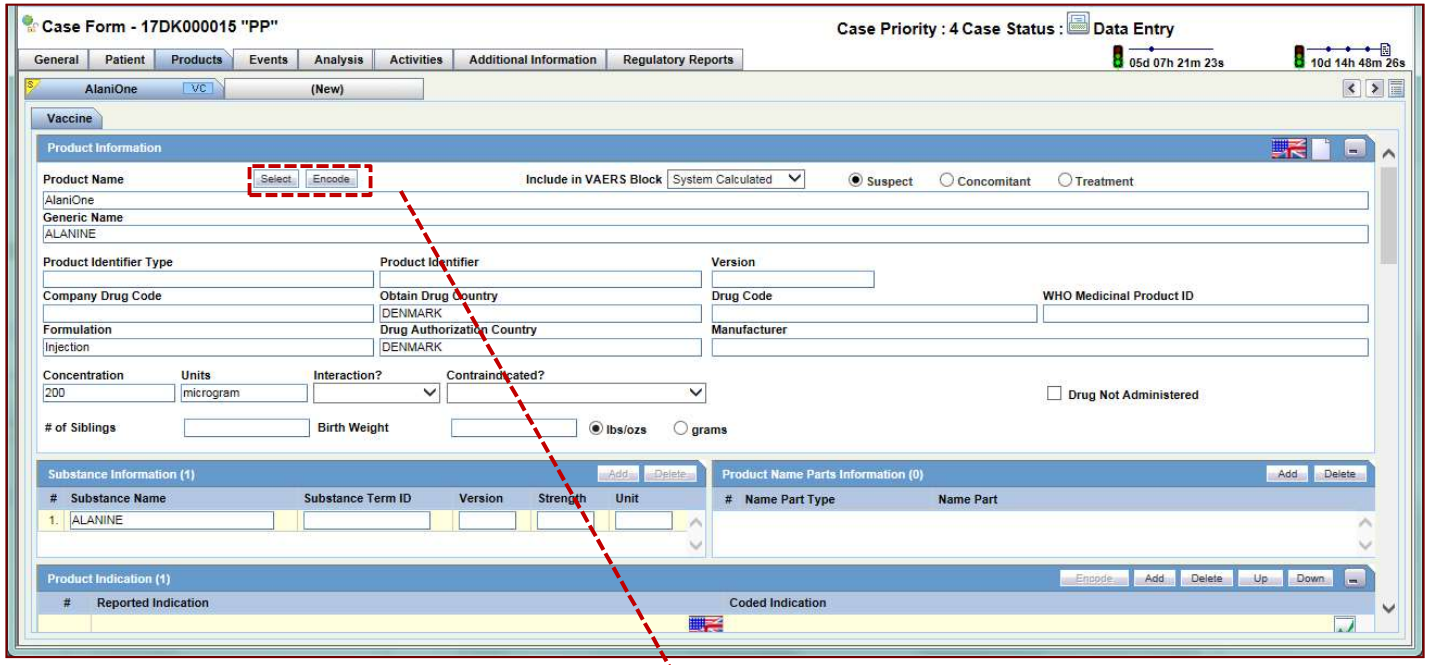
Argus Safety Case Processing - Patient



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

Coding against MedDRA

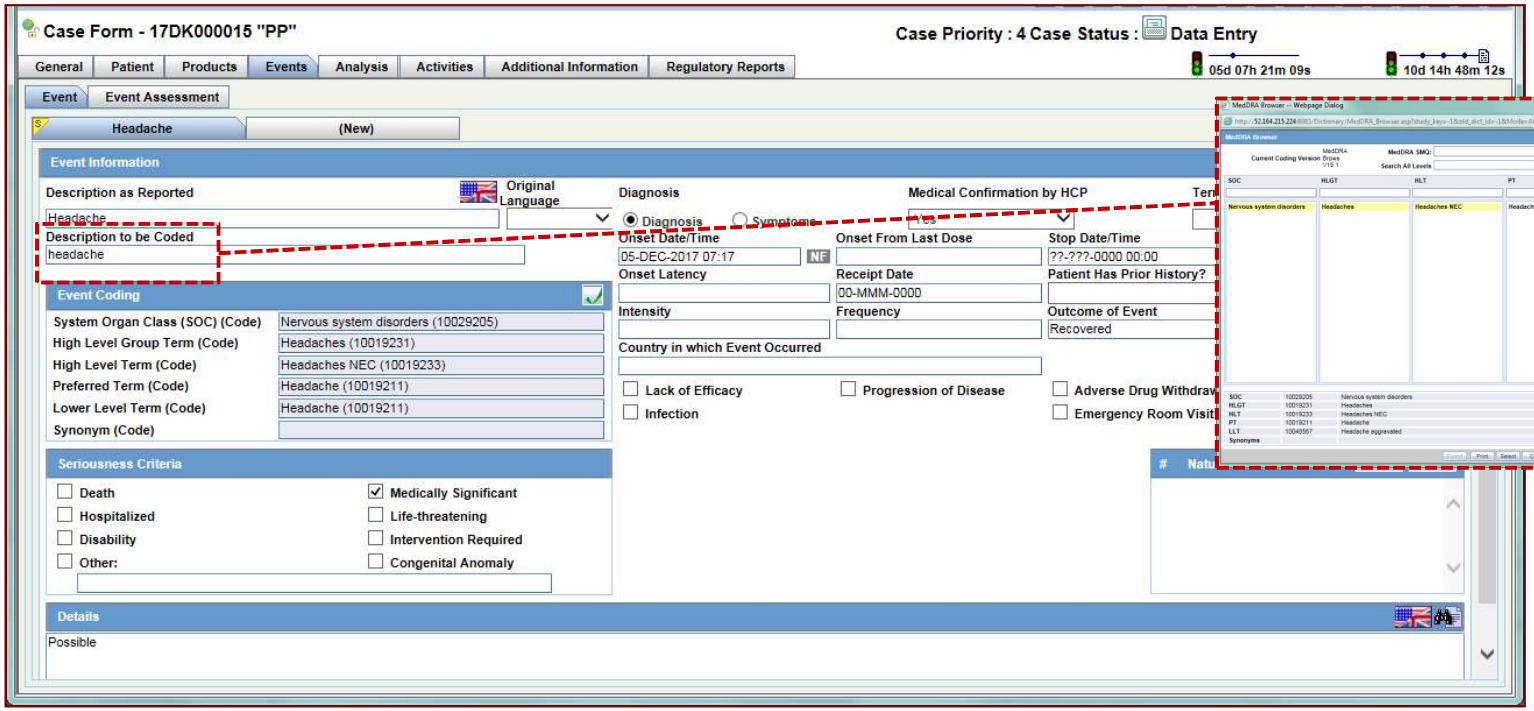
Argus Safety Case Processing - Vaccines



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

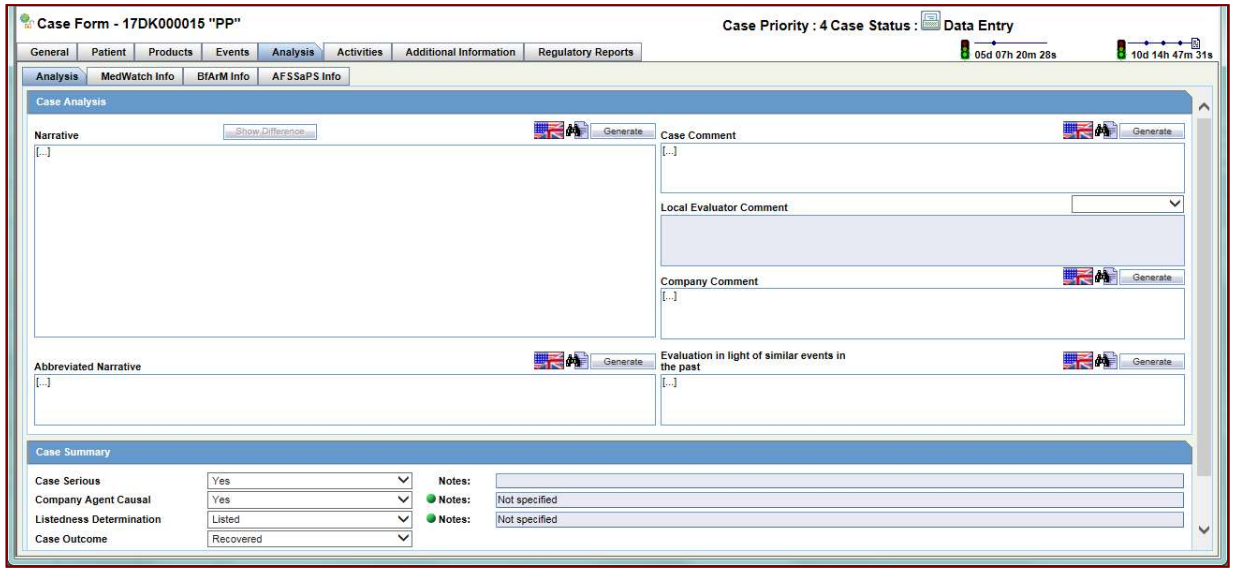


Coding of Events

Argus Safety Case Processing - Assessments

The Assessment tab contains the assessment of causality for all suspect product / event pairs and assessment of Listedness for all related Licenses/Registrations

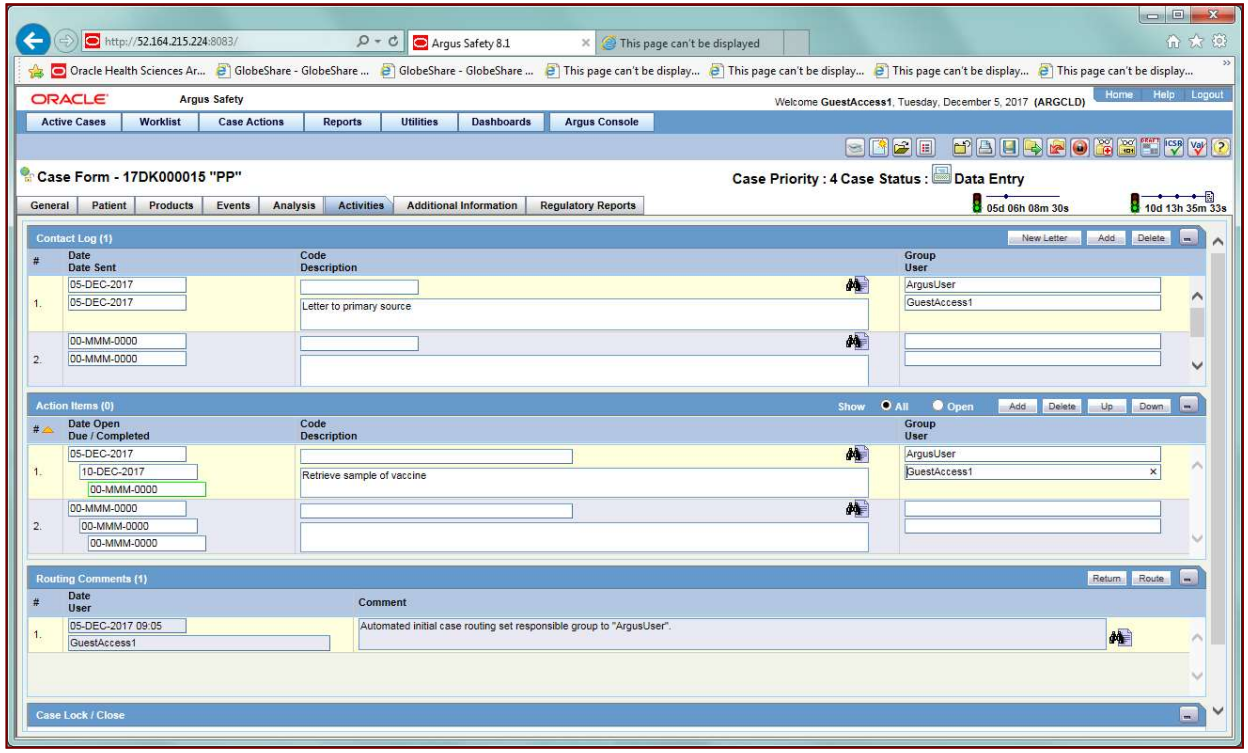
Argus Safety Case Processing - Analysis



The Analysis tab contains narratives and overall case assessments.

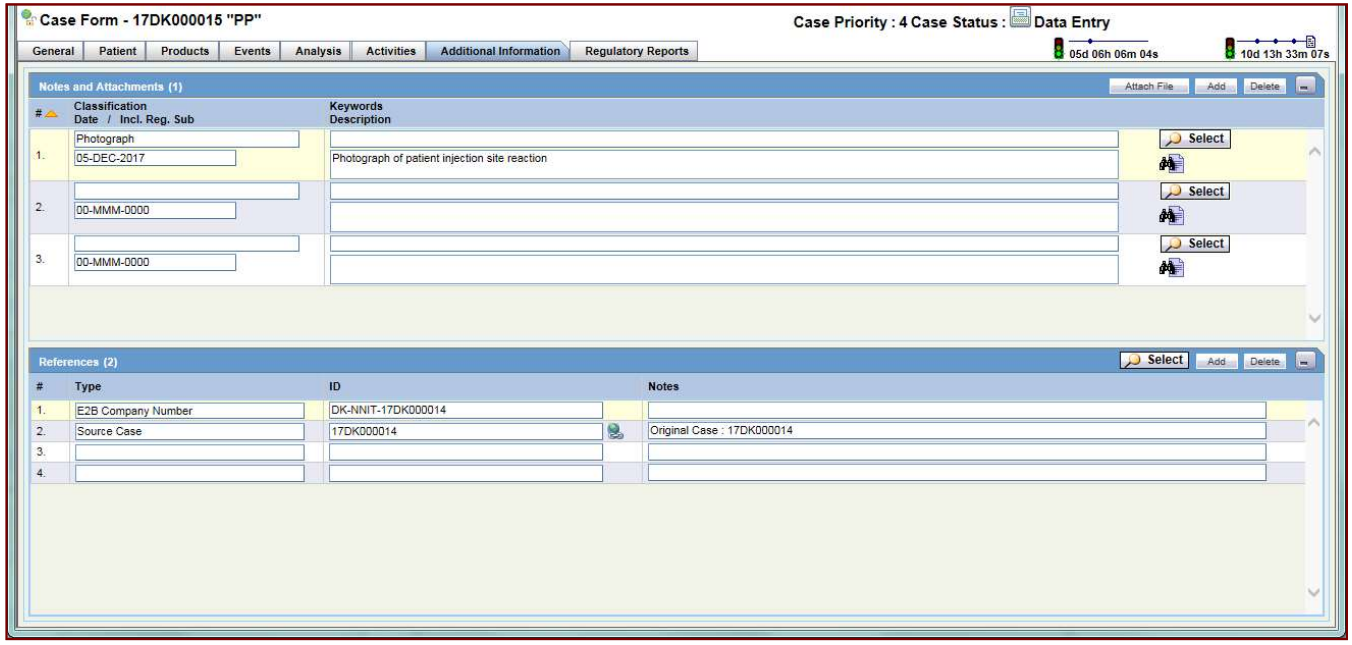
Often these are auto-generated.

Argus Safety Case Processing - Activities



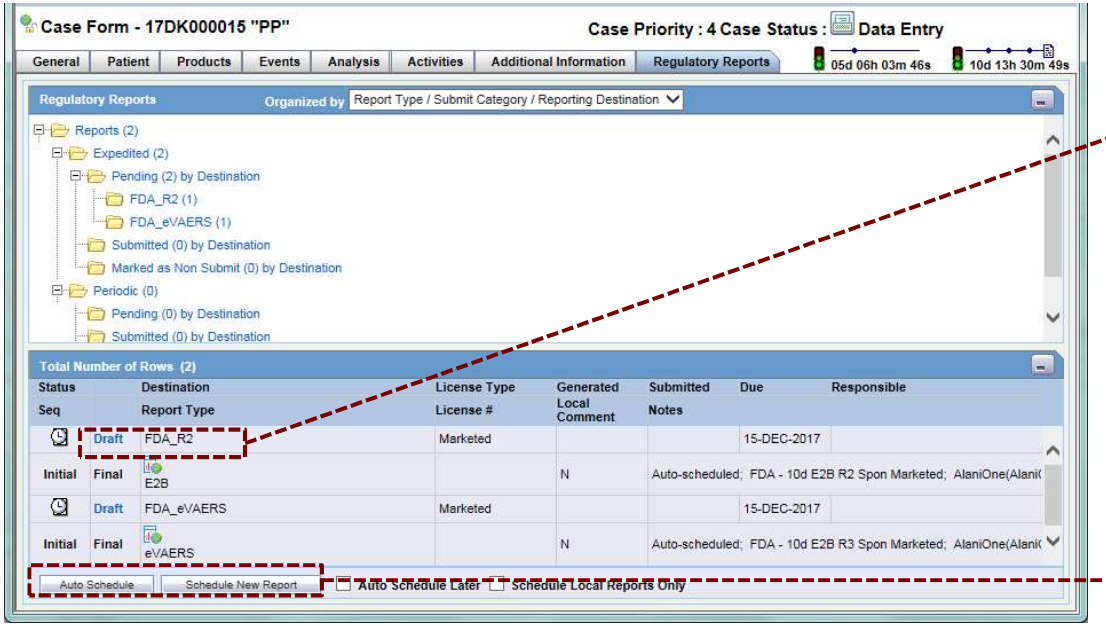
This tab contains actions, letters and routing details

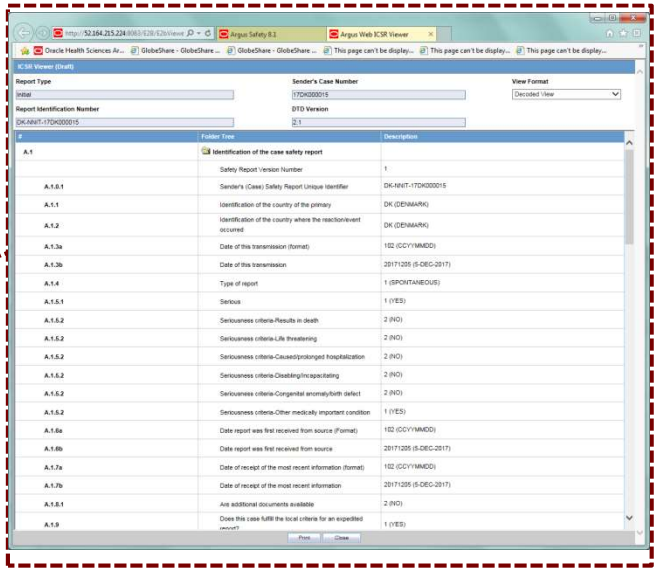
Argus Safety Case Processing - Additional



Additional information contains Attachments and other references

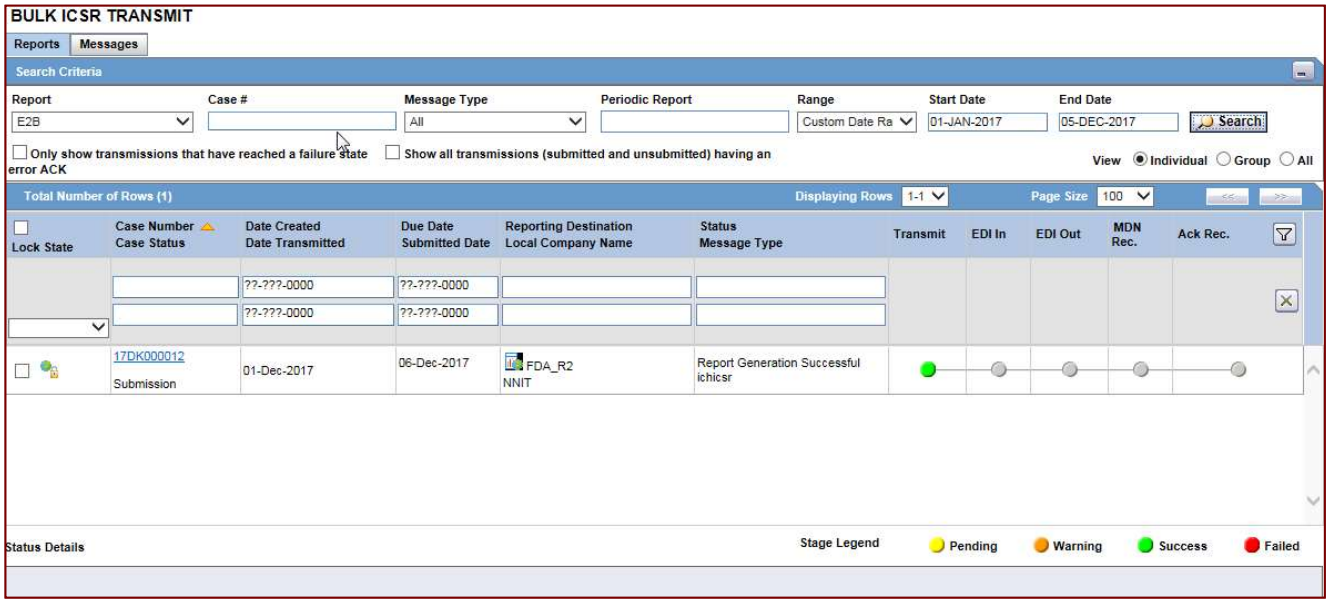
Argus Safety – Regulatory Reports





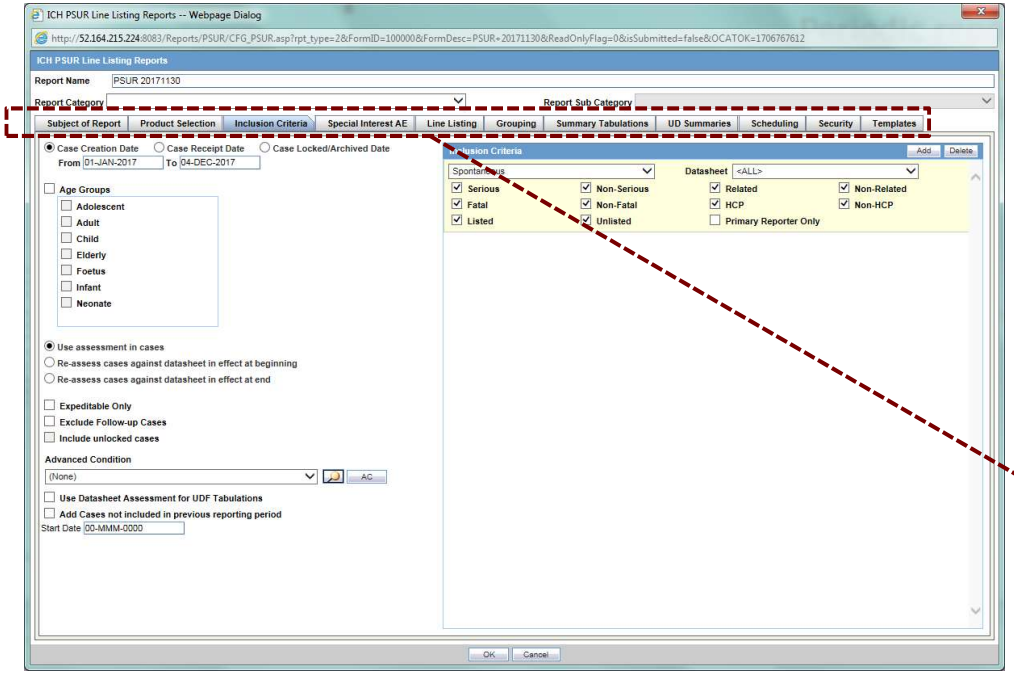
Manual and automated scheduling

Submission Worklist Example



Tracking of Expedited report submissions

Periodic Reports



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

STEP 1

Configuration of business specific settings

STEP 2

Setup custom integrations (if required)

STEP 3

Migrate existing data into the system

STEP 4

Training & SOP updates

STEP 5

Expedited Submission testing if Gateway solution is used

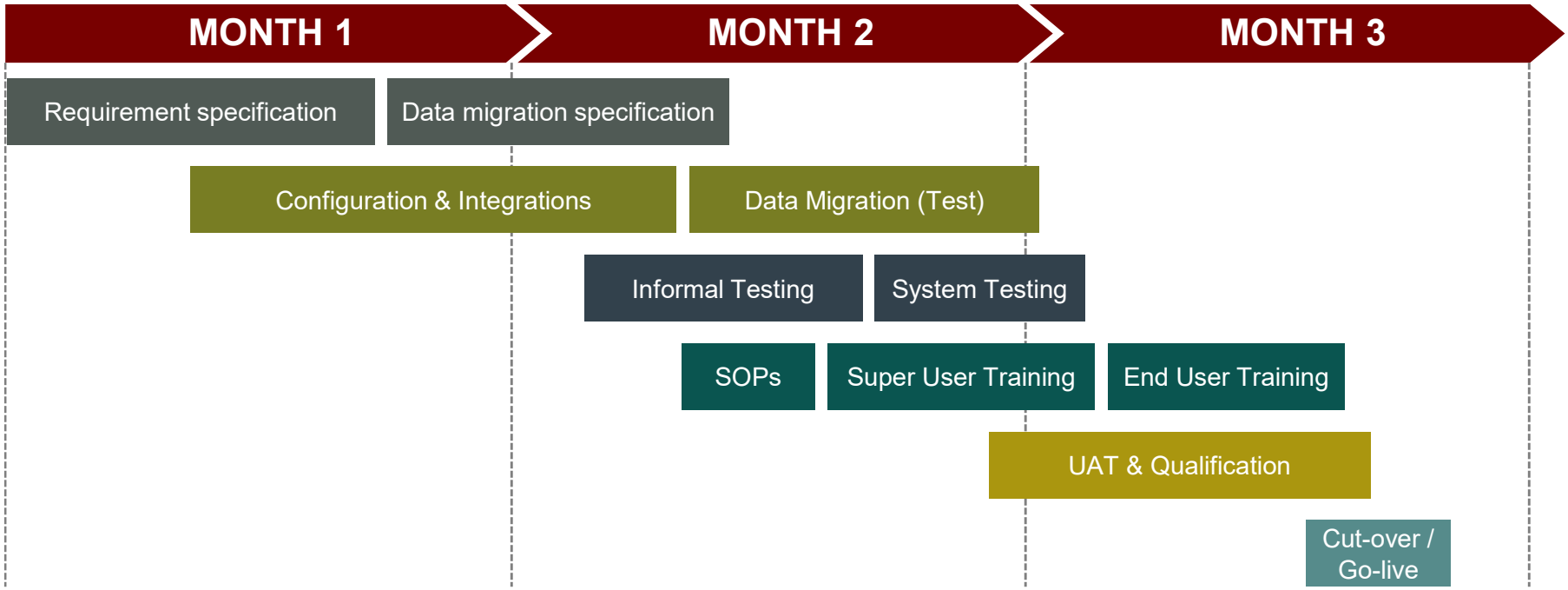
STEP 6

User acceptance testing and Qualification of business requirements

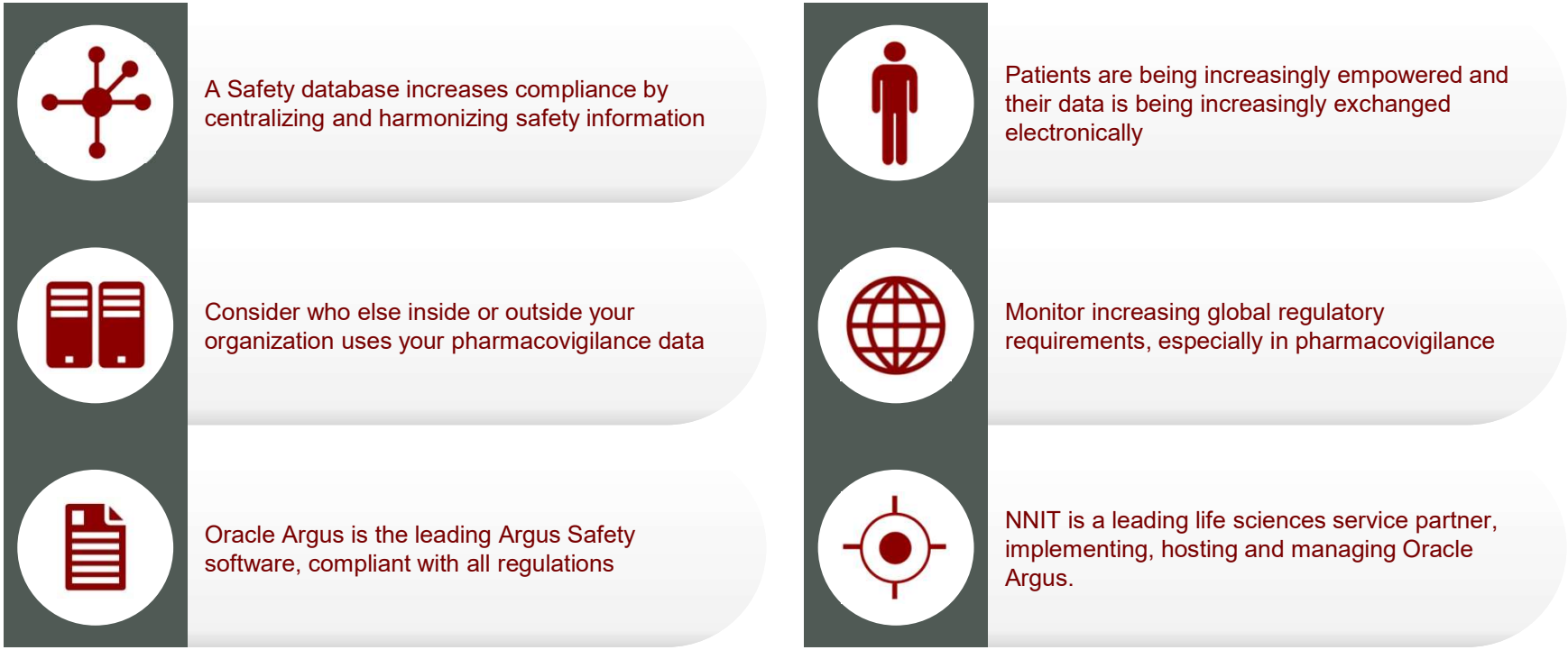
STEP 7

Go live

Project Plan (Example)



Key take-aways from this webinar



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Q&A

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