

Pharmacovigilance, Drug safety and Risk Management

Outsourcing Pharmacovigilance

Use a secure web-base interface to develop a collaborative partnership between Sponsor and CRO

Nicolas Limbos



Agenda

- Keyrus BioPharma
- PV activity outsourcing challenges
- Solution in a secure web-based interface
- Tool : e-SaPh’

European full-service CRO for biopharmaceutical, medical device and nutritional industries

Keyrus BIOPHARMA



- Project Management & Global Monitoring
- Regulatory Affairs Strategy and Support
- Clinical Operations Phase I-IV
- Data Management
- Medical review and coding
- Biostatistics
- **Drug Safety & Pharmacovigilance**
- Quality Assurance

Outsourcing solution

- Publication management
- Scientific and Medical Writing
- Medical Information

Helping our clients to bring their new products to market through a combination of integrated and wide range of services.

Keyrus BIOPHARMA



Pharmacovigilance, Drug safety and Risk Management

Outsourcing Pharmacovigilance activity challenges

Keyrus BIOPHARMA

Why outsource Pharmacovigilance



- Medication registration
- Data collection, sources and reportability
- Safety surveillance
- Regulatory requirement
- Good Practice
- Resources & trainings

- New activity or increase of safety activity
- Constant improvement and guidance updates

- Expertise and knowledge
- Flexibility
- Cost control
  - PV set up
  - System access

PV activity outsourcing challenges



Day to day PV activities

- Case management
- Literature review and analysis
- Interaction with investigators
- Medical revision, causality assessments
- Compliance to regulatory requirements
- Distribution and submission

Reports and signals

- Line listings generation
- Aggregate reports writing
- Risk management
- Signal detection activities



Keyrus BIOPHARMA

PV activity outsourcing challenges



Day to day PV activities

- Collection
- Processing
- Distribution
- Local
- World Wide
- Tradition
- Sponsored
- I.I.S.
- Local
- World Wide
- Assessment
- World Wide and FDA
- Local rules
- EEA
- FDA
- ASIA

Reports and signals

- Line listings generation
- Aggregate reports writing
- Risk management
- Signal detection activities

Keyrus BIOPHARMA

PV activity outsourcing challenges



Day to day PV activities

- Processing
- Local
- World Wide
- Tradition
- Sponsored
- I.I.S.
- Local
- World Wide
- Assessment
- World Wide and FDA
- Local rules
- EEA
- FDA
- ASIA

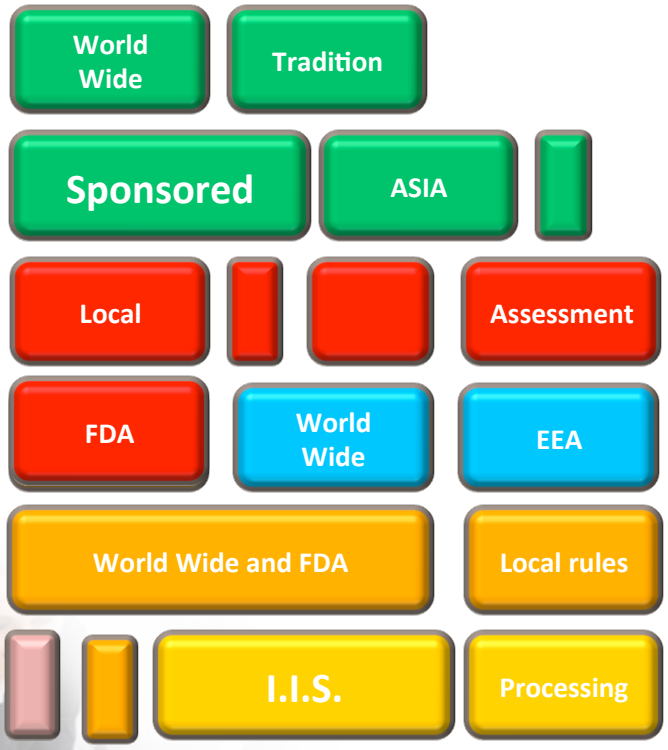
Reports and signals

- Line listings generation
- Aggregate reports writing
- Risk management
- Signal detection activities

Keyrus BIOPHARMA

PV activity Roles and Responsibilities

- Define roles and responsibilities
- Define timelines
- Specify communication and transfer of information tools
- Insist on training and knowledge of the process to all stakeholders



Signal detection activities

Aggregate reports writing

Line listings generation

Risk management

PV activity outsourcing challenges



Day to day PV activities

Full picture of safety data

Accurate metrics and KPIs

Listings and trends

Compliance monitoring

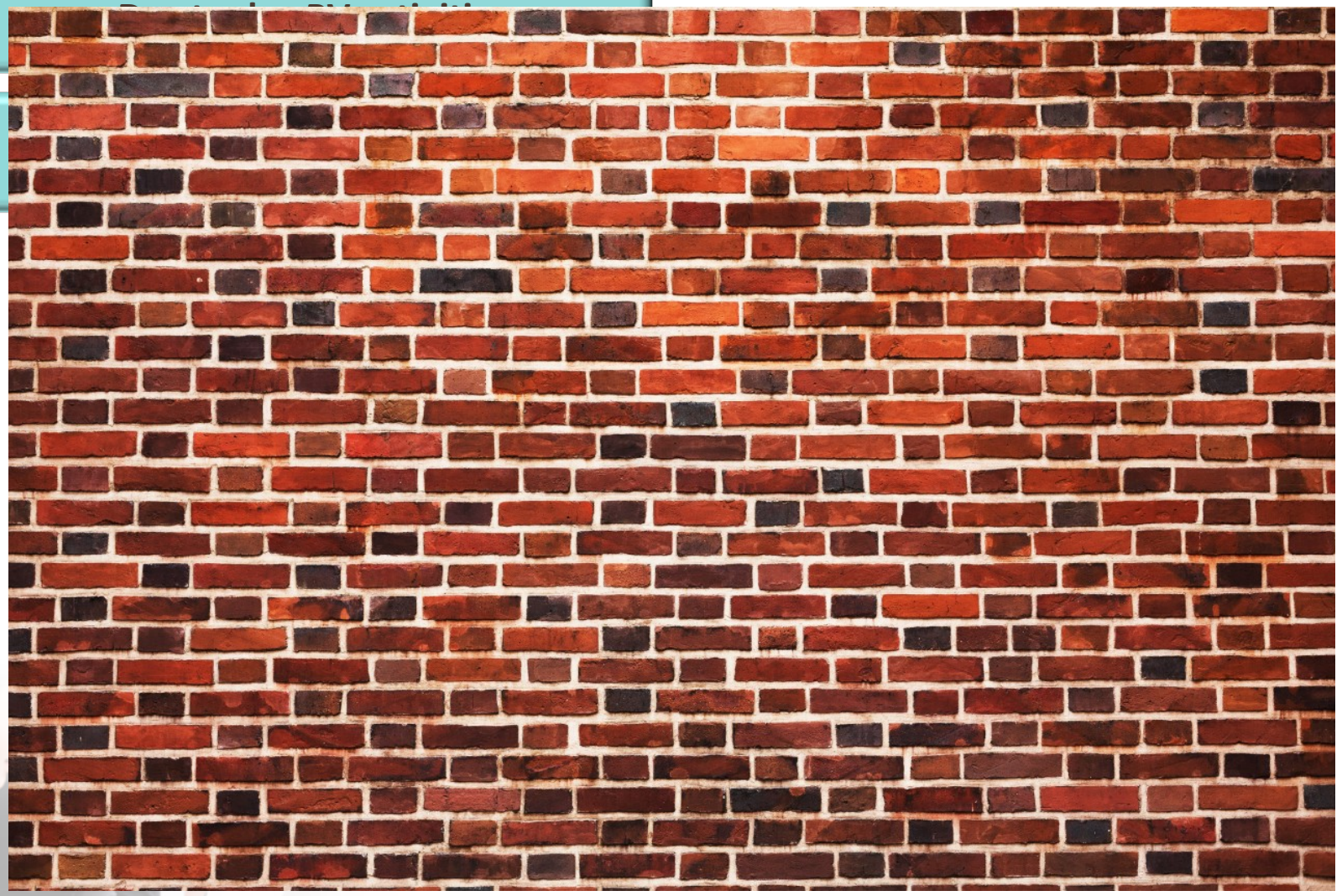
Benefit/Risk evaluation management

Efficient decision making



Keyrus BIOPHARMA

PV activity outsourcing challenges



Keyrus BIOPHARMA

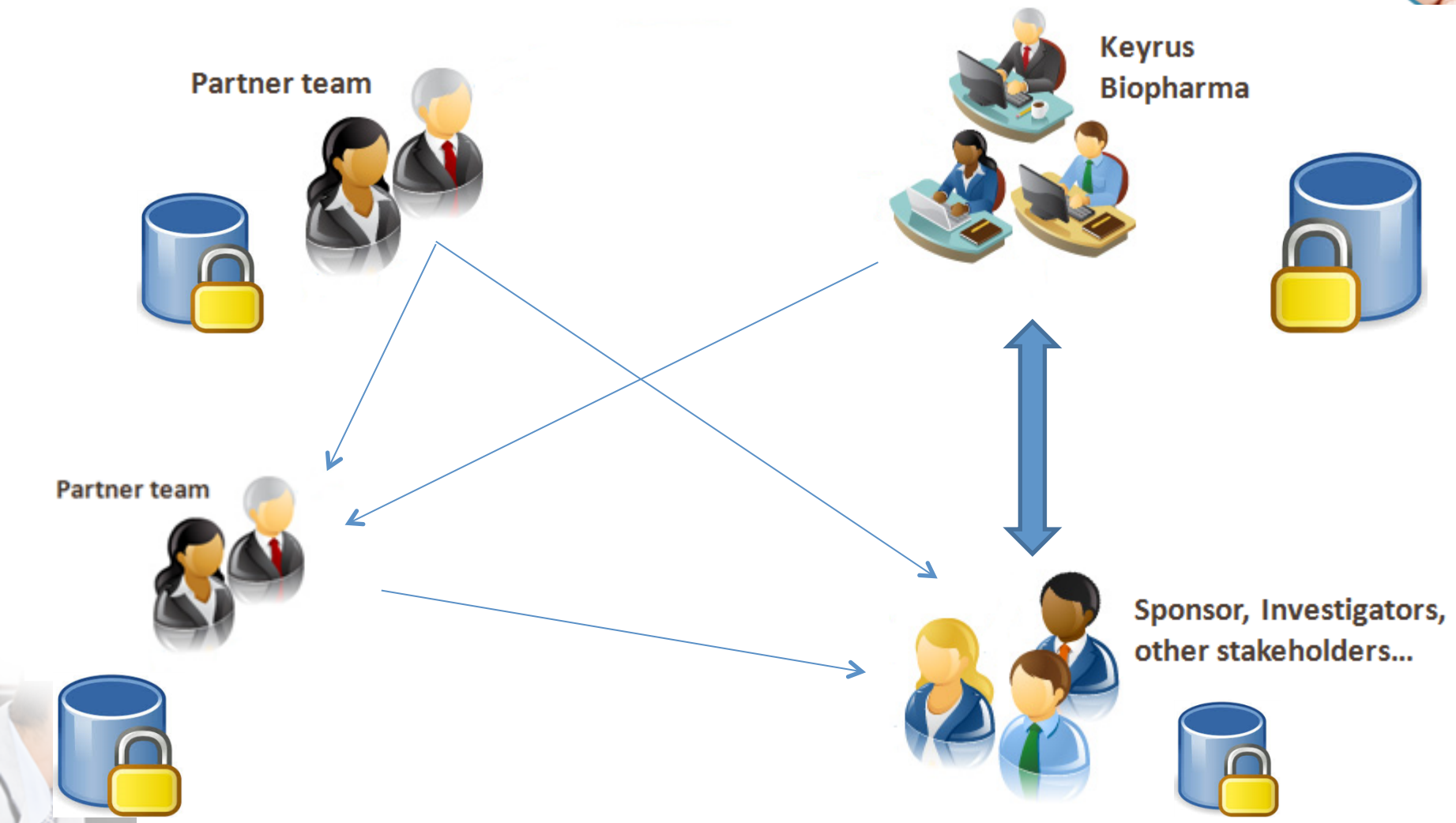


Pharmacovigilance, Drug safety and Risk Management

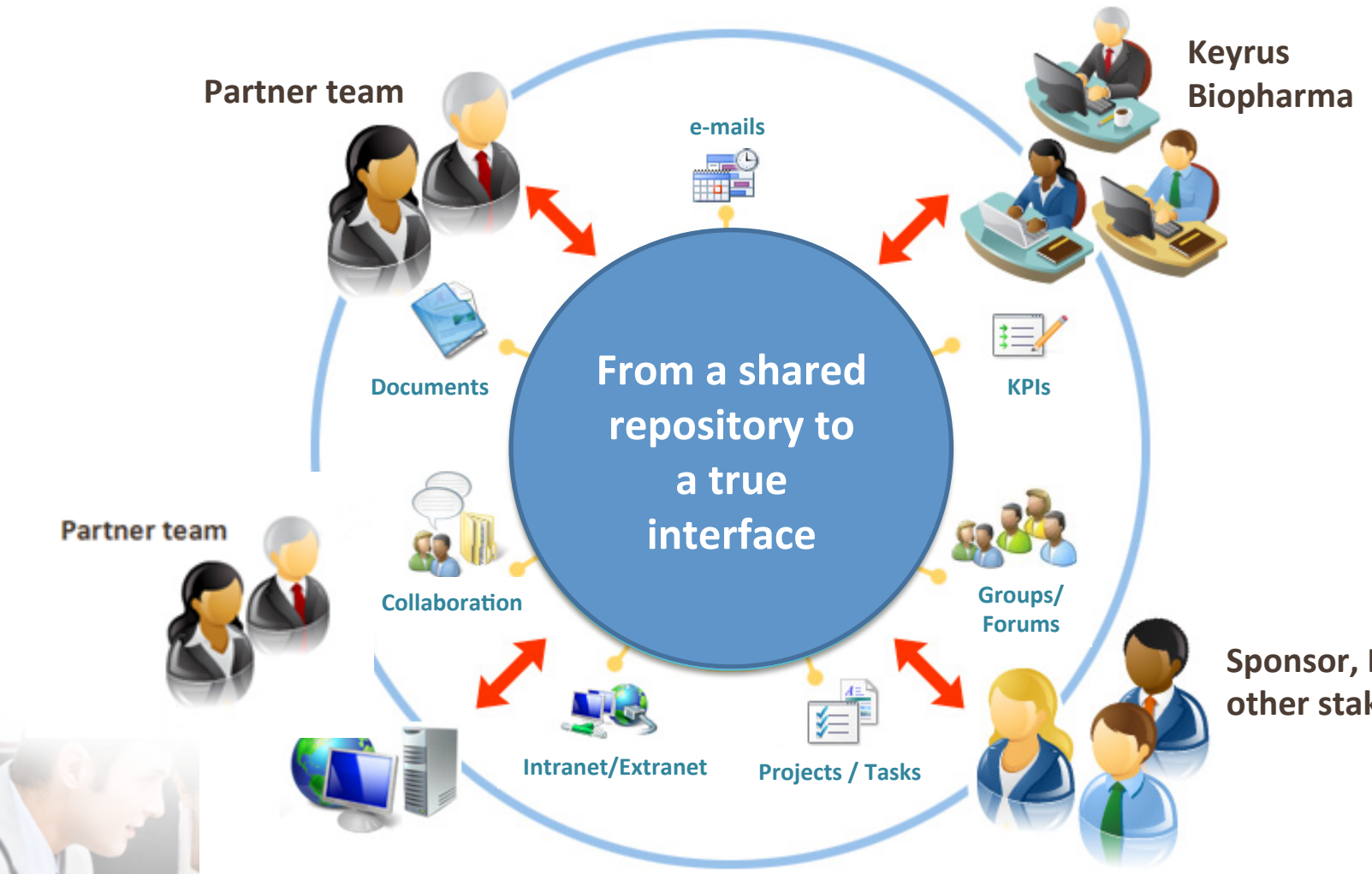
Use a secure web-base interface to develop a collaborative partnership

Keyrus BIOPHARMA

Collaborative environment – Virtual Office



Collaborative environment – Virtual Office



PV activity Roles and Responsibilities

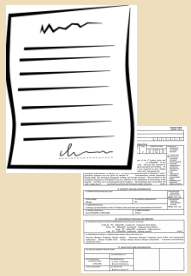


- Roles and responsibilities
- Sharing information
- Electronic paths of collaboration
- Access to the stakeholders
- Information workflows
- Actions and tasks

➢ Define needs
  - Views
  - Key information
  - Performance indicators
  - Accessibility, set ups, design and flexibility



Case Management Process



Virtual Office

Safety Database

Data Entry

Quality Control

Medical Review

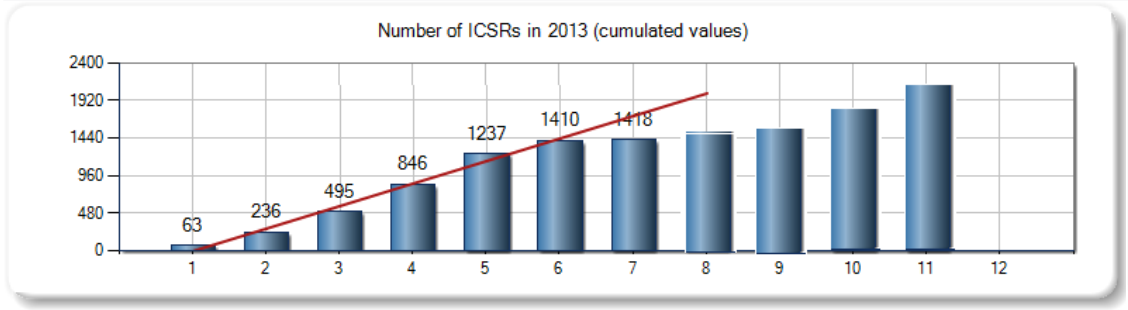
Reporting / Submission

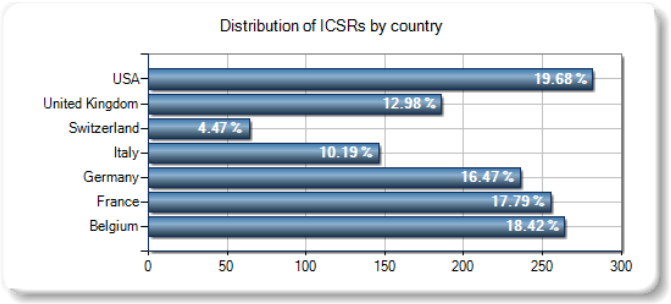
Case closure

PV Business Process

Keyrus BIOPHARMA

PV activity outsourcing challenges





Indicator	Goal	Status
Clinical trial serious D/LT cases	98%	
Spont. serious D/LT cases	95%	
Serious cases	95%	
Non Serious cases	80%	

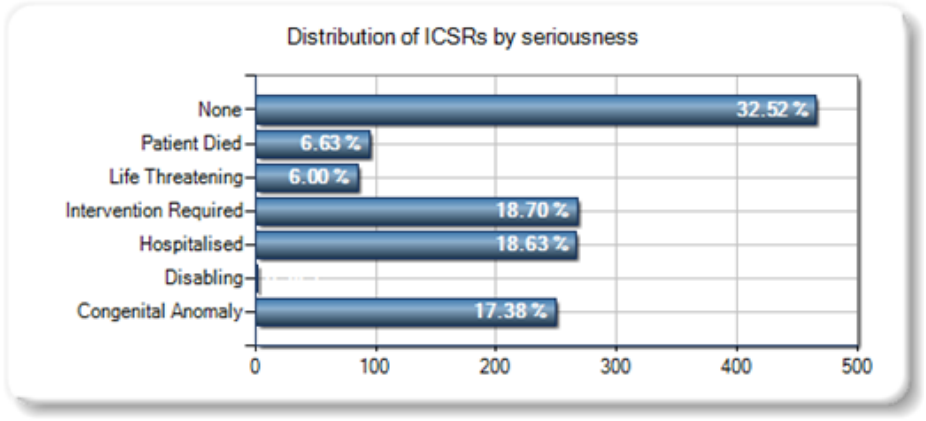
Current open serious cases (D/LT)

ICSR ID	Status	Due Date	Reason for Seriousness	Report Type
KBP-CASE-00268-FU4	4-Reporting and Submission	11/11/2013	Life Threatening	Spontaneous
KBP-CASE-00298-FU3	2-QC Check	11/16/2013	Life Threatening	Spontaneous
KBP-CASE-00304-FU3	2-QC Check	11/4/2013	Life Threatening	Clinical trial
KBP-CASE-00331-FU4	3-Medical Review	11/12/2013	Life Threatening	Spontaneous
KBP-CASE-00348-FU4	4-Reporting and Submission	11/5/2013	Life Threatening	Spontaneous
KBP-CASE-00351-FU2	3-Medical Review	11/7/2013	Patient Died	Spontaneous
FR-12345-In	2-QC Check	11/14/2013	Life Threatening	Clinical trial
KBP-PASCAL-0001-I	3-Medical Review	12/18/2013	Patient Died	Spontaneous

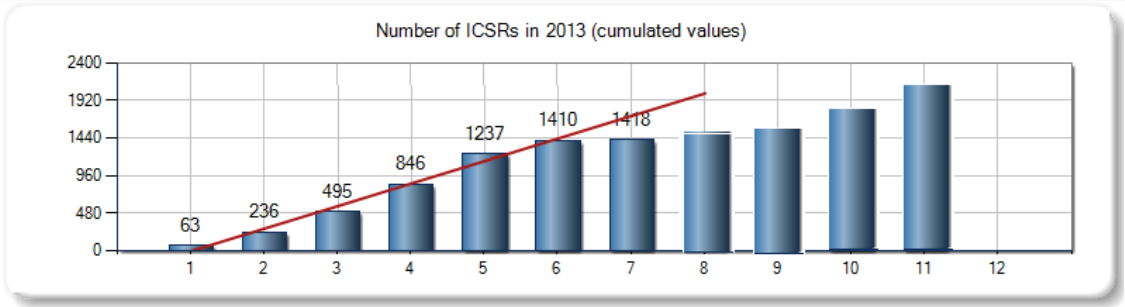
Serious cases that need to be reported to authorities within the next 5 days

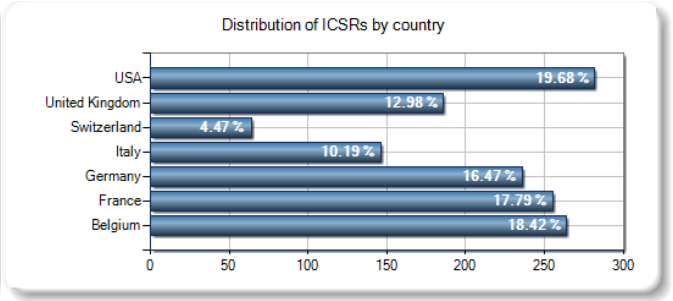
ICSR ID	Assigned To	Status	Due Date	Reason for Seriousness





PV activity outsourcing challenges





Indicator	Goal	Status
Clinical trial serious D/LT cases	98%	
Spont. serious D/LT cases	95%	
Serious cases	95%	
Non Serious cases	80%	

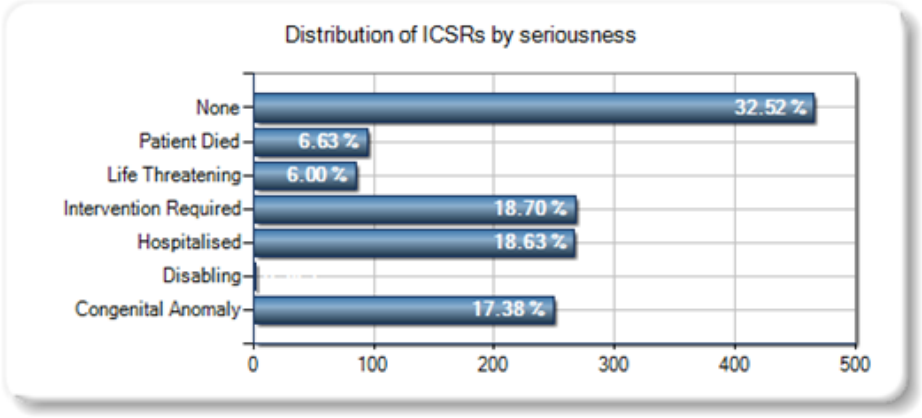
Current open serious cases (D/LT)

ICSR ID	Status	Due Date	Reason for Seriousness	Report Type
KBP-CASE-00268-FU4	4-Reporting and Submission	11/11/2013	Life Threatening	Spontaneous
KBP-CASE-00298-FU3	2-QC Check	11/16/2013	Life Threatening	Spontaneous
KBP-CASE-00304-FU3	2-QC Check	11/4/2013	Life Threatening	Clinical trial
KBP-CASE-00331-FU4	3-Medical Review	11/12/2013	Life Threatening	Spontaneous
KBP-CASE-00348-FU4	4-Reporting and Submission	11/5/2013	Life Threatening	Spontaneous
KBP-CASE-00351-FU2	3-Medical Review	11/7/2013	Patient Died	Spontaneous
FR-12345-In	2-QC Check	11/14/2013	Life Threatening	Clinical trial
KBP-PASCAL-0001-I	3-Medical Review	12/18/2013	Patient Died	Spontaneous

Serious cases that need to be reported to authorities within the next 5 days

ICSR ID	Assigned To	Status	Due Date	Reason for Seriousness





Keyrus BIOPHARMA

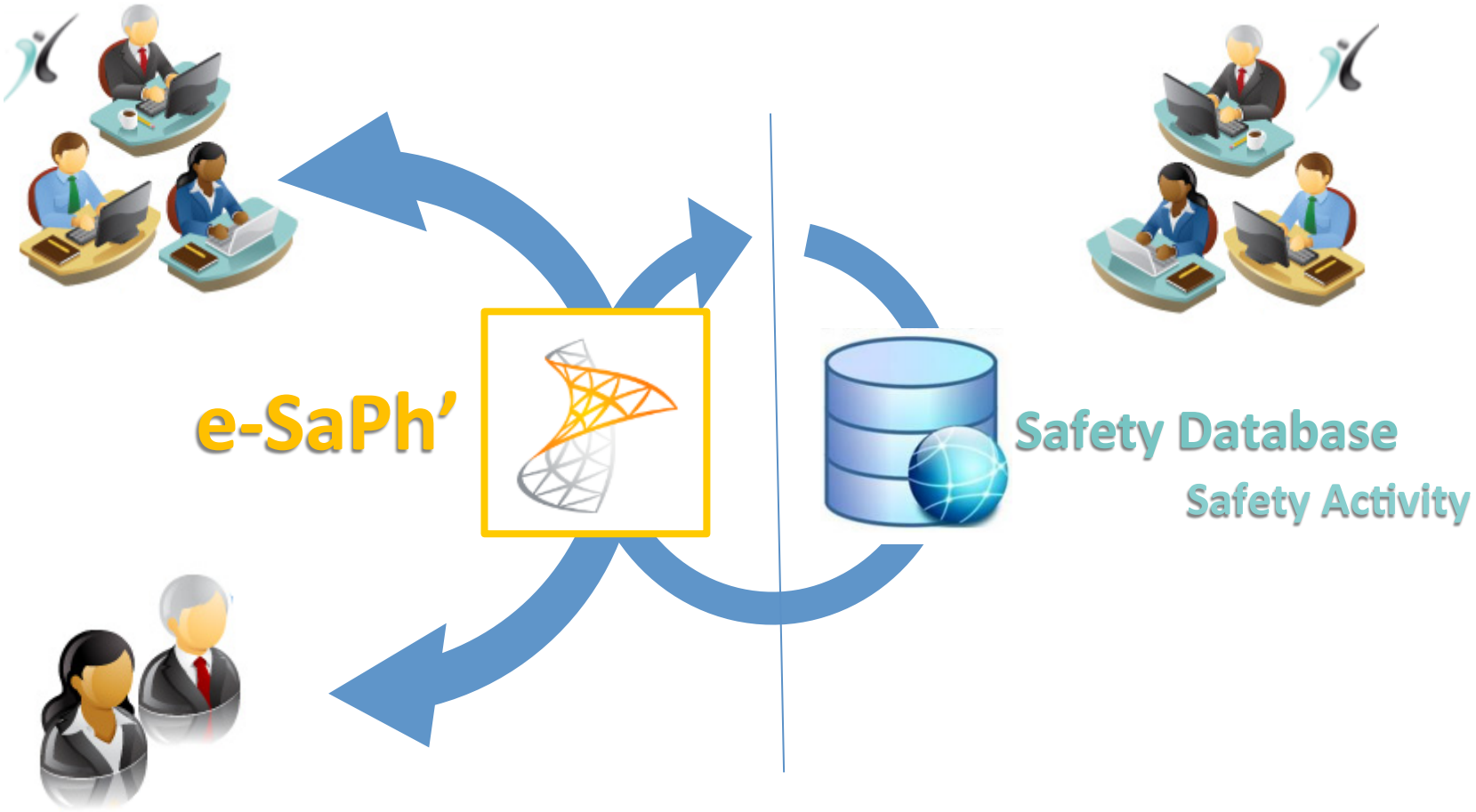


Pharmacovigilance, Drug safety and Risk Management

e-SaPh'
Electronic Safety and Pharmacovigilance

Keyrus BIOPHARMA

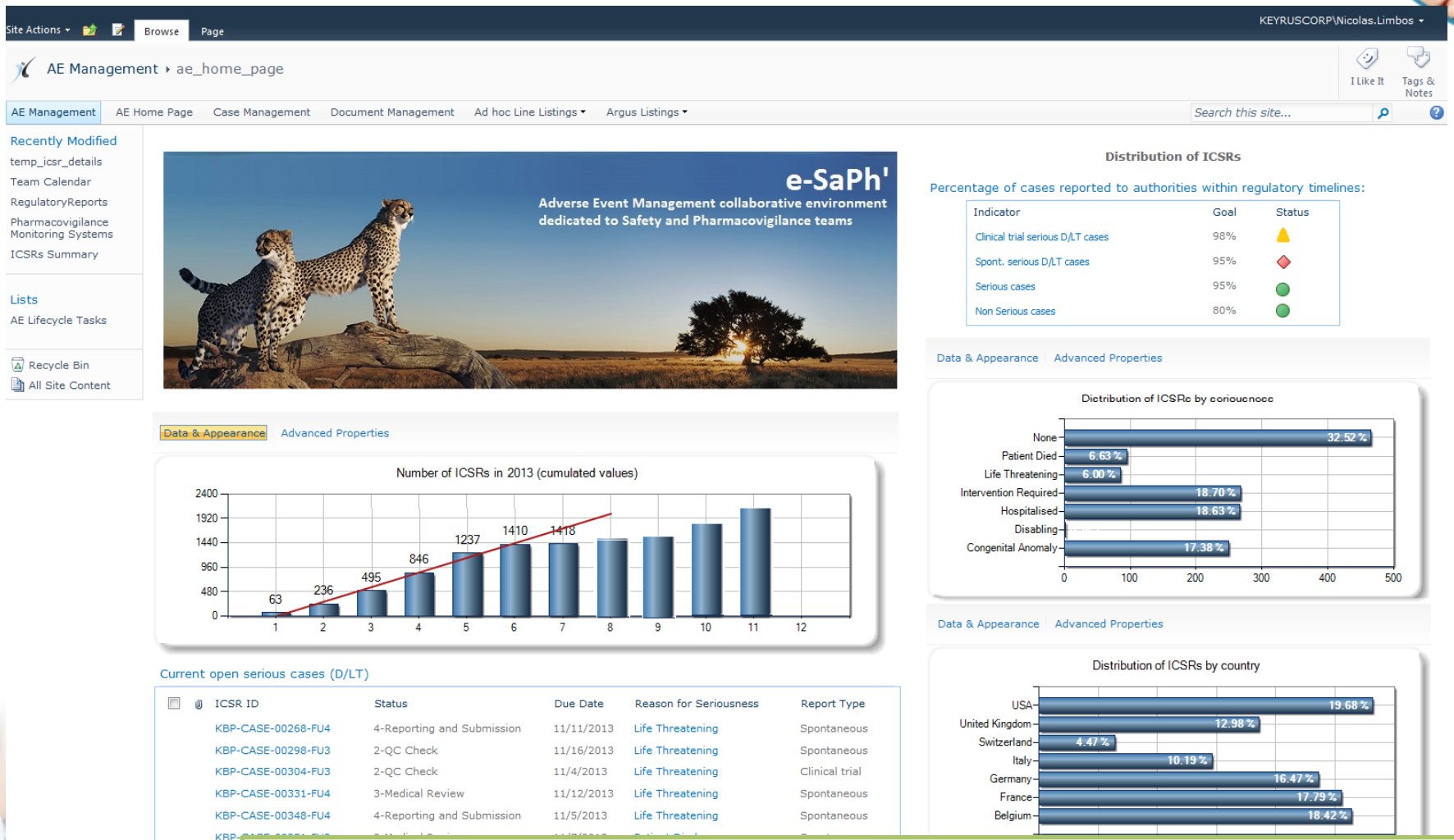
e-SaPh' Overview



Constant interaction and information exchange with stakeholders
Proactive approach ensured by the use of Metrics and KPIs

Use the tools for what they are designed for.

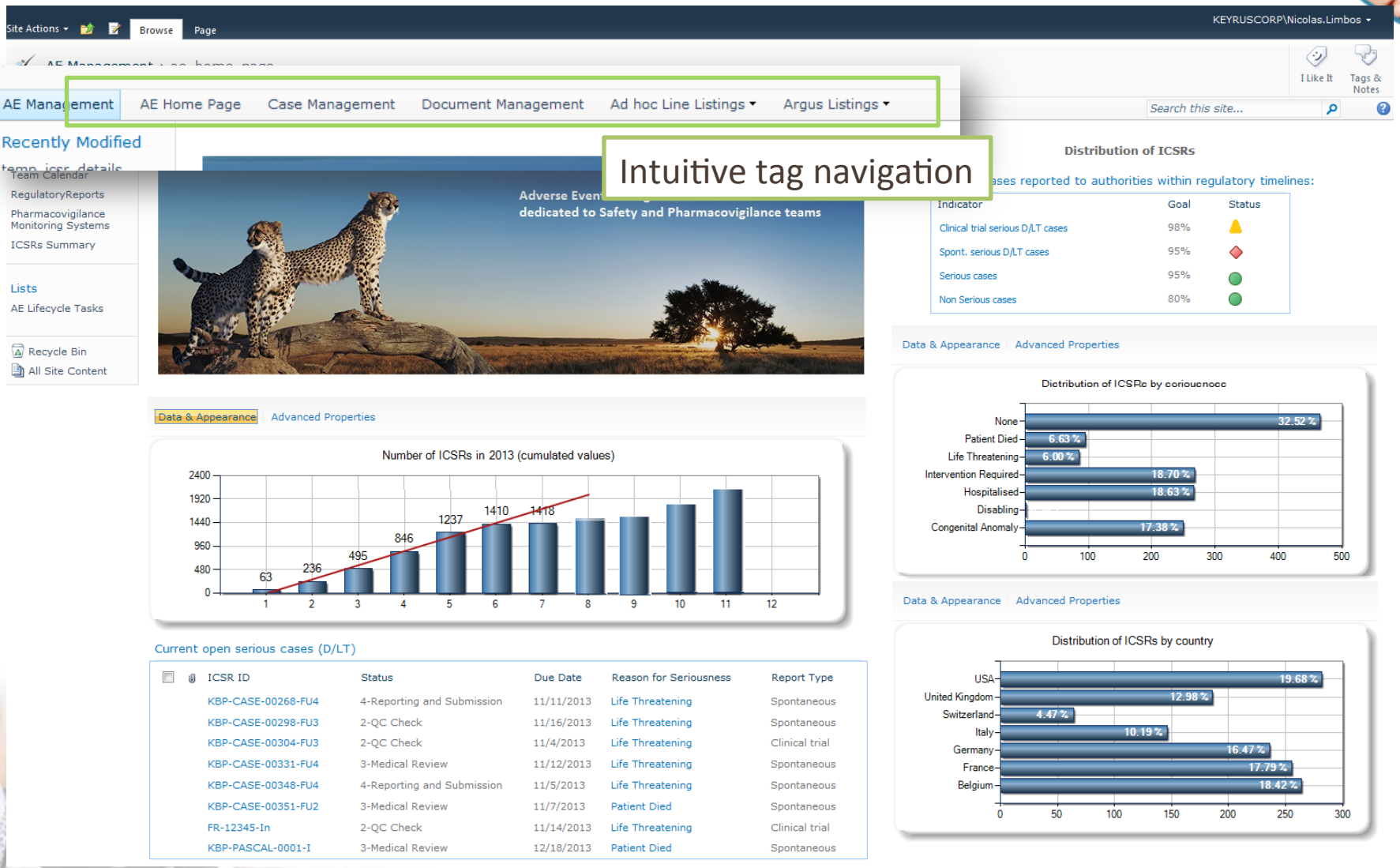
e-SaPh' Comprehensive dashboard



Clear and customizable Dashboard for easy PV activity surveillance

Keyrus BIOPHARMA

e-SaPh' Comprehensive dashboard



e-SaPh' Comprehensive dashboard



Site Actions | Browse | Page | KEYRUSCORP\Nicolas.Limbos

AE Management ▸ ae_home_page

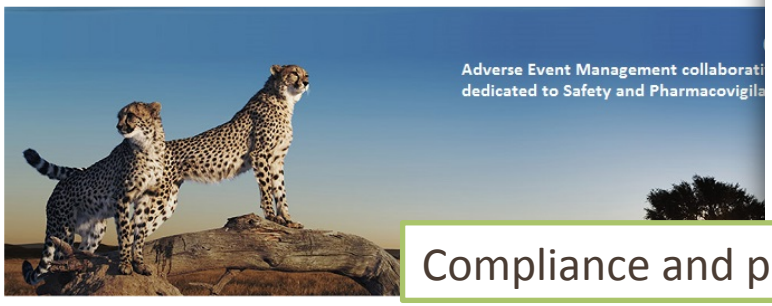
I Like It | Tags & Notes

AE Management | AE Home Page | Case Management | Document Management | Ad hoc Line Listings | Argus Listings

Recently Modified
temp_icsr_details
Team Calendar
RegulatoryReports
Pharmacovigilance Monitoring Systems
ICSRs Summary

Lists
AE Lifecycle Tasks

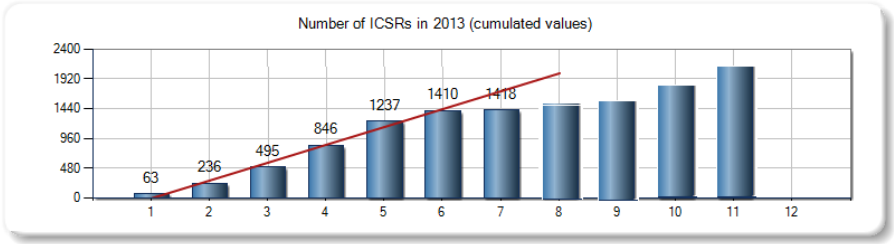
Recycle Bin
All Site Content

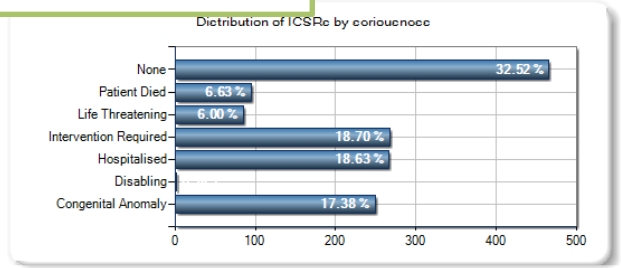


Indicator	Goal	Status
Clinical trial serious D/LT cases	98%	
Spont. serious D/LT cases	95%	
Serious cases	95%	
Non Serious cases	80%	

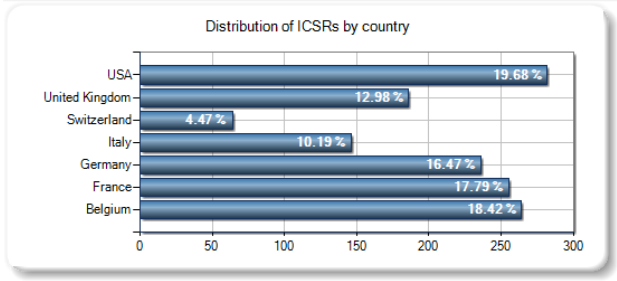
Compliance and performance indicators

Data & Appearance | Advanced Properties





Data & Appearance | Advanced Properties

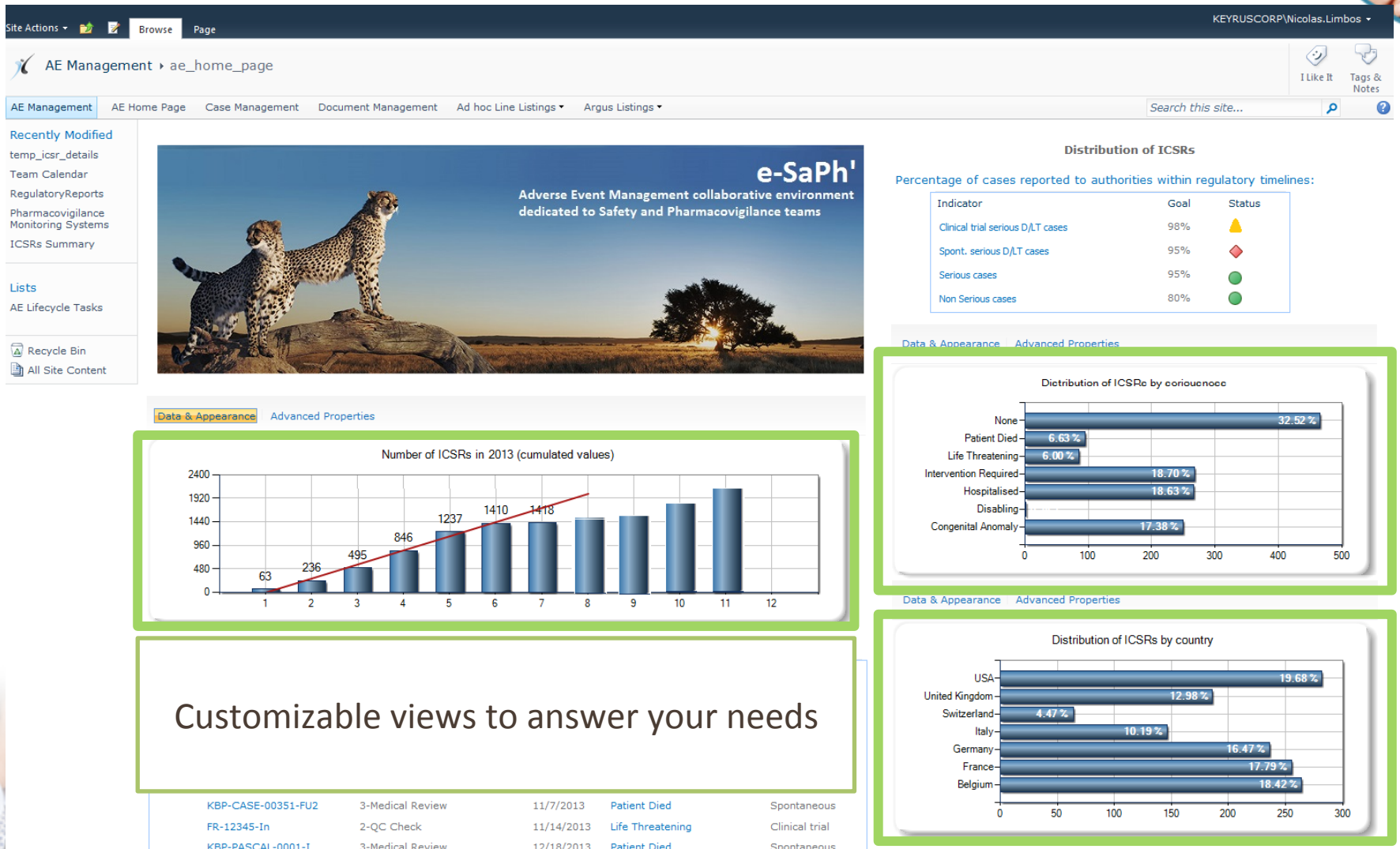


Current open serious cases (D/LT)

ICSR ID	Status	Due Date	Reason for Seriousness	Report Type
KBP-CASE-00268-FU4	4-Reporting and Submission	11/11/2013	Life Threatening	Spontaneous
KBP-CASE-00298-FU3	2-QC Check	11/16/2013	Life Threatening	Spontaneous
KBP-CASE-00304-FU3	2-QC Check	11/4/2013	Life Threatening	Clinical trial
KBP-CASE-00331-FU4	3-Medical Review	11/12/2013	Life Threatening	Spontaneous
KBP-CASE-00348-FU4	4-Reporting and Submission	11/5/2013	Life Threatening	Spontaneous
KBP-CASE-00351-FU2	3-Medical Review	11/7/2013	Patient Died	Spontaneous
FR-12345-In	2-QC Check	11/14/2013	Life Threatening	Clinical trial
KBP-PASCAL-0001-I	3-Medical Review	12/18/2013	Patient Died	Spontaneous

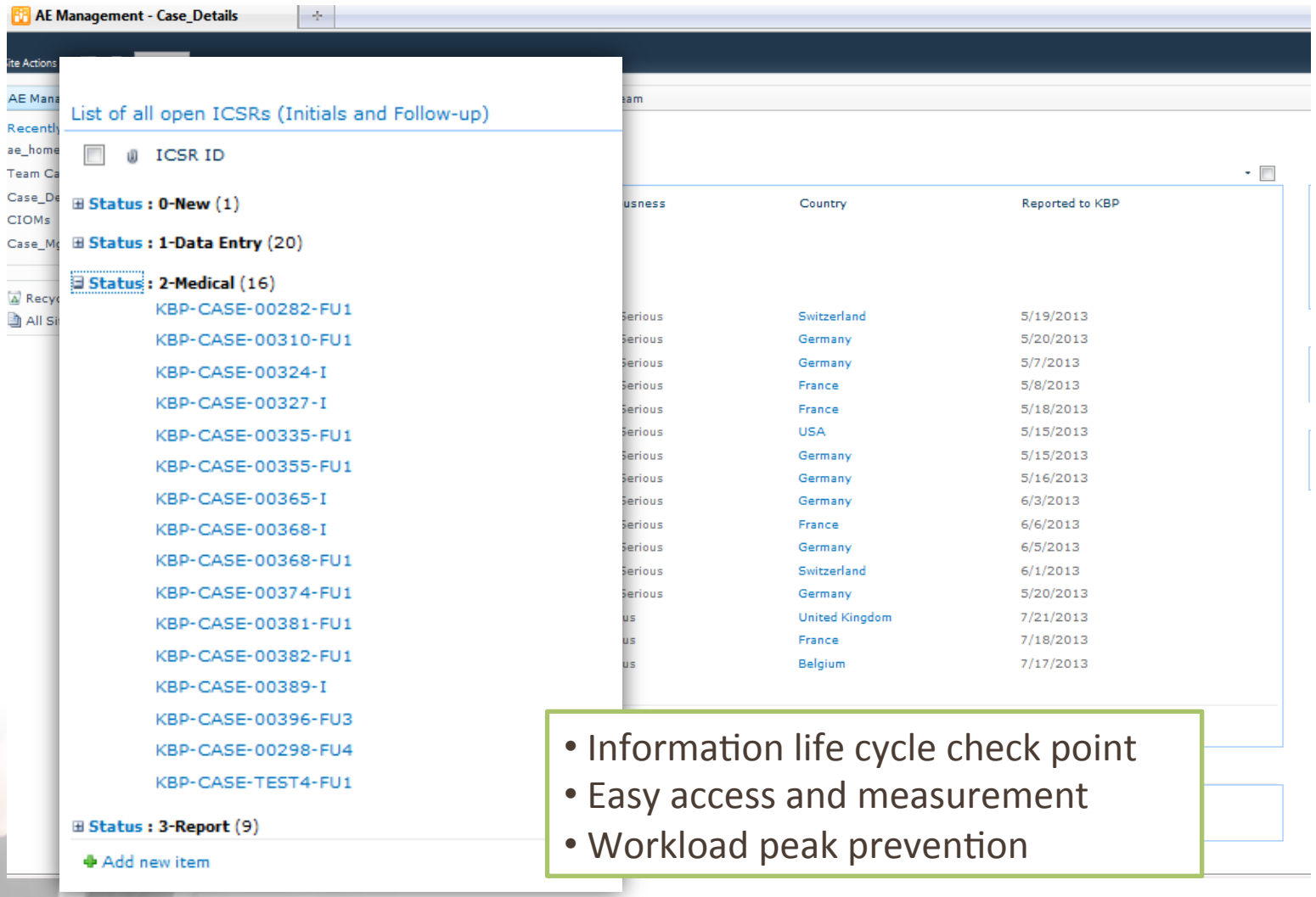
Keyrus BIOPHARMA

e-SaPh' Comprehensive dashboard



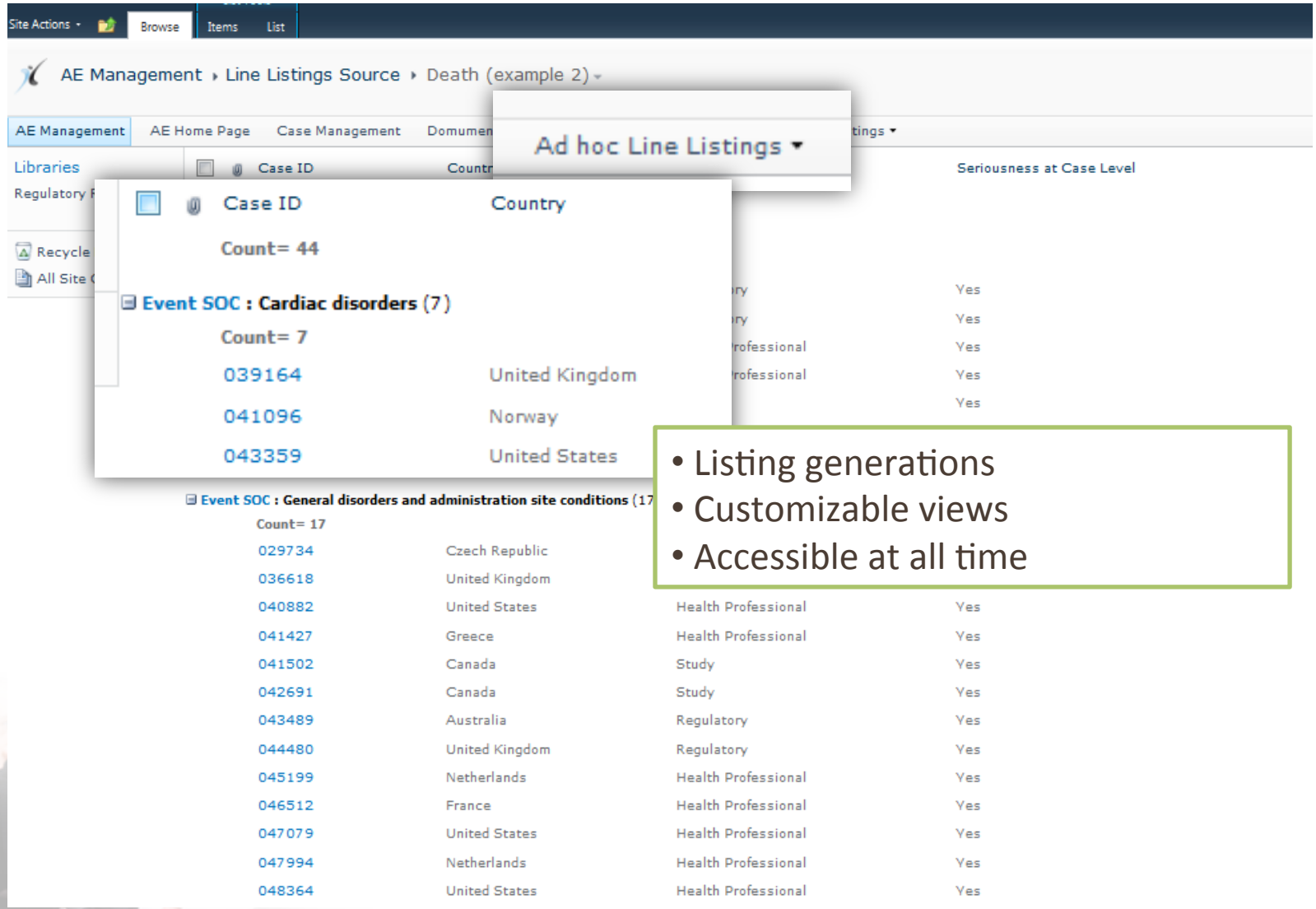
Customizable views to answer your needs

e-SaPh' Case management details



- Information life cycle check point
- Easy access and measurement
- Workload peak prevention

e-SaPh' Ad hoc line listing



- Listing generations
- Customizable views
- Accessible at all time

Keyrus BIOPHARMA

How can e-SaPh' help us to fulfill your needs?

Site Actions | Browse | Page | KEYRUSCORP\Nicolas.Limbos

AE Management ▸ ae_home_page

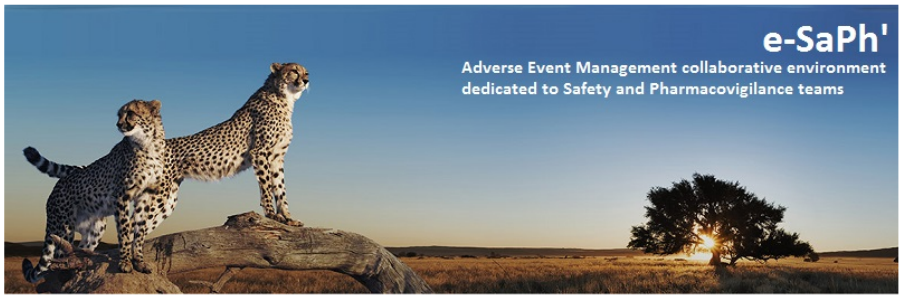
I Like It | Tags & Notes

AE Management | AE Home Page | Case Management | Document Management | Ad hoc Line Listings | Argus Listings | Search this site...

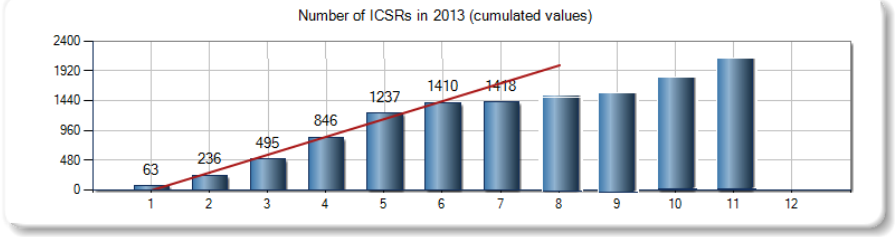
Recently Modified
- temp_icsr_details
- Team Calendar
- RegulatoryReports
- Pharmacovigilance Monitoring Systems
- ICSRs Summary

Lists
- AE Lifecycle Tasks

- Recycle Bin
- All Site Content



Data & Appearance | Advanced Properties



Current open serious cases (D/LT)

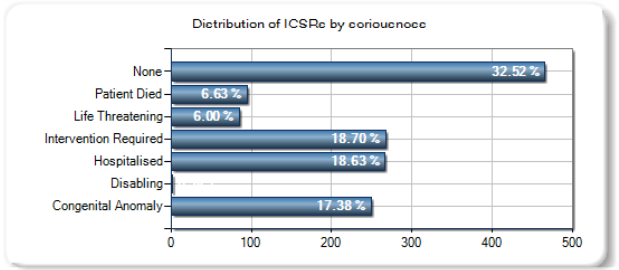
ICSR ID	Status	Due Date	Reason for Seriousness	Report Type
KBP-CASE-00268-FU4	4-Reporting and Submission	11/11/2013	Life Threatening	Spontaneous
KBP-CASE-00298-FU3	2-QC Check	11/16/2013	Life Threatening	Spontaneous
KBP-CASE-00304-FU3	2-QC Check	11/4/2013	Life Threatening	Clinical trial
KBP-CASE-00331-FU4	3-Medical Review	11/12/2013	Life Threatening	Spontaneous
KBP-CASE-00348-FU4	4-Reporting and Submission	11/5/2013	Life Threatening	Spontaneous
KBP-CASE-00351-FU2	3-Medical Review	11/7/2013	Patient Died	Spontaneous
FR-12345-In	2-QC Check	11/14/2013	Life Threatening	Clinical trial
KBP-PASCAL-0001-I	3-Medical Review	12/18/2013	Patient Died	Spontaneous

Distribution of ICSRs

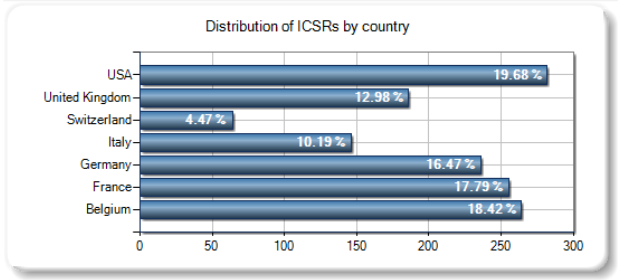
Percentage of cases reported to authorities within regulatory timelines:

Indicator	Goal	Status
Clinical trial serious D/LT cases	98%	▲
Spont. serious D/LT cases	95%	◆
Serious cases	95%	●
Non Serious cases	80%	●

Data & Appearance | Advanced Properties



Data & Appearance | Advanced Properties



Keyrus BIOPHARMA

e-SaPh' Documents sharing



Master ICSR / AE : Case 12082014_01 FU1 (1)

Master ICSR / AE : CASE ID FROM ARGUS- INI (1)

✓ Case ID from ARGUS - NIN - SD	...	Source document	CASE ID FROM ARGUS- INI

Master ICSR / AE : Jet-2014-12345 INI (1)

Master ICSR / AE : KBP - CASE - 000555 - INI (1)

Master ICSR / AE : KBP-CASE-00001-I (1)

Master ICSR / AE : KBP-CASE-00003-I (2)

Master ICSR / AE : KBP-CASE-00053-I (1)

Master ICSR / AE : KBP-CASE-00095-I (5)

KBP-CASE-00095 - Ini - SD	...	Source document	KBP-CASE-0009
KBP-CASE-00095 - Ini - FC	...	Final CIOMS	KBP-CASE-0009
KBP-CASE-00095 - Ini - MRF 2	...	Medical Review Form	KBP-CASE-0009
KBP-CASE-00095_-_Ini__-_MRF Revision	...	Medical Review Form	KBP-CASE-0009
JET-TEST-CASE INI SD	...	Source document	KBP-CASE-0009

Orphan Documents

new | upload | edit | share

✓ Name	
CT-OCR-JP-00029 Medical Summary	...
CT-US-O-00001 CIOMS	...
CT-US-O-00001 Medical Summary	...
CT-US-O-00002 CIOMS	...
name of the doc - info	...

✓ Literature screening	...	17 juillet
Meeting Minutes	...	22 août
Process description and agreements	...	17 juillet
Product information	...	17 juillet
RMP	...	26 août
Templates	...	25 août
Training material	...	25 août



Keyrus BIOPHARMA

How can e-SaPh' help us to fulfill your needs?



Through a well design web interface, a shared repository can become a real and efficient safety tool giving access to all information to all stakeholder in real time.

- Outsource your safety activity keep in touch with it
- Various functions for various roles and responsibilities
- Customizable views and search tool for any purposes
- Flexibility and efficiently a low price



PV activity outsourcing challenges



Day to day PV activities

Reports and signals

Full picture of safety data

Accurate metrics and KPIs

Listings and trends

Compliance monitoring

Benefit/Risk evaluation management



Cost control

Efficient decision making

Keyrus BIOPHARMA

How can e-SaPh' help us to fulfill your needs?



- ✓ Immediate user adoption
- ✓ Speed up interaction between stakeholders
- ✓ Secure environment
- ✓ Real time information
- ✓ Comprehensive dashboard
- ✓ User interface fitted to your needs
- ✓ Infinite listings generation
- ✓ Cost reduced (DB license, training…)



Keyrus BIOPHARMA

REACHING FOR **CLINICAL RESEARCH EXCELLENCE**



Thank You

France
+33 1 41 34 28 28

Belgium
+32 2 627 51 30

Lebanon
+961 3 99 73 44

Tunisia
+216 71 79 52 00

www.keyrusbiopharma.com