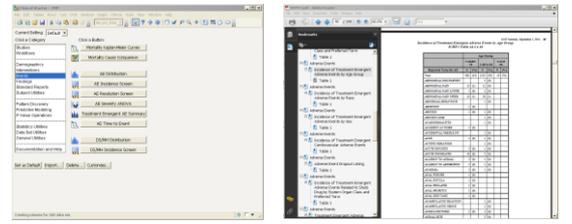


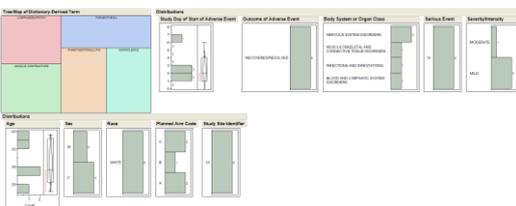
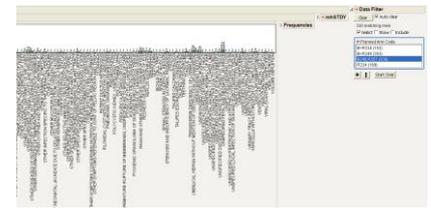
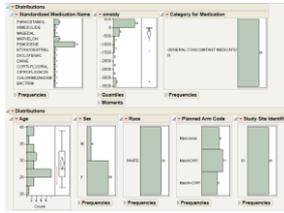
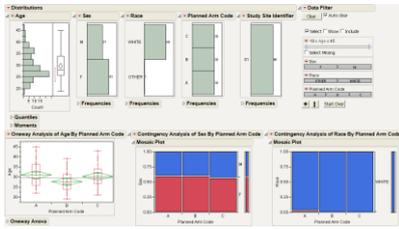
# JMP Clinical for the Exploration of Legacy studies

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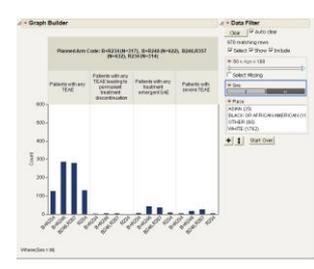
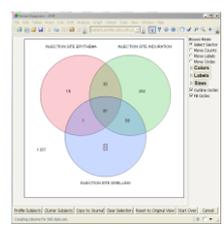
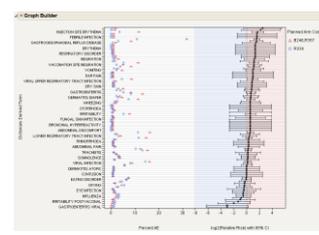
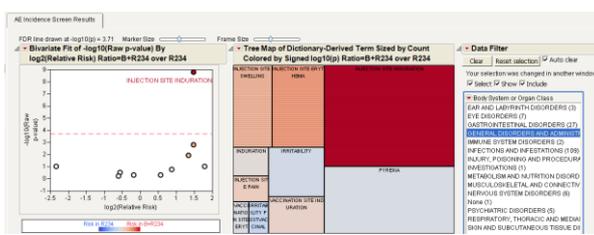
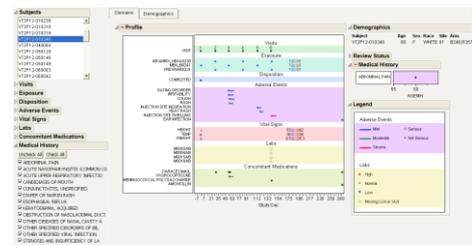


## Introduction

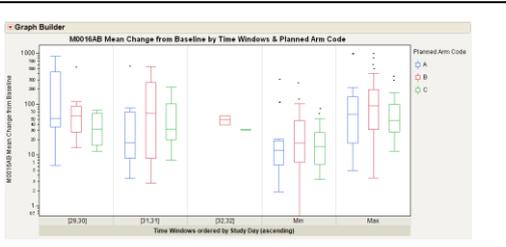
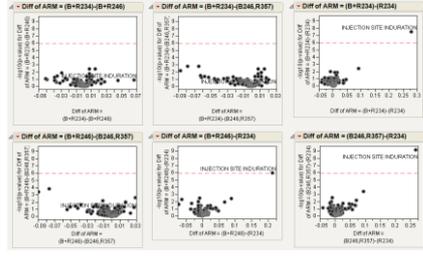
The JMP Clinical application was explored during the CDISC conversion project of more than 150 Legacy studies at Novartis Vaccines & Diagnostics. Experience with JMP Clinical on these Legacy studies forms part of an evaluation for use on ongoing studies in the near future, when all NV&D trials are converted to CDISC standards. This JMP extension or add-in has been on the market for one year now and is currently in version 3, the version used for this evaluation. JMP Clinical combines JMP and SAS software in one tool that enables the exploration and analysis of CDISC data. One issue is to what extent it can replace existing standard software that is currently used for submissions. Other points of interest are, what are the benefits of the JMP Clinical interface when exploring legacy and ongoing trials for the different participants involved, and more in general what will be the impact of the shift from document-centric submissions to data-centric submissions?



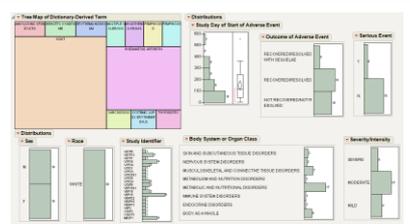
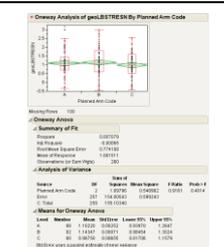
**Distributions**  
The different domains like DM, MH, CM, AE and DS are approached using dashboards that provide summary views of key variables and allow dynamic and interactive zooming and filtering of the data. Subject level detail across domains is available in the Patient Profiles and regarded as an outstanding feature of the application. One-way ANOVA and Contingency Analysis with the JMP options across treatment arms or any other variable are provided as statistical tests.



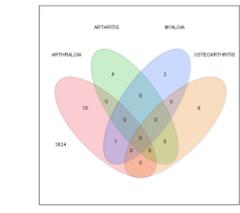
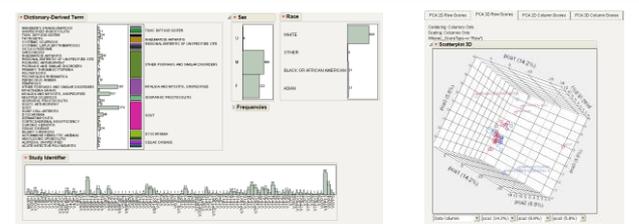
**Events**  
Tree views, Volcano plots, Risk plots and Venn diagrams are available that allow easy identification and selection of subgroups for further analysis and drill-down into patient profiles.



**Findings**  
Box plots as a function of time can be modified using the Graph builder. Antibody titers as analyzed in vaccine trials require a log transformation of the LBSTRESN value. Cross domain analyses are possible after creating cross domain datasets.



**Pooled studies**  
To explore pooled data, SDTM datasets from individual studies were concatenated and stored in a single study like folder structure. After selecting certain subgroups, these can be explored with the usual distributions, events and findings dashboards. As an example a list of autoimmune diseases was used to retrieve a subset of subjects from the 150 pooled legacy studies for further analysis. The subjects and their MH and AE terms were clustered and analyzed using Principal Component Analysis. Such pattern discovery may allow a more mechanistic classification of immunological diseases and together with appropriate lab data the identification of susceptible subject profiles.



**Conclusions**  
Although a limited number of the options of JMP Clinical were explored on the Legacy CDISC data, the graphical and interactive features make it appealing to both the SAS programmer and the non-programmer engaged in clinical trials. A large number of options for both visual exploration and statistical testing are available for routine safety analysis. If these can be performed by non-programmers, the current practice of requesting the creation of ad-hoc tables and graphs during the trial can diminish and decrease the workload of programmers. However, extending these options with e.g. custom domains will require both SAS and JMP scripting skills. Exploring current ongoing trial data will require a connection to a remote server, a feature not tested here. More experience with e.g. the Journal and Log facility is required to see how the results can be documented for further use in submissions of clinical trials.