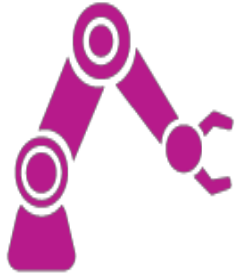


Mark Demesmaeker, PhD
Director, Industry Analytics

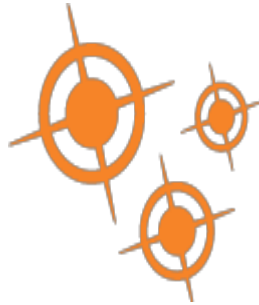
October 2013

FIRST TO INSIGHT. FIRST TO ACTION.



Automation

- Messaging
- SOA
- BPM
- MDM



Event Processing

- Events/CEP
- Rules
- In-memory



Analytics

- Visual Analysis
- Data Discovery
- Statistics



Cloud

- Private/hybrid Cloud Platform
- Apps
- Deployment Option

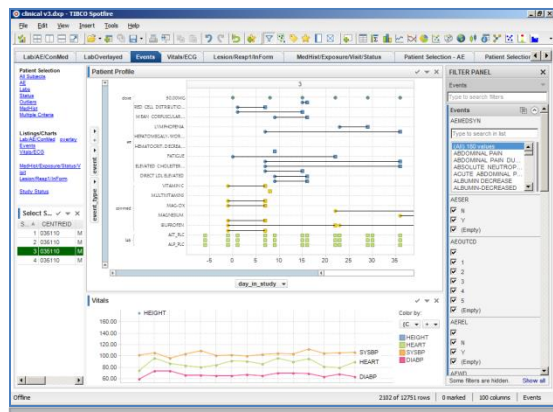


Social

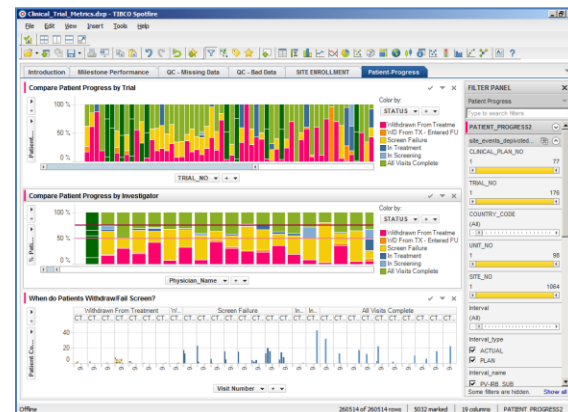
- Enterprise Social Media
- Collaboration



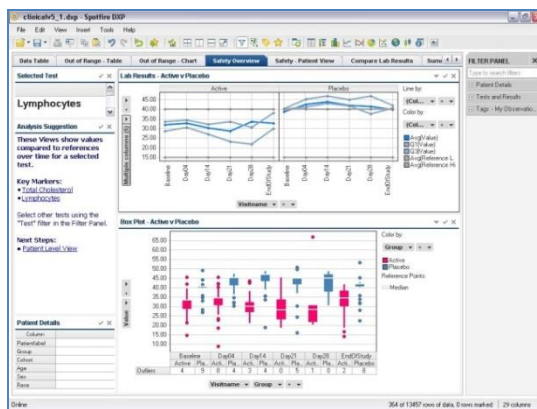
Clinical Development Use Cases



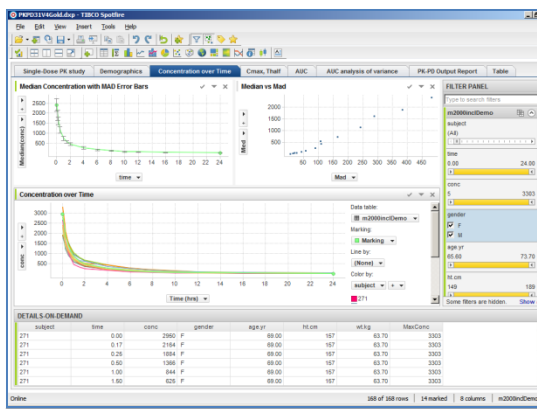
Clinical/Medical Data Review



Trial Operations



Safety and PV



Data Management



SafetyFirst Initiative: all TA's, phases

- Templates for Instream Safety; Post-Mktg Safety (validated); Operations; Graphics



Clinical Data Visibility (CDVT): all TA's, phases

- Templates for Instream Safety, Rolling Safety Initiative; Exploratory Analysis; Graphics



Clinical Data Analysis: early phase w migration to late phase

- Dose/Exposure Response, Exploratory Analysis



Safety Data review (SDRT): all TA's, all phases

- S+ Safety Analytics; DSMB outsourced analysis; Operations; Graphics



Safety Data review, Clinical Operations: all TA's, all phases

- Templates for Instream Safety; Operations; Graphics



Clinical Data Review, Cross-trial analysis, Post-marketing, ...

- Gilenia: FDA Approval



Clinical Data Analysis, Review, Operations: Spotfire everywhere

- Templates for Safety, Operations, Graphics



Safety Data Analysis/Review, PV: Oncology TA

- Templates for Instream Safety, Post-mktg Safety



© 2000



Inc. All



Patent & Proprietary Information.



Use case: Medical Review

- **Access data from multiple sources**

- Oracle Clinical / LSH, SAS – SDD, EDC/RDC (Medidata),...
- Operations, Resources, Safety, Finance
- Member of CDISC Healthcare Link Interoperability Network (HLIN)

- **Increase agility by enabling users to interactively explore unexpected trends & hidden relationships**

- Assess safety vs. dosing, dm, ex, ae, cm, lb, vs,...

- **Rapid medical review of clinical data**

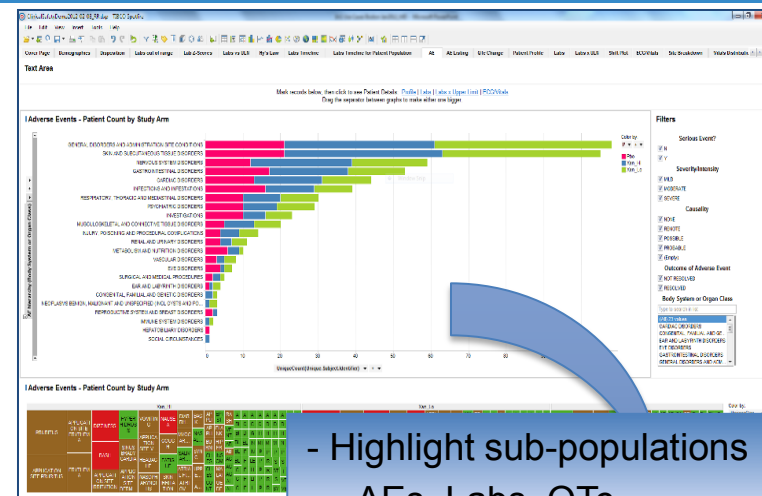
- Drill-down from population- to subject level (patient profile)
- Drastically reduce reliance on IT and time for data preparation
- Decrease manual listings & processes

- **Fast & accurate data quality assessment**

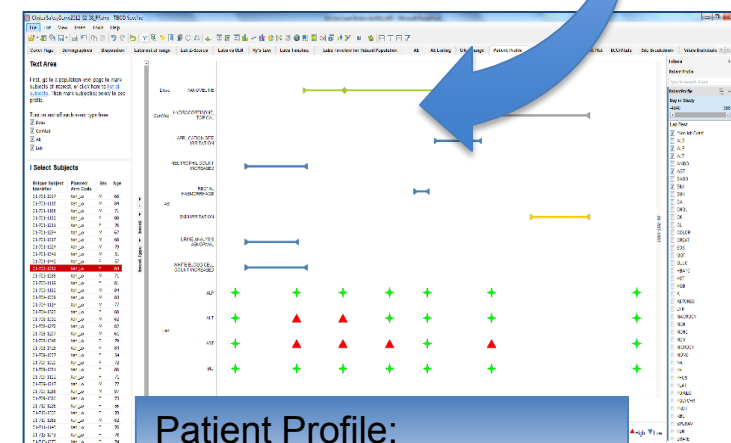
- Reduce data quality issues & link to operational data
- Detect suspicious or fraudulent behavior across sites

- **Fundamental process improvement**

- Early identification of drop-outs & protocol violations
- Data-driven monitoring & dimension-free data exploration



- Highlight sub-populations
AEs, Labs, QTc...
- Drill to subject data



Patient Profile:
Subject Data - ex, ae, cm,
lb, vs,... at Fingertips

Drug Induced Liver Injury – Hy's Law

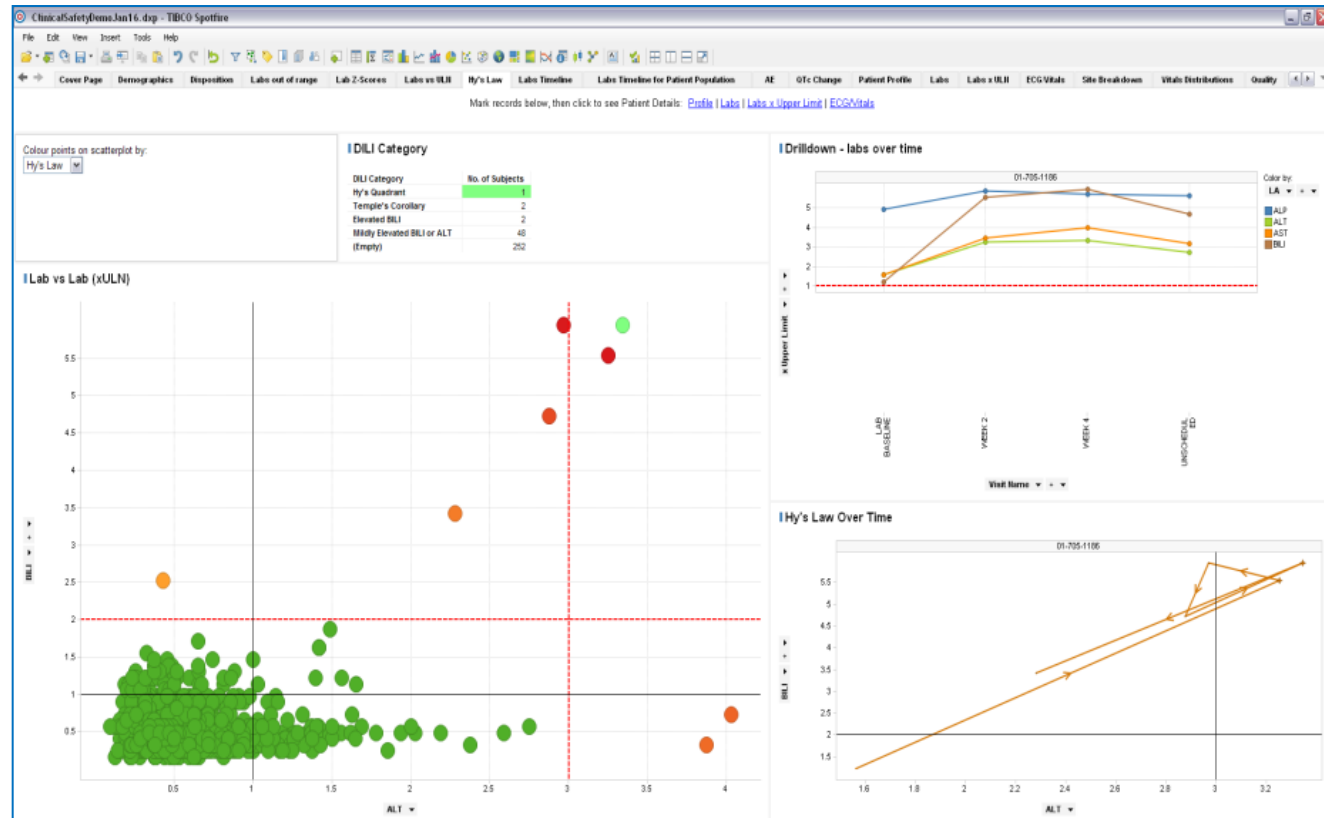
Hyman Zimmerman's
criteria for evaluating drug
induced liver injury (DILI)

Guidance for Industry Drug-Induced Liver Injury: Premarketing Clinical Evaluation

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
July 2009
Drug Safety



Innovative Medicines Initiative



"Interactive graphical data exploration provides an efficient, powerful and flexible tool to improve both detection and systematic assessment of safety signals"

Michael Merz, MD, Head Safety Networks, Novartis

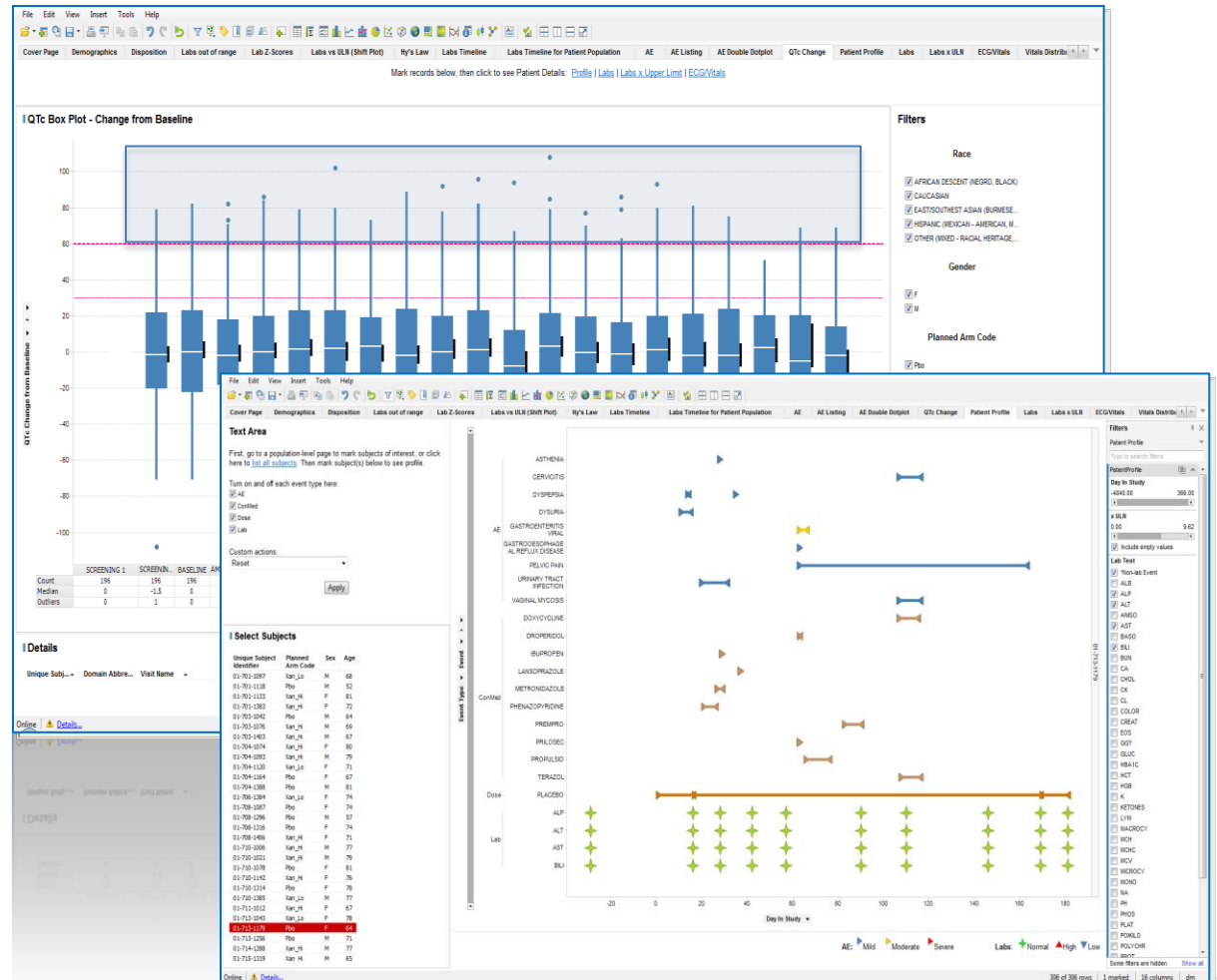


QT/QTc Prolongation – Subject and Population Analysis

Guidance for Industry

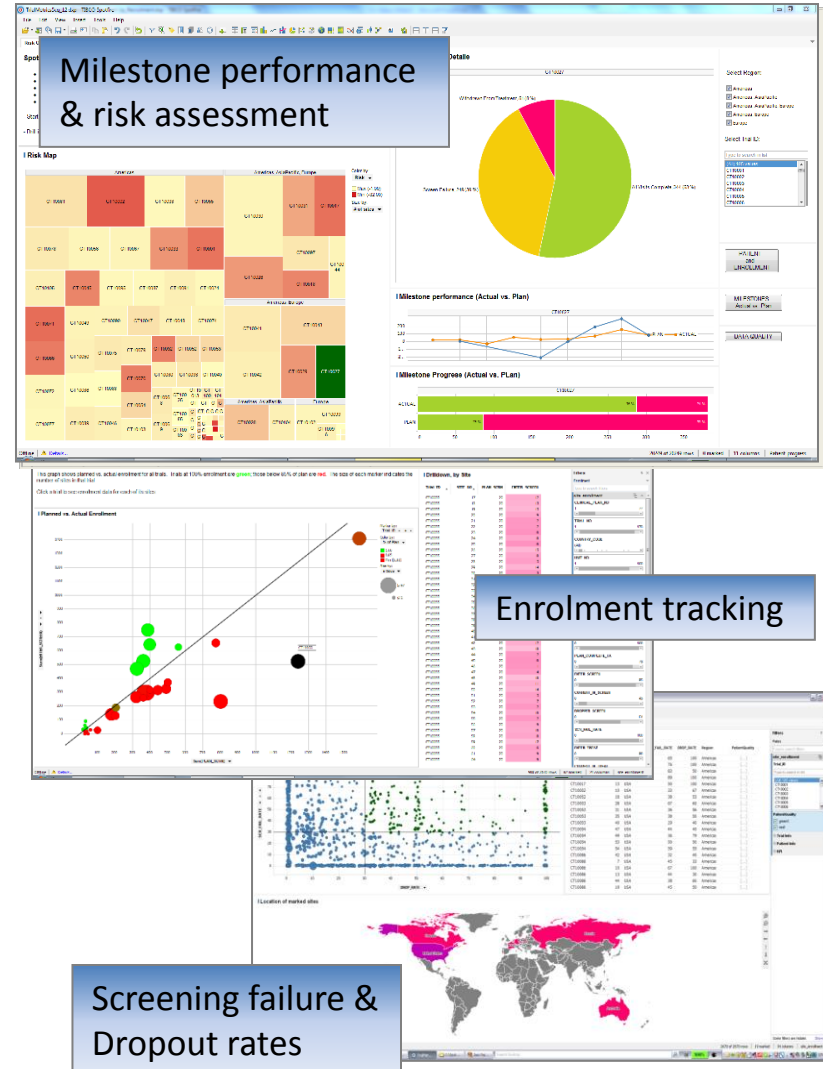
E14 Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
October 2005
ICH

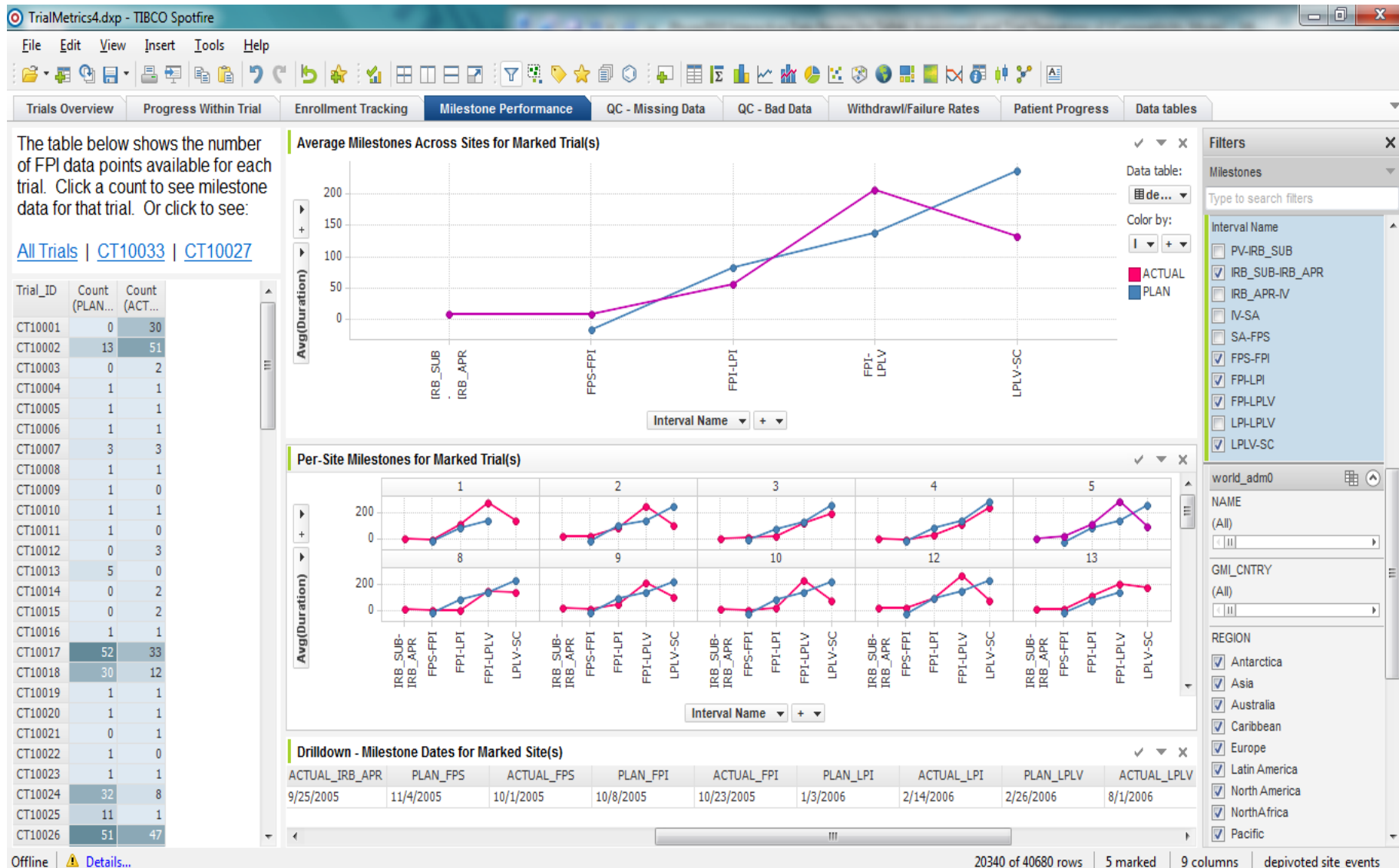


Use case: Trial Metrics and Operations

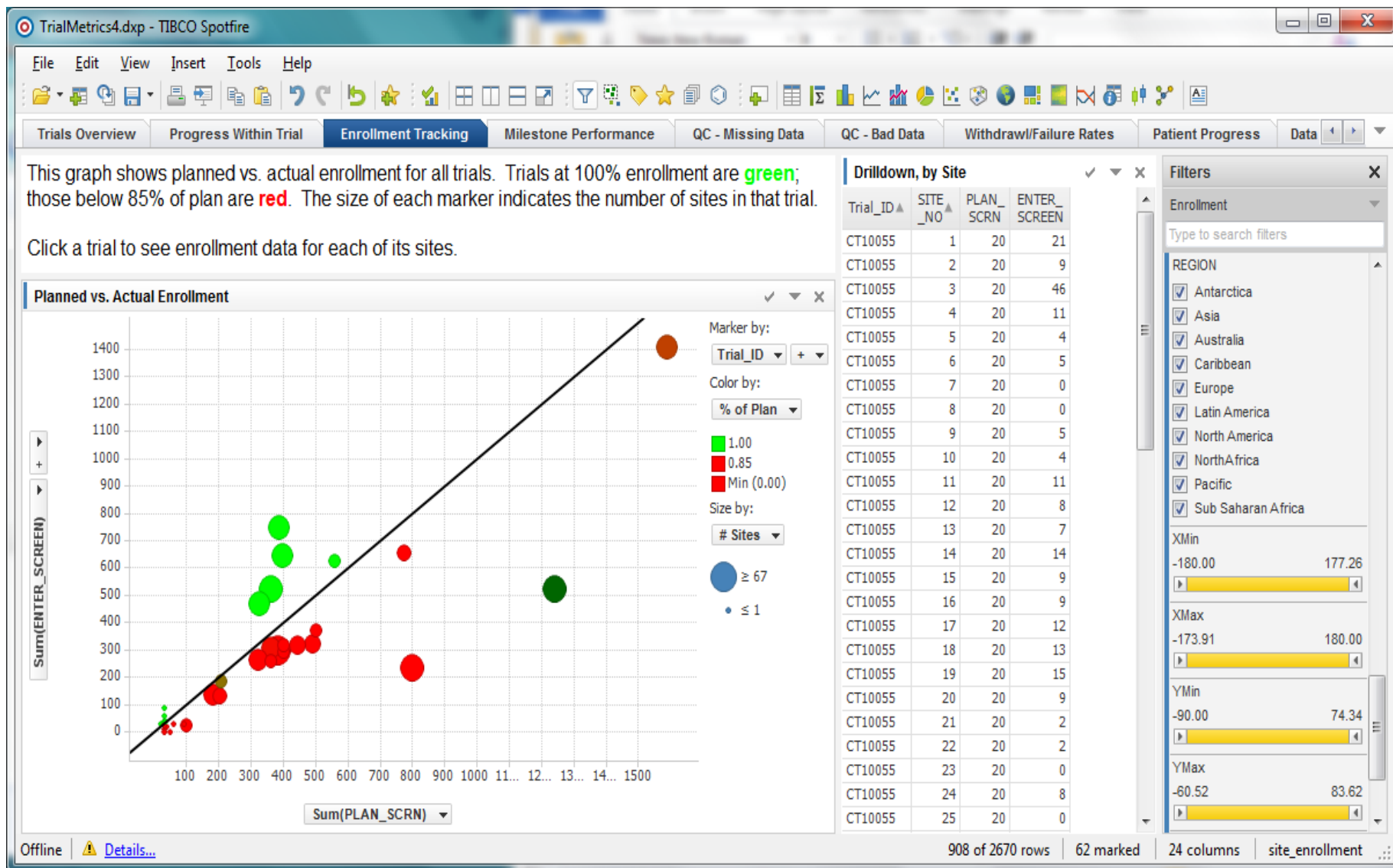
- **Rapid interactive KPI analysis & performance scorecards**
 - KPI's e.g. enrollment, screening, dropouts, budget, milestones, protocol violations
-> by region, country, site...
 - Planned vs. actual comparisons
- **Enrolment and cross-trial analysis**
 - Understand recruitment patterns across countries, sites and trials
 - Discrepancies (queries) analysis & drill to root cause
 - Identify and retain best performing sites
 - Optimized resource management based on enrolment projections
- **Link to clinical / safety data**
 - Sites with disproportionate AE frequencies etc.
- **Save trial costs through efficient & data-driven clinical trial operations!**



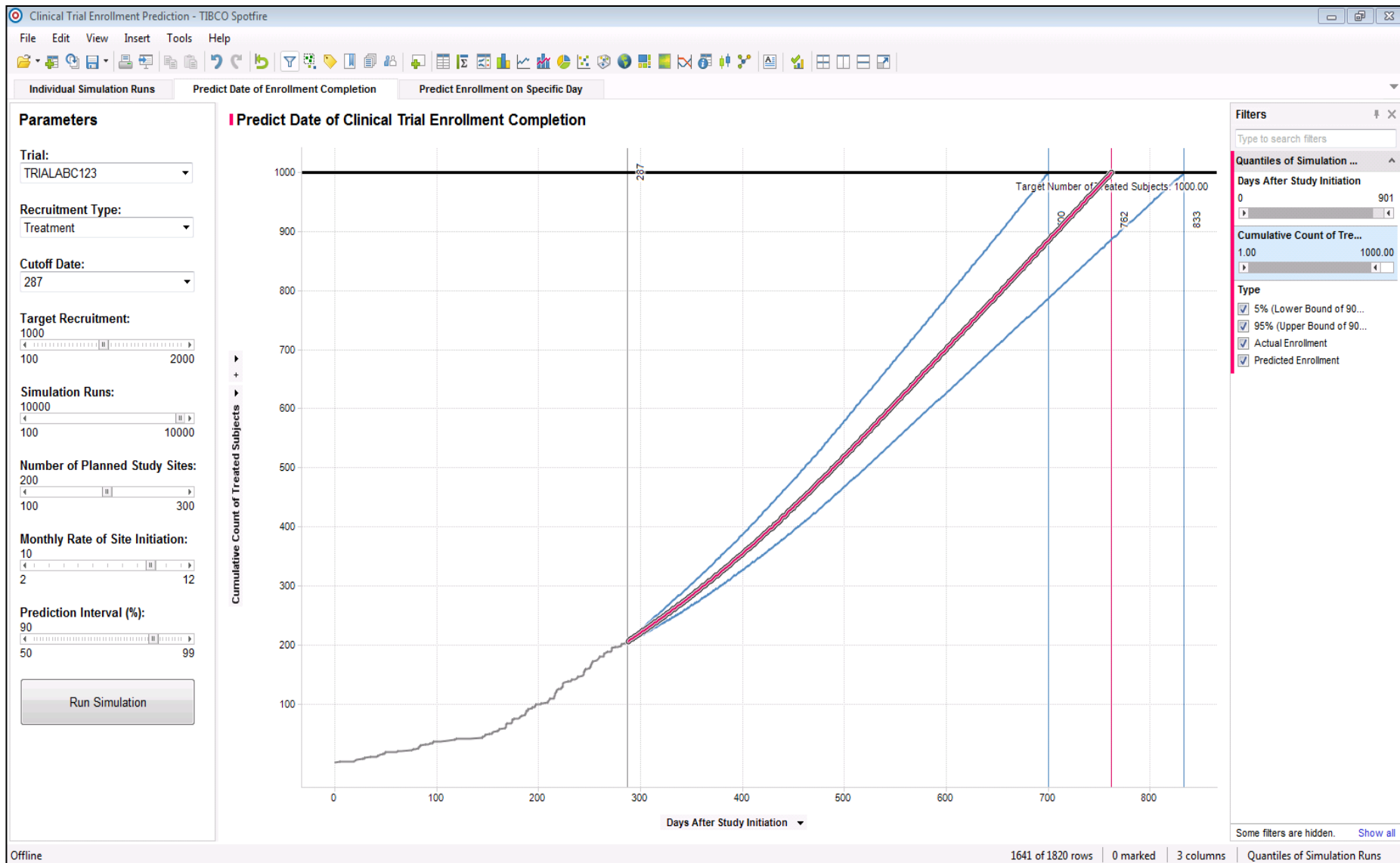
KPI Milestones by Site

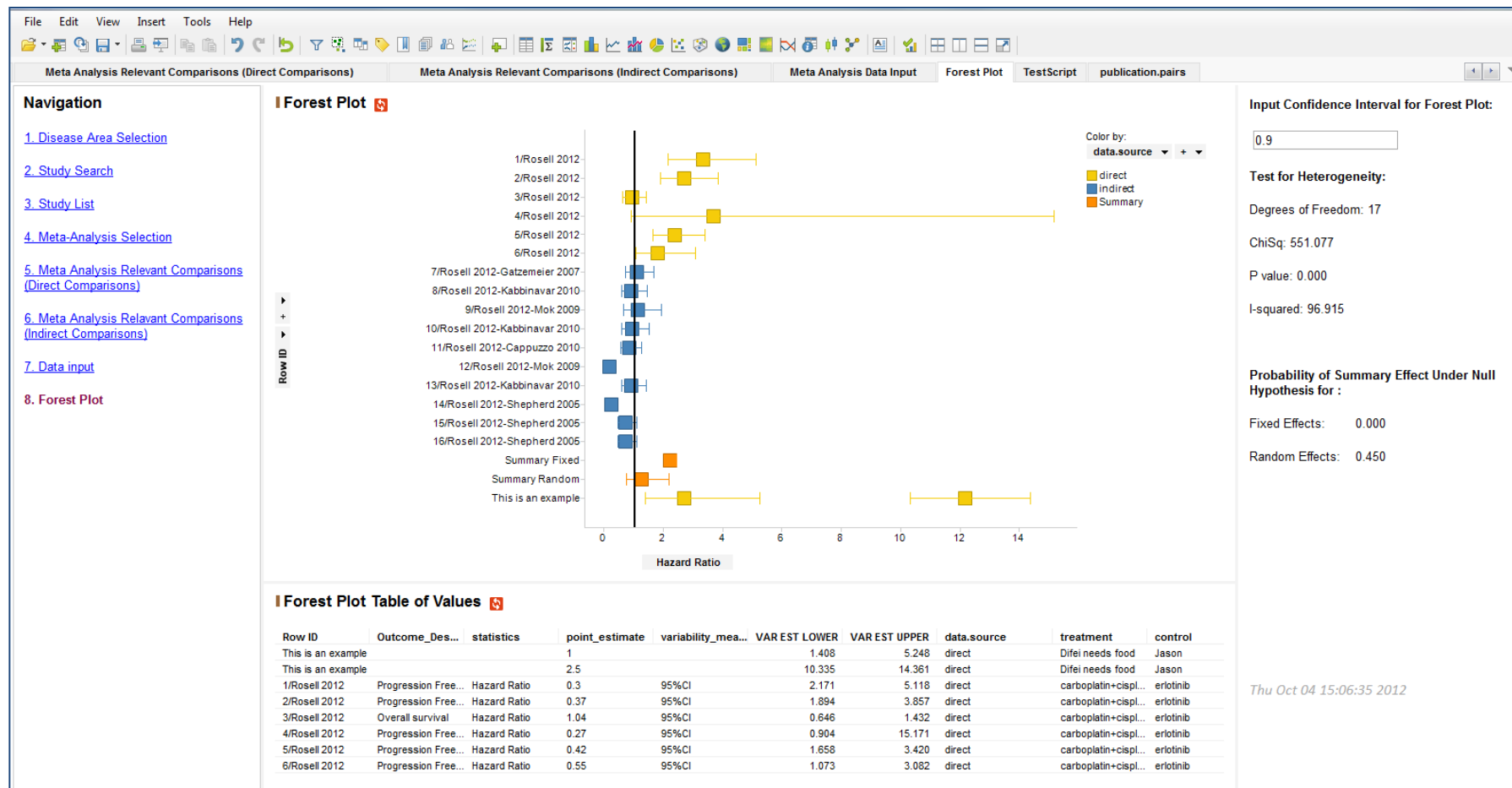


Cross-Trial Enrolment Tracking



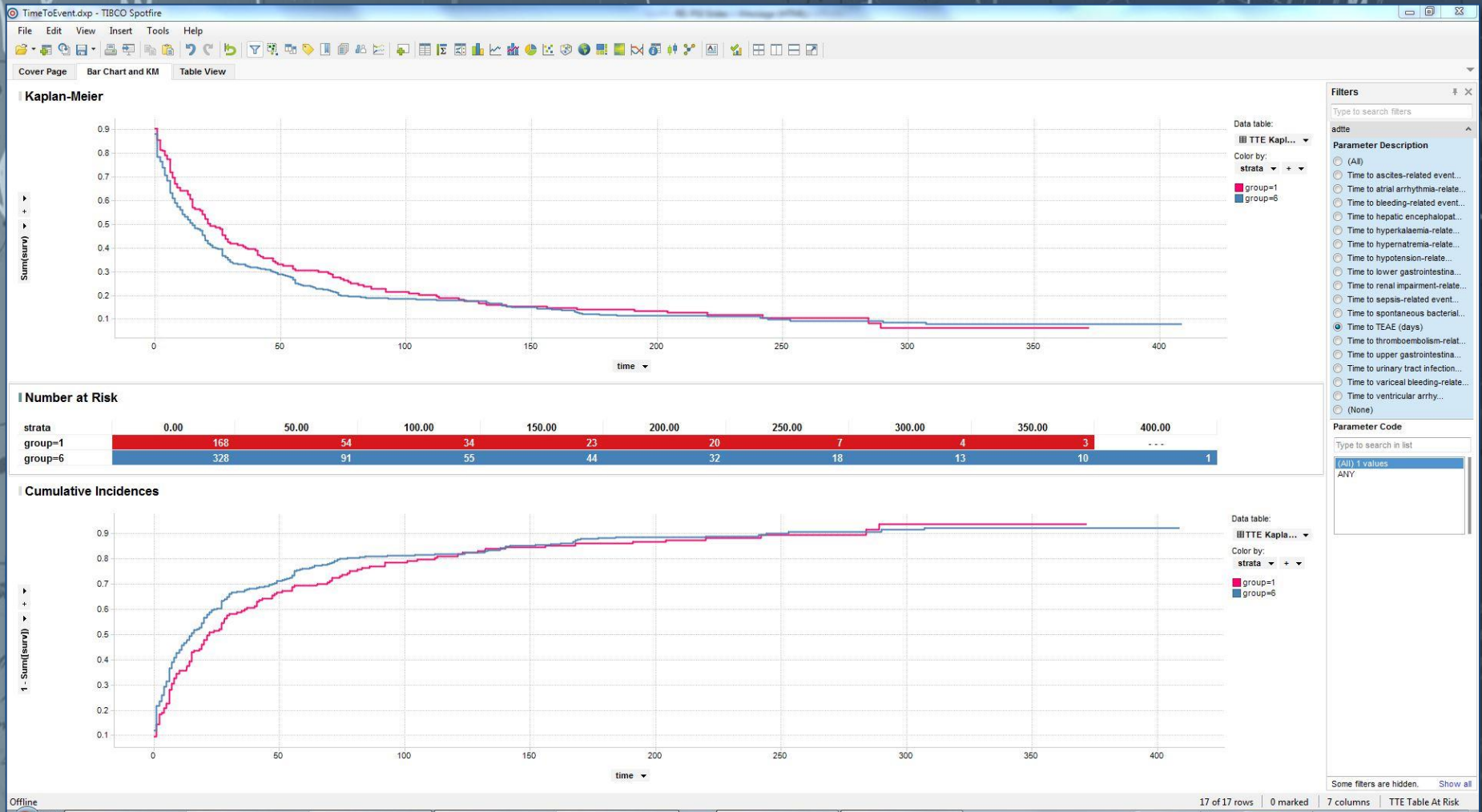
Enrolment Prediction





Statistics & Predictive Modeling

Spotfire blends powerful models & predictive analytics into analytic dashboards & guided apps



Manage Statistical Programming Centrally



Develop statistical routines in S+, R, or SAS. Define inputs, outputs.



Deploy and Register these routines to Stats Services.



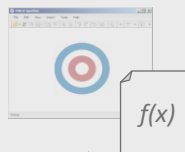
Requires Spotfire Professional and either S+ or R.

Statistical Programmer
Or
Application Builder

Build Statistical Applications



Insert a statistical routine from the Library into a Spotfire document



Configure Spotfire application to provide required inputs and interpret any results



Requires Spotfire Professional

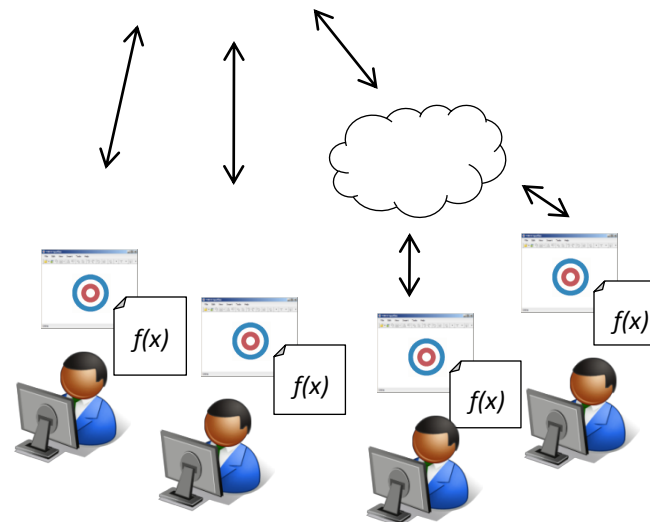


Business Author
Or
Application Builder

Deploy Statistical Applications Globally



Spotfire business users run Spotfire applications that communicate with S+, R or SAS



Business Users
Spotfire Enterprise Player

Business Users
Spotfire Web Player

More Info: Customer Case Studies:

- Case Studies
 - Novartis: Pre-clinical and clinical safety
 - Nycomed (Takeda): Drug Safety / Pharmacovigilance
 - GSK: Clinical Graphics
 - Dana Faber/Genzyme: Vaccine development
- Information on Spotfire Clinical
 - Recent customer webcasts: Novartis, AstraZeneca, Roche, Lundbeck, Pfizer
 - Recent customer presentations & papers
 - Roche at PHUSE (won best paper)
 - AstraZeneca at DIA (Europe)
 - Allergan at DIA (US)
 - Lundbeck at PSI
- Whitepaper
 - *Spotfire Analytics – Transforming Clinical Development*

SUCCESS STORY



Spotfire®

"Interactive graphical data exploration provides an efficient, powerful and flexible tool to improve both detection and systematic assessment of safety signals,"

Michael Merz, MD, Head Safety Networks, Novartis Institutes for BioMedical Research Basel

Novartis
Operating in 140 countries with global headquarters in Basel, Switzerland, Novartis offers a wide range of healthcare products through Pharmaceuticals, Vaccines and Diagnostics, Sandoz and

Using TIBCO Spotfire for Exploratory Data Analysis and Safety Assessment in Preclinical and Clinical Studies

SUCCESS STORY



Spotfire®

"Spotfire quickly gave us a visual analysis of major trends and main clusters of activity, highlighting neglected areas and graphically pointing out the glaring need of many of these cancers for additional vaccine development."

Vladimir Brusic, Dana-Farber CVC's Director of Bioinformatics

TIBCO Spotfire Provides Dana-Farber Cancer Institute with Unprecedented Insight into Cancer Vaccine Clinical Trials

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+41 78 621 5476

Contact:

alistair@dootsonic.com

+44 161 236 0961

❑ Spotfire Technology Network: <http://stn.spotfire.com>

- ❑ e.g. search Knowledge Base section for “integration with S+ and R”

