JMP® Clinical

Streamline safety and efficacy studies throughout the drug development process

By providing role-based reports and visualizations aligned with regulatory guidances, JMP Clinical streamlines the exploration, review and submission of clinical trials data to the FDA. Its visual paradigm – based on interactive graphics tied to interactive tables – speeds discovery, revealing trends and outliers that spreadsheets tend to hide.

JMP Clinical software from SAS simplifies data discovery, analysis and reporting in clinical trials, bringing greater efficiency and accuracy to studies of safety and efficacy data at every phase of the drug development process. Capabilities include:

- RECIST-based oncology visualizations.
- Automated patient narratives and patient profiles.
- Data monitoring.
- Advanced statistical analyses.

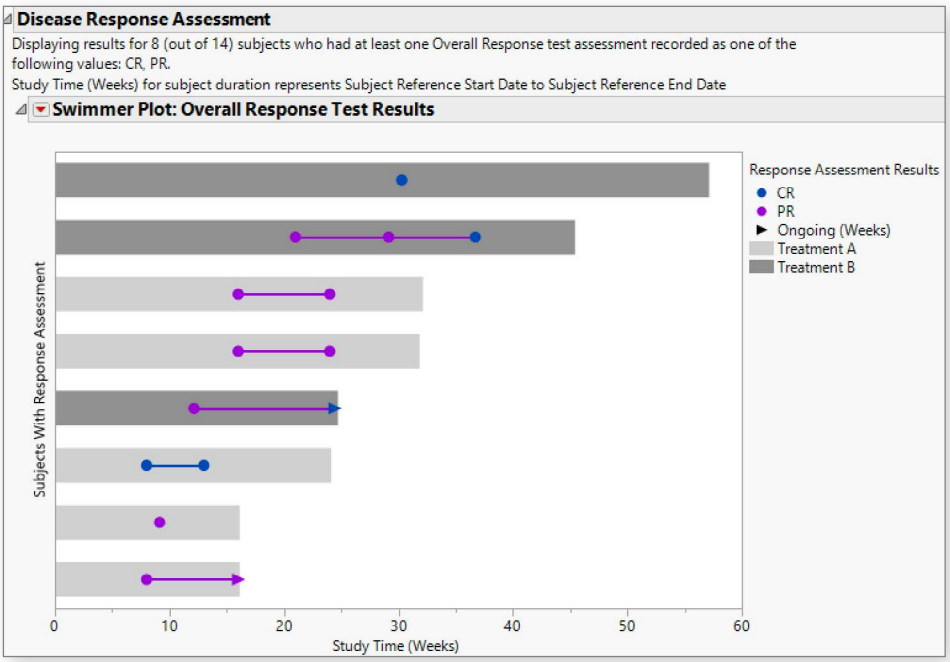
Workflows, templates and reporting tools customized according to user role make it easy for clinical data scientists, medical writers, clinical operations, data managers and biostatisticians to see and explore trends and outliers, and then communicate their discoveries.

Clinical data scientists and medical monitors

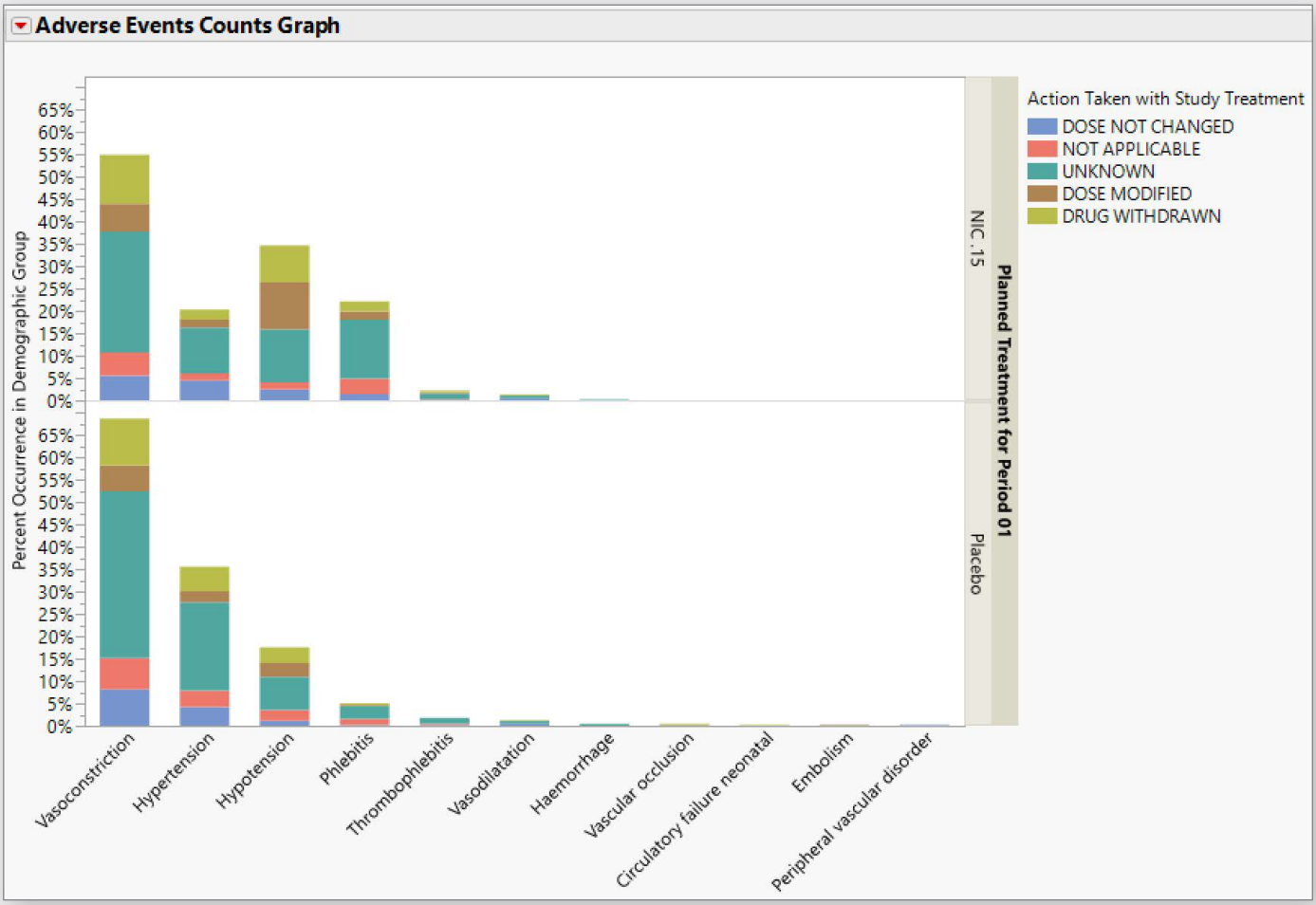
Summary dashboards in JMP Clinical enable medical reviewers to evaluate safety and efficacy issues with the click of a button. Create interactive reports of adverse events, concomitant medications, labs and vital signs, and drill down to customized patient profiles and patient narratives.

Tumor Response Analysis

Using visualizations tailored to RECIST criteria, including survival plots, swimmer plots, waterfall plots and spider plots, JMP Clinical lets you quickly identify efficacy signals in solid tumor clinical trials and determine whether subjects show complete response (CR), partial response (PR), progressive disease (PD) or stable disease (SD).



Swimmer plots, one of a variety of visualizations in JMP Clinical tailored to RECIST criteria, clearly reveal subject-level qualitative response across time.



Linked graphical and tabular formats make it easy for medical monitors to quickly assess safety signals either across all subjects or within patient subgroups.

Patient Profiles

JMP Clinical lets medical officers instantly generate patient profiles for an individual or group of subjects simply by selecting subjects, and it displays clinical results visually, making it easier for nonstatisticians to understand.

Interventions

The Exposure Summary report in JMP Clinical helps you identify differences in dose and duration of exposure across treatment groups, providing context for all downstream analyses. Incidence screens of concomitant medications and substance use allow clinicians to identify drug-drug interactions. JMP Clinical also enables analysis of distributions, event rates and estimations of risk over time.

Events

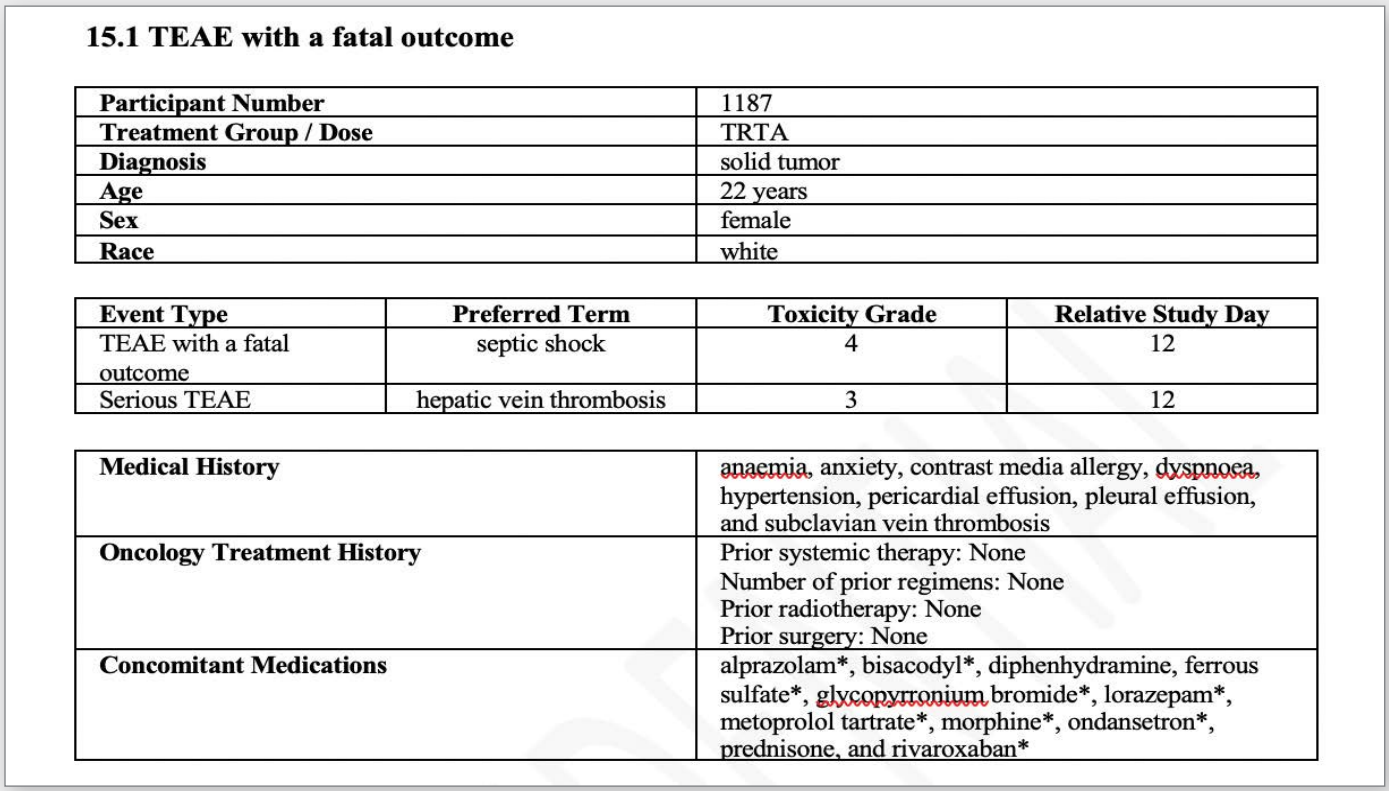
Determine the onset of an adverse event and its outcomes with time-to-event analyses and resolution screening, respectively. JMP Clinical supports the MedDRA hierarchy, allowing examination of any term level, including Standardized MedDRA Queries, to help you discern adverse event patterns across treatment groups.

Findings

Quickly evaluate safety and efficacy using FDA-prescribed criteria and industry-standard visualizations. JMP Clinical equips medical reviewers with measures of central tendency, outlier detection and trends over time so that they can quickly identify potentially harmful symptoms, including liver toxicity, that develop during the clinical trial.

JMP Clinical provides a powerful self-service analysis tool for the entire clinical trial team. While everybody has access to the same trial data, JMP Clinical offers a user-role concept that provides each role with a specific set of analysis functions.

Dr. Peter Bewerunge
Head of Life Sciences
accantec



15.1 TEAE with a fatal outcome

Participant Number	1187
Treatment Group / Dose	TRTA
Diagnosis	solid tumor
Age	22 years
Sex	female
Race	white

Event Type	Preferred Term	Toxicity Grade	Relative Study Day
TEAE with a fatal outcome	septic shock	4	12
Serious TEAE	hepatic vein thrombosis	3	12

Medical History	anaemia, anxiety, contrast media allergy, dyspnoea, hypertension, pericardial effusion, pleural effusion, and subclavian vein thrombosis
Oncology Treatment History	Prior systemic therapy: None Number of prior regimens: None Prior radiotherapy: None Prior surgery: None
Concomitant Medications	alprazolam*, bisacodyl*, diphenhydramine, ferrous sulfate*, glycopyrronium bromide*, lorazepam*, metoprolol tartrate*, morphine*, ondansetron*, prednisone, and rivaroxaban*

JMP Clinical lets you automatically compose a configurable patient narrative for each subject who experienced an adverse event (AE).

Medical writers

Producing adverse event narratives for clinical study reports (CSRs) can be a painstaking, time-consuming process with significant consequences for inaccuracies or delays. With JMP Clinical, medical writers can automate patient profiles and patient narratives and reduce the time and complexity of creating output for review and submission to regulatory agencies.

JMP Clinical can automatically compose a configurable patient narrative for each subject who experienced an adverse event (AE), including reporting for deaths, serious AEs, AEs of special interest and AEs resulting in study discontinuation.

Clinical operations

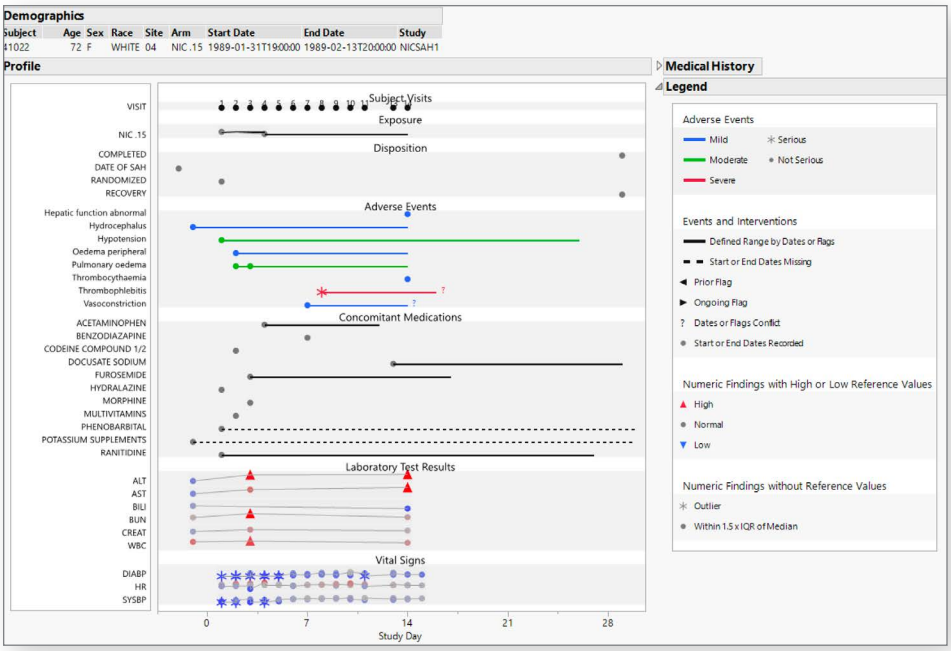
The goal of clinical operations is to mitigate data quality risks that could hinder a regulatory submission or drug approval. Risk-based monitoring tools in JMP Clinical help you identify data anomalies at the vendor, monitor, site and country level, and determine the factors responsible for lapses in safety or data quality. The result is a paradigm shift toward more efficient clinical trial review, reducing costly on-site source data verification while preserving data integrity and the safety of study participants.

Risk metrics derived from recommendations by TransCelerate BioPharma, a consortium of pharmaceutical and biotech companies, provide a foundation for assessment. Site-level tables deliver color-coded risk levels at a glance, allowing easy identification of any sites requiring immediate attention.

Biostatisticians

By combining the most sophisticated statistical algorithms with innovative visualizations, JMP Clinical allows biostatisticians to dig deep into clinical events, findings and interventions from a clinical trial.

Bayesian hierarchical models, unique in JMP Clinical, find rare adverse events that might put a clinical trial at great risk. These models complement our incidence screens analyses based on more commonly used frequentist methods. JMP Clinical also provides advanced predictive modeling techniques to optimize treatment or other trial characteristics.



Graphical patient profiles on a study day timeline lead you from summary analyses to in-depth subject-level understanding.

Data managers

Scrupulously maintaining the validity of all data and reporting throughout the trial process is crucial. JMP Clinical helps data managers visually monitor the status of all data and quickly identify new, modified, deleted or duplicate data. This lets you expedite database locking and ensures that downstream analysis will always be based on valid data.

With JMP Clinical, you don't need to be a statistician or a programmer to detect fraud or data quality problems. JMP Clinical offers unique tools for summarizing clinical trials data in a way that makes it easy to identify unintentional or intentional errors in data about individual subjects or clinical sites.

Without an interactive visualization tool, the only alternative was to flip back and forth between hundreds of pages of tables and listings to figure out what was going on. What JMP Clinical allows us to do is rapidly identify emerging safety events and characterize them.

Mark Williams
Vice President and CIO
ACI Clinical

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