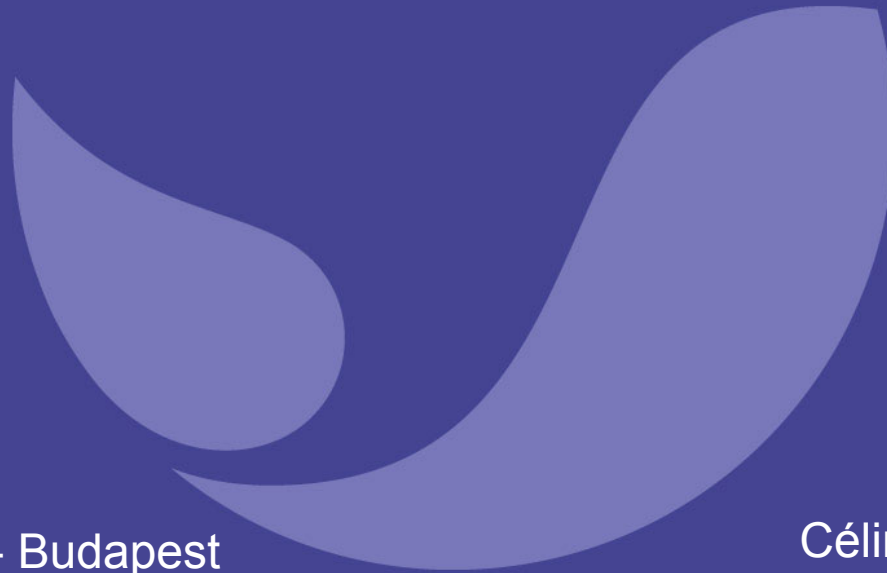




A Maestro for our Clinical Data



PhUSE 2012 - Budapest
Paper AD05

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Agenda



-
- **Maestro**
 - **Maestro Program**
 - Definition
 - Objectives
 - **Maestro Project Release 1 :**
 - Scope
 - Process
 - CDH
 - Safir
 - **Service Implementation Strategy**
 - **Definition**
 - **Strategy**
 - **Next steps**
 - **Questions**



Orchestrating a Technical Solution to Exploit Integrated Clinical Data

MAESTRO Program Definition



- **What is the MAESTRO Program?**

The MAESTRO Program is a set of integrated projects and workstreams that will iteratively provide a technical framework to facilitate the early assessment of safety signals and benefits of our compounds in all phases of development.

- **Long Term MAESTRO Vision:**

To maximize value incrementally from our clinical data in support of our objectives for safety analysis, benefit risk assessment and enhanced analytics by 2013.

MAESTRO Program Definition



MAESTRO

ABILITY TO **AGGREGATE AND CONSOLIDATE** CLINICAL DATA IN ONE LOCATION FOR A BROADER NUMBER OF USERS

ABILITY TO FACILITATE **SIGNAL DETECTION**

ABILITY TO FACILITATE **BENEFIT/RISK ANALYSIS**

ABILITY TO **EXTEND THE USAGE** OF ACQUIRED DATA

PROGRAM PRINCIPLES

- From phase I to phase IV, **automate and standardize fast data integration** on an ongoing basis
- Use interactive tools to allow **on line data visualization**, including detection of qualitative safety signal
- Development of sophisticated, **interactive, graphical data analyses capabilities** to better exploit available data - better display efficacy and safety to support B/R assessment
- Allow **further data exploitation** beyond compounds

MAESTRO Project Release 1

Scope



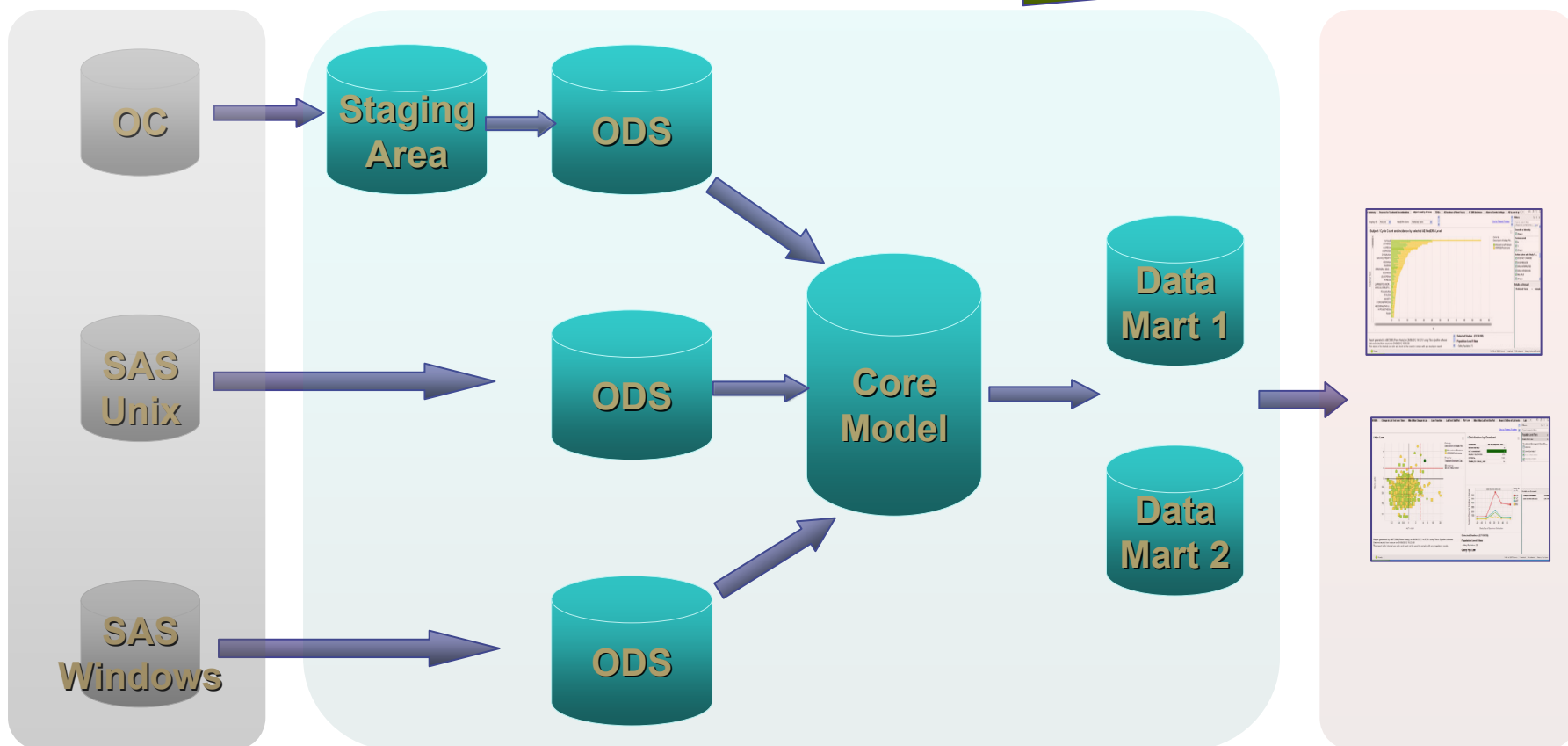
- **Clinical Data Hub (CDH)**
 - CDH builds the Clinical Data Hub by implementing, customizing, and configuring the physical data model and building the initial set of required interfaces between source systems and the hub.
 - **SAFety Interactive Review (SAFIR)**
 - SAFIR implements the user-interface reporting solutions used to provide access to the clinical safety data in the hub, to support medical review and safety signal detection .
 - **Target users**
 - **Clinical department :**
 - Medical operations
 - Business units
 - **Global Pharmacovigilance and Epidemiology**
 - **Biostatistics department**
-

MAESTRO Project Release 1 Process



Informatica Power Center

Spotfire®



Source Systems

Clinical Data Hub

SAFIR

MAESTRO Project Release 1 CDH



- Consolidation and aggregation of legacy and on-going study data
 - Integration of the identified source systems
 - Develop and implement the data model / data marts for downstream users
- Support of the work to be performed on Safety Signal Detection (Safir project)
 - Establish data processing workflows within the CDH to support activities:
 - Transformation / Enrichment, Facilitation of Study Pooling
 - Data Load services (Mapping, etc...)
- Access / Security Management (Data & User)
- Overall data, programs and outputs traceability
- Development and implementation of Service Model to support future system / data integration

MAESTRO Project Release 1

SAFIR - Objectives

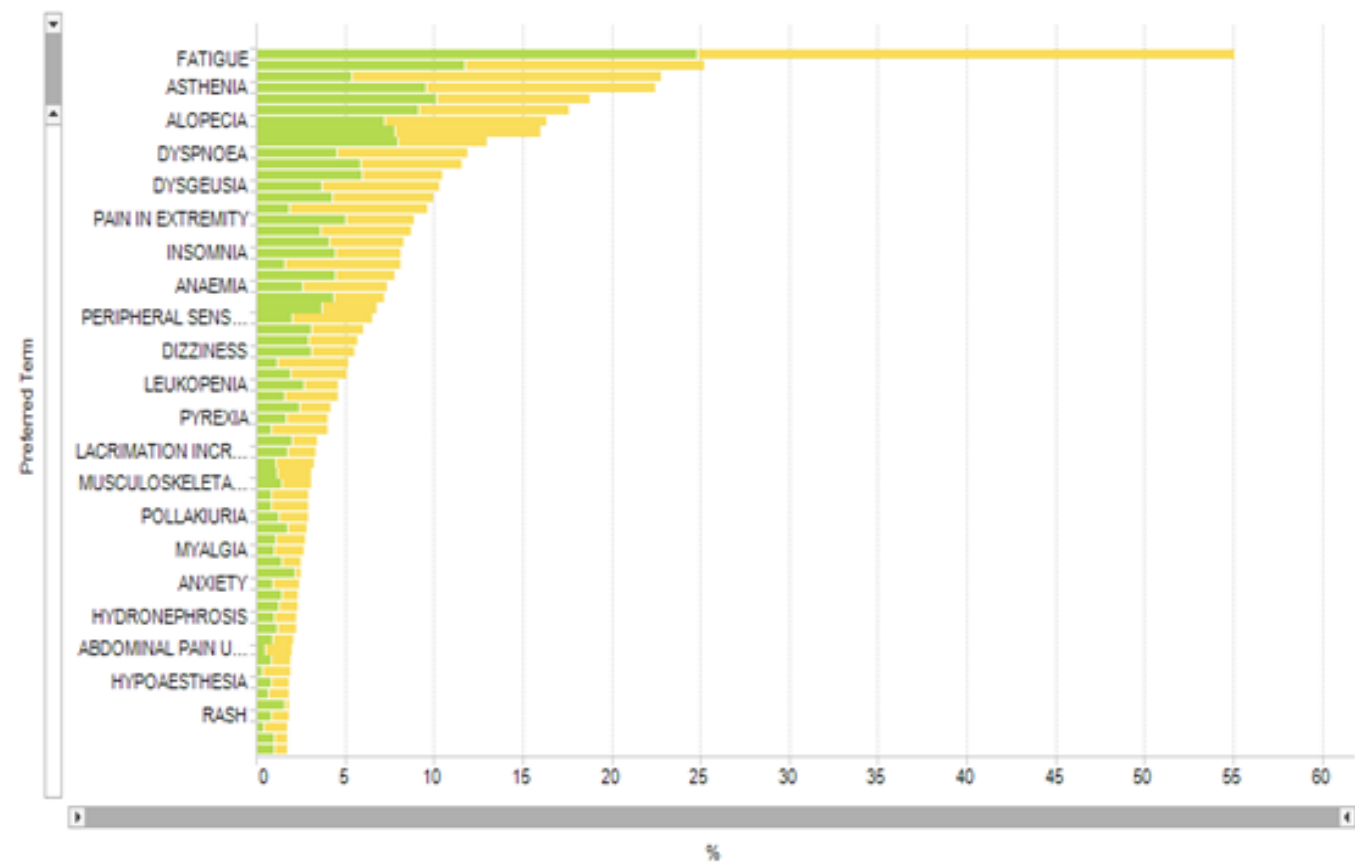


- Ability to perform analysis of clinical safety data within the centralized solution for any given program
 - Ability to respond to regulatory safety questions with greater reliability and confidence in the responses provided
 - Ability to perform signal detection across a broader pool of data, both quantitative and exploratory for improved earlier decision-making
 - Ability to provide access to these data to a broad spectrum of data users and reviewers
 - Moving away from paper-based listings to visualization and graphics tools
-

Display By : Percent MedDRA Term: Preferred Term

[Go to Patient Profiles](#)

Subject / Cycle Count and incidence by selected AE MedDRA Level



Color by:
Description of Actually Re...

■ ■

Filters

Type to search filters

Severity or Intensity

☒ (Empty)

Serious event

☒ N

☒ Y

☒ (Empty)

Action Taken with Study Tr...

☒ DOSE NOT CHANGED

☒ DOSE REDUCED

☒ DRUG INTERRUPTED

☒ DRUG WITHDRAWN

☒ MULTIPLE

☒ (Empty)

Details-on-Demand

Preferred Term	Domain
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Report generated by [REDACTED] on 26/06/2012 14:52:51 using Tibco Spotfire software
 Data extracted from source on 01/06/2012 16:25:00
 This report is for internal use only and must not be used to comply with any regulatory needs

Selected Studies : [REDACTED]
 Population Level Filters
 - Safety Population: (Y)

(None)

AAAAAA

BBBBBB

Ref Trt:

(None)

AAAAAA

BBBBBB

Test Trt:

1.00

18.00

MedDRA Term:

System Organ Class

Please, check if No zoom is active. Otherwise, reset zoom :

☒ False

[Go to Patient Profiles](#)

Filters

Type to search filters

Population Level Filters

Randomized Population

☒ (Empty)

Safety Population

☐ N

☒ Y

Description of Planned Arm

☒ AAAAAA

☒ Screen Failure

☒ BBBBBB

Description of Actually Rece...

☒ (Empty)

☒ AAAAAA

☒ BBBBBB

Study Identifier

☒

Country code

Type to search in list

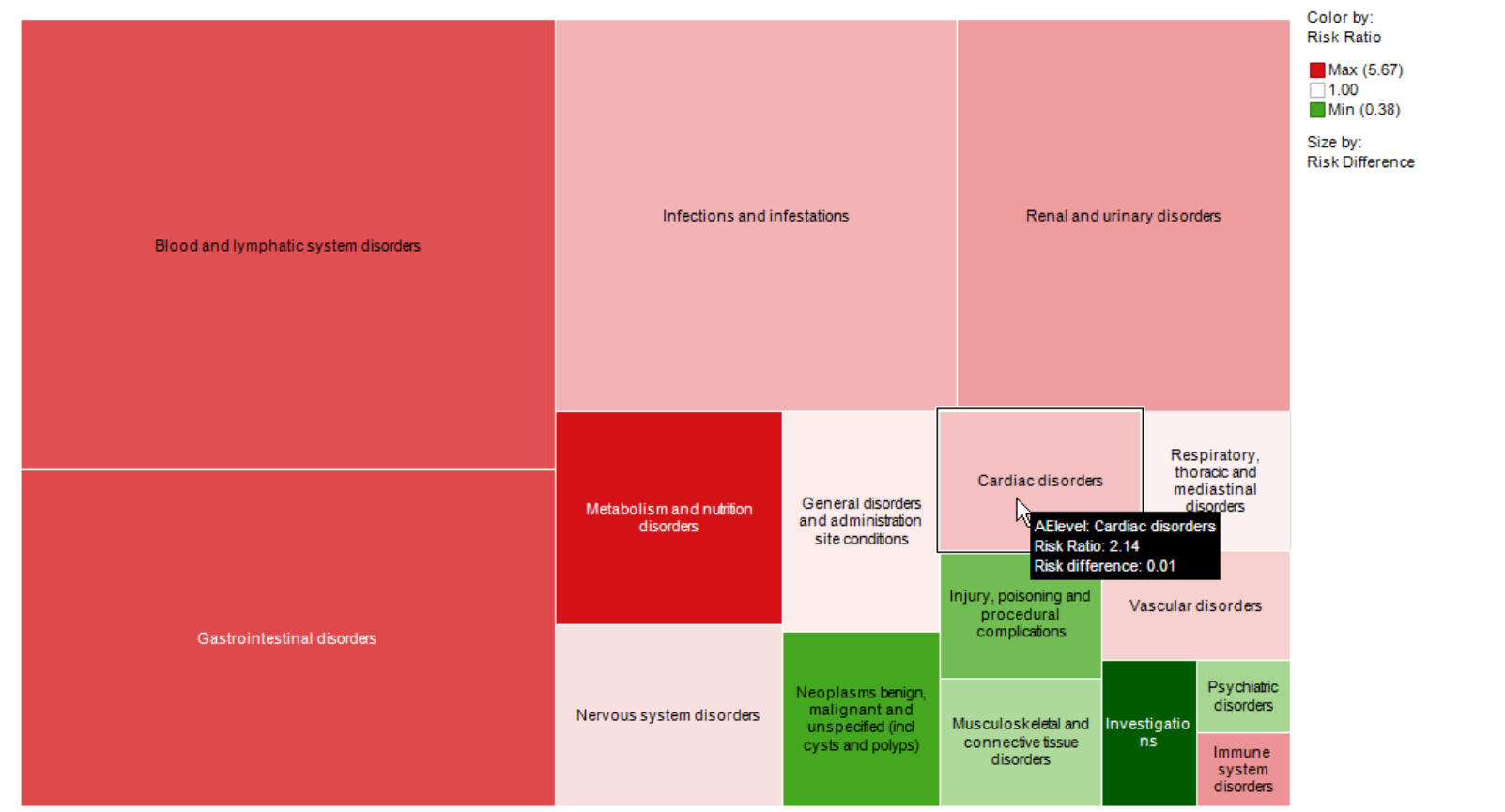
(All) 26 values

ARG

Details-on-Demand

AElevel	treatment
Investigations	AAAAAA
Investigations	BBBBBB

Risk Ratio Treemap Analysis



Report generated by [redacted] on 10/12/2012 1:44:53 PM using Tibco Spotfire software
 Data extracted from source on 7/10/2012 3:59:38 PM
 This report is for internal use only and must not be used to comply with any regulatory needs.

Selected Studies : [redacted]

Population Level Filters
 - Safety Population: (Y)

(None)

(Empty)

AAAAAA

Ref Trt:

BBBBBB

(None)

(Empty)

AAAAAA

Test Trt:

BBBBBB

1.00

155.50

MedDRA Term:

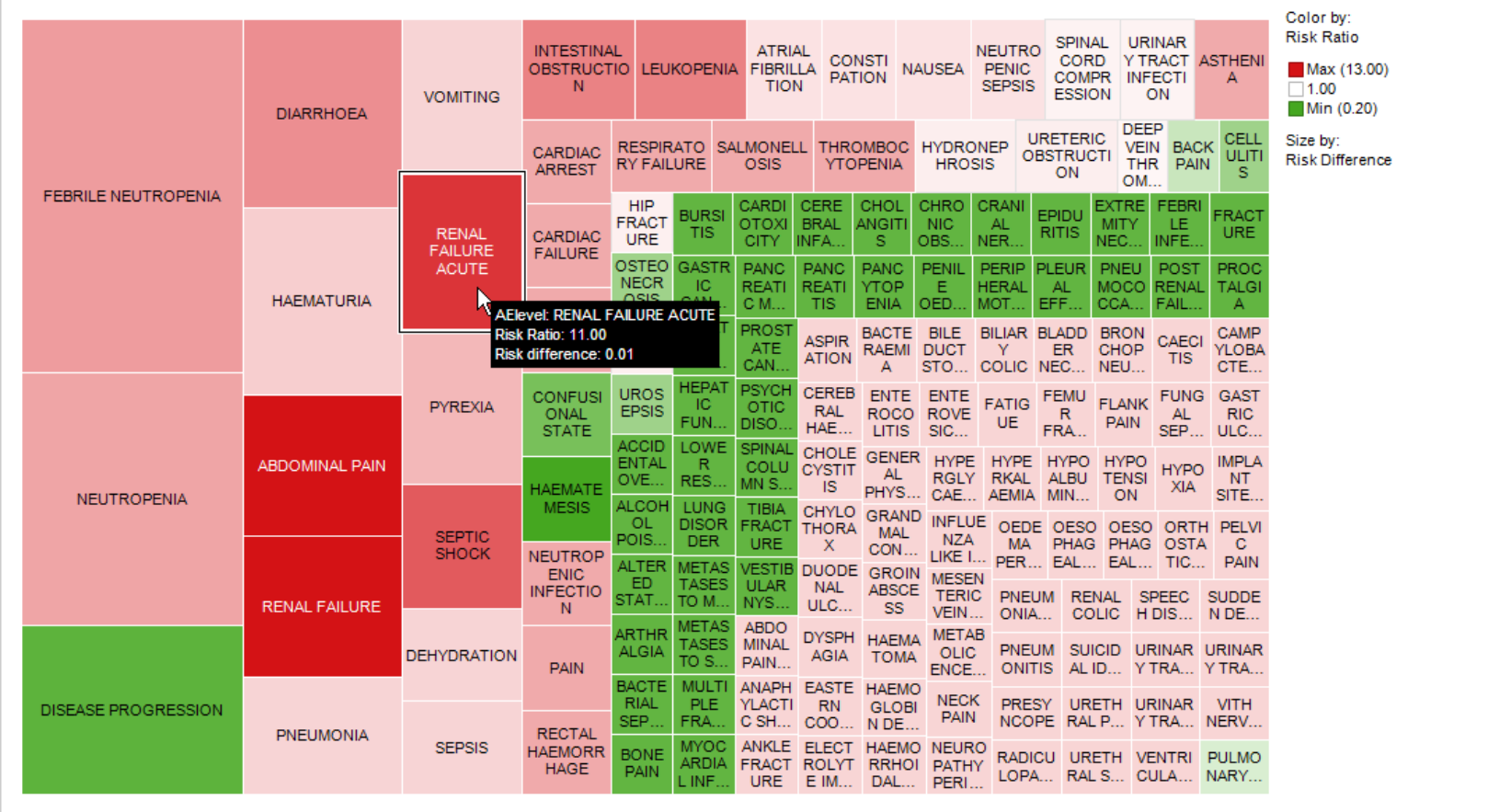
Preferred Term

Please, check if No zoom is active. Otherwise, reset zoom :

☒ False
 ☐ True

[Go to Patient Profiles](#)

Risk Ratio Treemap Analysis



Report generated by

on 10/12/2012 1:44:53 PM using Tibco Spotfire software

Data extracted from source on 7/10/2012 3:59:38 PM

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Selected Studies :

Population Level Filters

- Safety Population: (Y)

Filters

Type to search filters

Population Level Filters

Randomized Population

☒ (Empty)

Safety Population

☐ N
 ☒ Y

Description of Planned Arm

☒ AAAAAA
 ☒ Screen Failure
 ☒ BBBBBBB

Description of Actually Rece...

☒ (Empty)
 ☒ AAAAAA
 ☒ BBBBBBB

Study Identifier

☒

Country code

Type to search in list

(All) 26 values

ARG

Details-on-Demand

AElevel

treatment

Adverse Events Listings

(Empty)

(None)

(Empty)

Ref Trt:

Test Trt:

MedDRA Term:

Preferred Term

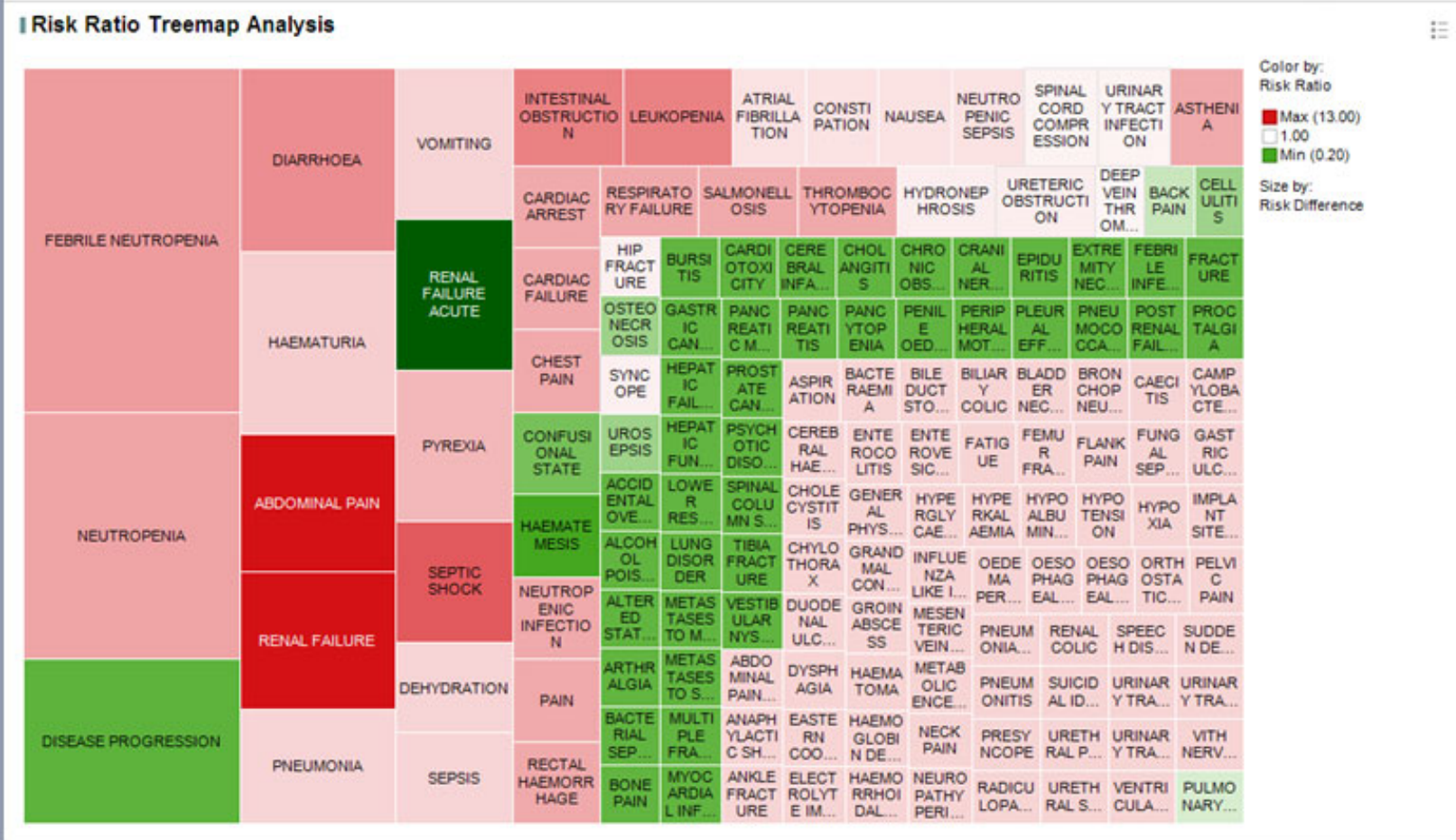
Please, check if No zoom is active. Otherwise, reset zoom :

False

1.00

155.50

[Go to Patient Profiles](#)



Report generated by [REDACTED] on 10/12/2012 1:44:53 PM using Tibco Spotfire software

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- Safety Population: (Y)

Filters

Type to search filters

Population Level Filters

Randomized Population

(Empty)

Safety Population

N

Y

Description of Planned Arm

Screen Failure

Description of Actually Rece...

(Empty)

Study Identifier

Country code

Type to search in list

(All) 26 values

ARG

Details-on-Demand

AElevel

treatment

RENAL FAILUR...

RENAL FAILUR...

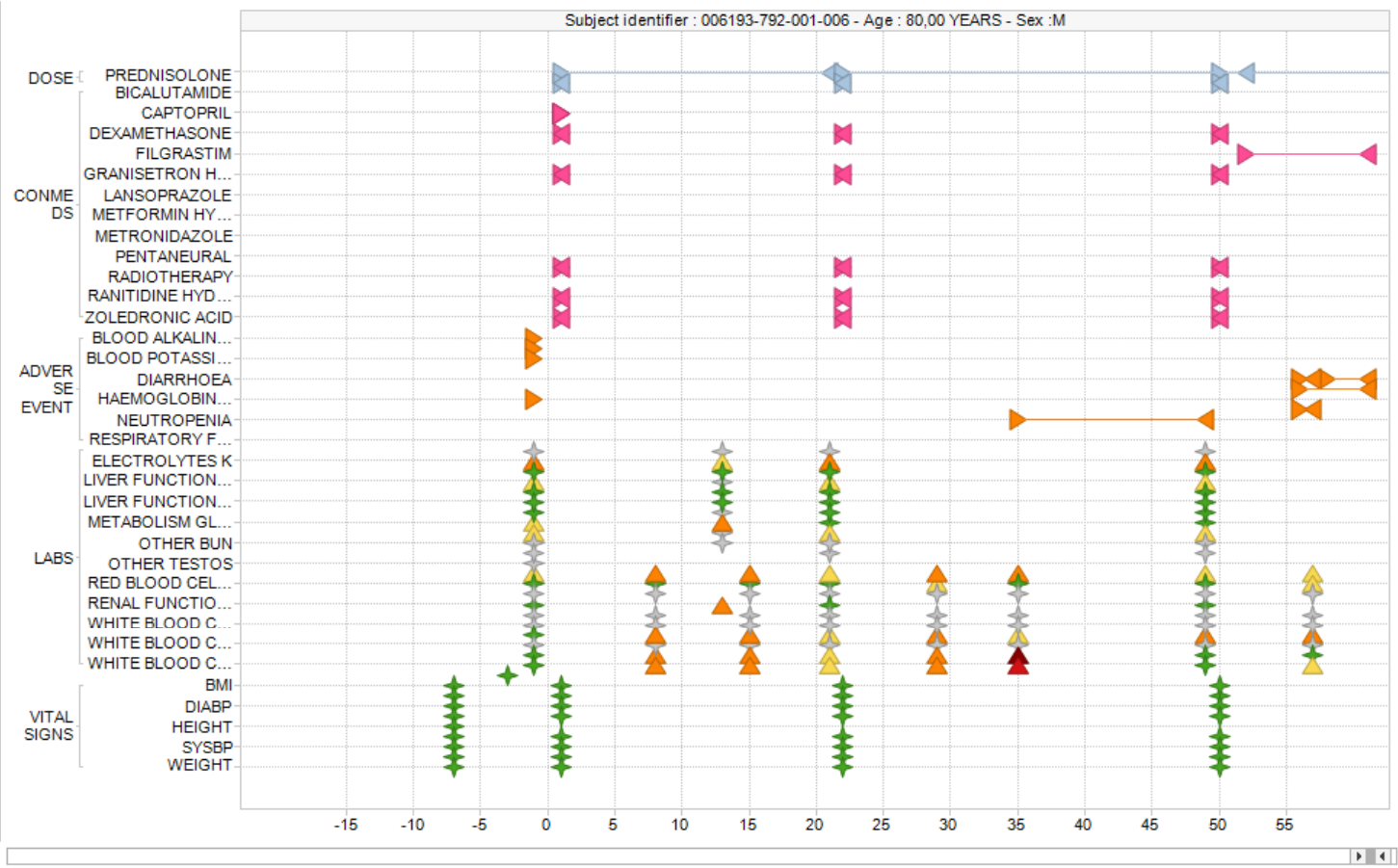
First, go to a population-level page to mark subjects of interest. Then mark subject(s) below to see profile.

Narrow down the selection of events by unchecking below

- ☒ DOSE
- ☒ CONMEDS
- ☒ MEDICAL HISTORY
- ☒ ADVERSE EVENT
- ☒ LABS

Subjects

Unique Subject Ident...	Sex	Description
006193-792-001-006	M	BBBBBB
006193-826-001-005	M	BBBBBB
006193-826-004-009	M	BBBBBB
006193-840-014-002	M	BBBBBB
006193-076-003-001	M	BBBBBB



Report generated by [redacted] on 10/12/2012 1:44:53 PM using Tibco Spotfire software
 Data extracted from source on 7/10/2012 3:59:38 PM
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Selected Studies : [redacted]
Patient Profile



[Go to Patient Profiles](#)

Filters

Type to search filters

Population Level Filters

Query Hys Law

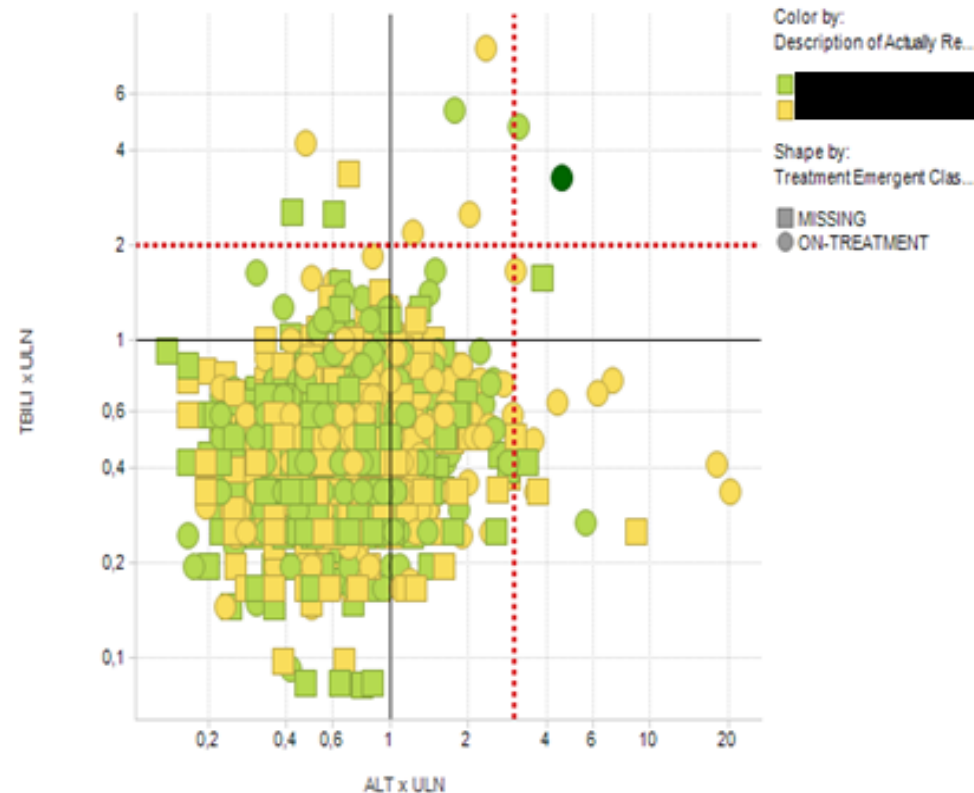
Treatment Emergent Classific...

- ☒ MISSING
- ☒ ON-TREATMENT
- ☒ POST-TREATMENT
- ☒ PRE-TREATMENT

Details-on-Demand

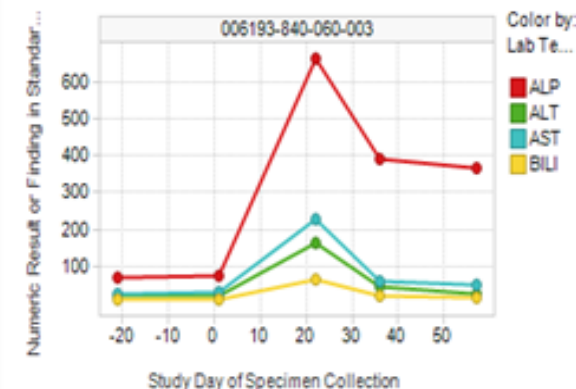
Subject Identifier	Treatm
006193-840-060-003	ON-TRE

Hys Law



Distribution by Quadrant

Quadrant	nb of Subjects / Per...
ELEVATED BILI	8
HY'S QUADRANT	2
MILDLY ELEVATED	276
NORMAL	1161
TEMPLE'S COROLLARY	14



Report generated by [REDACTED] on 26/06/2012 14:52:51 using Tibco Spotfire software
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Selected Studies : [REDACTED]

Population Level Filters

- Safety Population: (Y)

Query Hys Law

Ready.

1461 of 2678 rows 1 marked 24 columns Query Hys Law



Service Implementation Strategy

Service Implementation Strategy Definition



- Definition of a service according to ITIL (IT Infrastructure Library)
 - A service is a mean of delivering value to customers by facilitating the achievement of results they wish without having to bear the costs and risks associated



Service Implementation Strategy Definition



SERVICE LINE: DATA INTEGRATION AND REPORTING

SERVICE NAME:

Maestro Service (CDH + Safir)

SERVICE OWNER:

Data Analytics Services Head

SERVICE MANAGER:

Maestro Solution Leader

SERVICE DESCRIPTION: The object of this service is to integrate the data from the source system to the Safir Data Mart.

IN SCOPE:

GENERAL SCOPE

- Data profiling of the new compound
 - Checking of data structure compatibility
 - Edit automatic report with the issues identified
- integration of data in the appropriate predefined data flow:
 - SAS
 - OC
 - Other sources
- Refreshing of data :
 - Report edition
- Analyze new demand not in the scope in order to improve and enlarge the service

OUT OF SCOPE:

- Perform the data Mapping useful for data integration (should be performed before integration based on target data model and data profiling results)
- Define the Compounds/studies priorities
- Validate the data

SERVICE CUSTOMER:

Clinical Platform

SERVICE USER(S):

Medical Operations / Business Units
GPE
Biostatistics

COST OF SERVICE:

The cost of the services will be estimated and integrated in the global budget of the clinical study

SERVICE AVAILABILITY HOURS:

- 24 x 7 worldwide
- Availability exception <URL>

SERVICE SUPPORT HOURS:

24 x 5 Hours from China, USA or France

SERVICE LEVEL: GOLD/SILVER/BRONZE

Level based on a pre-defined agreement
(Service Level Agreement document)

PREREQUISITES TO REQUEST SERVICE:

- Belong to Service users

SERVICE REQUEST FORMS:

- On building

Service Implementation Strategy



● Dry-run

● Objectives

- Assess the capability of the process to integrate data from studies, products and therapeutic areas different from those used for the development
- Define precisely the contents of the Service in term of tasks, timing, work load and cost

● Implementation

- SAS Windows Flow
 - Integration of a new study from a product used for the development
 - Integration of a study from a product not used for the development
- SAS Unix Flow
 - Integration of a study from a product not used for the development
- Oracle Clinical Flow
 - Integration of a study from a product not used for the development

● Results

- assessment of the work load to allow the data integration

● Governance committee

- According to the work load assessment, a Governance Committee decides if the study can be loaded or not into the Clinical Data Hub

Next steps



-
- Service implementation
 - Maestro release 2
 - Enhanced (Flexible) CORE Model
 - Linear Data Model Support (SDTM)
 - Metadata Driven Data Models
 - Pooling / Coding Solution Integration
 - Benefit / Risk Assessment Solution
 - Phase I / IV Data Integration
 - CDH Administration Interface
 - External (CRO, Labs, etc) Data Load Capabilities
 - SAS Engine Integration
 - Planning
 - Release in several steps between Q4 2013 and Q3 2014



Thank you for your attention

Questions ?

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