

The World's Best Software for Exact Distribution-Free Inference with Continuous or Categorical Data

What is Special about StatXact?

StatXact is the only software package in the world providing a complete set of exact hypothesis tests, exact confidence intervals, and exact power or sample size calculations. There are over 130 procedures in StatXact, and all these procedures are exact, the gold standard for statistical inference. Most other statistical packages rely on large-sample assumptions for their inferences: this can lead to incorrect conclusions if the data sets are not normally distributed. StatXact utilizes powerful numerical algorithms that make exact inferences by permuting the data that were actually observed, thus eliminating the need to make distributional assumptions. With StatXact data sets can be small or large, balanced or unbalanced, sparse or dense, or in the form of contingency tables with small and zero cell counts. The end-user is shielded from all these complex calculations by a simple, intuitive calculator-like user interface.

Who Needs StatXact?

StatXact is widely used by researchers in biostatistics, epidemiology, psychiatry, sociology, environmental science, and

numerous other fields where experimental data are gathered and interpreted under uncertainty. Any investigator whose studies are submitted to refereed journals or subject to regulatory review needs StatXact. Diverse groups ranging from biomedical scientists to expert witnesses testifying in lawsuits have found StatXact indispensable to their work.

Announcing Cytel Studio

While the core of StatXact is its large collection of exact procedures, it is often necessary to perform more routine statistical tasks such as summarizing and plotting data, transforming variables, and importing and exporting data in diverse file formats. For SAS® users, Cytel provides StatXact PROCs, a version of StatXact that is fully integrated into the SAS system. For non-SAS users, Cytel is now introducing Cytel Studio as an integral part of StatXact v6.0. Cytel Studio offers basic statistics, t-tests, ANOVA, multiple linear regression, histograms, scatterplots, bubbleplots, routine data manipulation capabilities and a script language for performing repetitive statistical tasks in a batch environment.

StatXact Features

StatXact uses unique, award-winning algorithms to create the largest collection of exact hypothesis tests, exact confidence intervals, and exact power and sample size calculations available anywhere.

StatXact offers more than 130 exact procedures covering the most frequently used statistical tests, confidence intervals and sample size requirements.

New in StatXact v6.0

Among the 40 new features in StatXact v6.0 are:

- Exact tests on unordered, singly ordered and doubly ordered RxC tables with stratification (exact Cochran-Mantel-Haenszel tests). **See Example 1 for an illustration.**
- Exact tests for superiority, equivalence and non-inferiority of paired binomial data. **See Example 2 for an illustration.**
- Exact confidence intervals for differences of proportions and odds ratios of paired binomial data. **See Example 2 for an illustration.**
- Exact interaction tests in stratified 2xC contingency tables.
- Exact power and sample size for comparing two binomials by Barnard's unconditional exact test. (More powerful than Fisher's exact test.)
- Additional exact power and sample size procedures for comparing two ordered multinomials.
- Additional exact power and sample size procedures for comparing K ordered binomials.
- **Cytel Studio:** Summary statistics, t-tests, ANOVA and linear regression, plotting routines, expanded Case and Table editors, and a new workspace organizer to handle multiple datasets. Expanded import/export capabilities.

See reverse for a complete list of features.

Examples

The following examples demonstrate exact tests for stratified R x C tables and exact confidence intervals for the difference of two related binomial proportions. You won't find these features in any other statistical software, including previous versions of StatXact.

EXAMPLE 1: Is Job Satisfaction Related to Income?

Respondents to the General Social Survey rated their level of satisfaction on the job.

The following tables show the number of people at each satisfaction level, by gender and income level (in thousands of dollars) for a subset of the survey population.

| Female | Dissatisfied | Little Satisfied | Very Satisfied | Total | Score |
|--------|--------------|------------------|----------------|-------|-------|
| 5-15 | 2 | 3 | 3 | 8 | 1 |
| 15-25 | 0 | 1 | 5 | 6 | 2 |
| >25 | 0 | 2 | 2 | 4 | 3 |
| Total | 2 | 6 | 10 | 18 | |
| Score | 1 | 2 | 3 | | |

| Male | Dissatisfied | Little Satisfied | Very Satisfied | Total | Score |
|-------|--------------|------------------|----------------|-------|-------|
| 5-15 | 0 | 3 | 1 | 4 | 1 |
| 15-25 | 0 | 8 | 3 | 11 | 2 |
| >25 | 0 | 1 | 2 | 3 | 3 |
| Total | 0 | 12 | 6 | 18 | |
| Score | 1 | 2 | 3 | | |

Source: Data are from General Social Survey, National Opinion Research Center, 1991: as cited in Agresti, A., Categorical Data Analysis, p. 287 (Wiley, 2002). A subset of the data is used and one cell altered for illustrative purposes.

This information is easily entered in StatXact in table form as shown.

In previous versions of StatXact, analysis of stratified RxC tables was not possible, so one would have to ignore the gender of the individuals and combine the two tables into one. An analysis of the resulting combined doubly ordered RxC table using the Linear by Linear test in StatXact v5.0 gives the following results:

Exact p-value: .049
Asymptotic p-value: .034

However, combining the two tables prior to the analysis is inappropriate since gender is an important covariate. Thus the analysis was performed again in StatXact v6.0, this time using the stratified data and

the Cochran-Mantel-Haenszel test for stratified doubly-ordered RxC data. The following p-values were returned.

Exact p-value: .058
Asymptotic p-value: .041

While the asymptotic result suggests significance, this value is questionable because of the number of null and low values in the cells of the tables. Only an exact analysis is correct, and shows that the results fall short of statistical significance – once gender is accounted for, there is not a significant relationship between job satisfaction and income level. Only StatXact v6.0 offers this exact test, without which one would incorrectly assume that a significant relationship exists between job satisfaction and income.

EXAMPLE 2: Difference of Two Related Binomial Proportions

Miyayaga (Japanese Journal of Soft Contact Lenses, 1994) conducted a cross-over clinical trial comparing a chemical disinfectant system (hydrogen peroxide) with a thermal disinfectant system for soft contact lenses. The effectiveness of each system was tested in a random order on 44 subjects. Excellent results were obtained. The thermal system was effective on 44/44 subjects (100% response rate), while the chemical system was effective on 43/44 subjects (97.7% response rate). Since the chemical system is simpler and cheaper to adopt than the

thermal system, we wish to determine if these data provide convincing evidence of non-inferiority for the chemical system. The claim of non-inferiority can be justified if it can be demonstrated, at the 5% level of significance, that the true response rate with the chemical disinfectant is at most 0.1 lower than the true response rate with the thermal disinfectant. There are two ways to solve this problem in StatXact v6.0.

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CONDITIONAL TEST OF NON-INFERIORITY USING DIFFERENCE OF TWO RELATED BINOMIAL PROPORTIONS
H0: p1_2-p0_2 >= .DE. delta_0 vs H1: p1_2-p0_2 < .LT. delta_0

Statistics based on the observed 2 by 2 table:

Observed proportion for population <Chemical> : pObs_1 = 0.9773
Observed proportion for population <Thermal> : pObs_2 = 1.0000
Observed difference of proportions : pObs_1-pObs_2 = 0.0227
Minimum margin of non-inferiority : p1_2-p0_1 = delta_0 = 0.0900
Exact restricted risk of error of p0_2-p0_1-delta_0 given delta_0 = 0.0020
Standardized test statistic: (1)-(pObs_2-pObs_1)/delta_0 = -1.7890

RESULTS:
-----
Method      1-sided P-value      95.0% Exact Confidence
            P(T <=E, U)
-----
Asympt      0.0020
Exact       0.0020
            0.0051
            0.0004
    
```

1. Exact Confidence Interval: We can compute a 95% exact upper confidence bound for the difference between the thermal response rate and the chemical

$$P_1(\bar{R}_j^{opt}) \geq P_1(\bar{R}_j) \text{ for all } j = 1, \dots, K$$

Are you a SAS User? StatXact v6.0 PROCs for SAS Users

If you perform all of your analysis using SAS software, it may not be practical for you to switch to a different package for exact procedures. But SAS software Version 9 offers only a limited number of exact and categorical analysis features. For this reason, Cytel has created StatXact v6.0 PROCs for SAS Users, a set of over ten PROCs that deliver all of the power of StatXact within the SAS environment. These exact PROCs are only available from Cytel Software.

SAS System Plus StatXact PROCs: An Unbeatable Pair

Adding StatXact PROCs to the SAS system more than doubles the number of exact tests and confidence intervals you will have available to you. For instance, SAS software Version 9 offers no exact tests for stratified data, K related samples, or

censored survival data, and cannot calculate exact power and sample size. StatXact PROCs offers over 51 new tests in these categories alone. The table on the next page details what exact tests and confidence intervals SAS software Version 9 and StatXact PROCs offer.

Create Reports and Run Batch Files Faster

StatXact PROCs are completely integrated, so that SAS users never have to switch between programs to call exact tests. All the procedures can be called through a batch file and documented for regulatory submission. Moreover, StatXact PROCs features an "automatic pilot" function that automatically distinguishes large data sets from small data sets, applies the appropriate exact test, and keeps your batch job running smoothly.

response rate and verify that the upper bound is less than 0.1.

2. Exact Test of Non-Inferiority: An alternative approach is to perform an exact test of non-inferiority using 0.1 as the non-inferiority margin.

StatXact v6.0 used the method of Tango (Statistics in Medicine, 1998) to obtain a 95% exact upper confidence of 0.0986, and a corresponding exact p-value of 0.0474. These results demonstrate non-inferiority at the 5% level of significance. In contrast if the upper confidence bound and non-inferiority p-value were

computed by treating the response rates as though they had arisen from two independent binomials, we would obtain an upper confidence bound of 0.1033 and a corresponding exact p-value of 0.0571. This result does not demonstrate non-inferiority at the 5% level of significance, and is therefore misleading. The assumption of independence of binomial populations is inappropriate because the same 44 subjects have generated both sets of responses.

What Reviewers Say

"With your software, I have a level of functionality in analysis of small data sets which was unheard of a few years ago. In fact, before the advent of your software, my predecessor wrote extremely complex basic programs to perform those calculations. It does everything I have needed to do."

Graeme Tucker Head
Health Statistics Unit Department
of Human Services, Government
of South Australia

"StatXact has two superior characteristics. One is the ease of use – StatXact is extremely easy to use and understand, which is a real draw. The second is that it's not only accurate, but it's accurate and effective even for small sample size, which makes it stand out from other statistical packages, none of which have as many options for exact tests. It's a terrific product."

William Fals-Stewart
Senior Research Scientist, Research
Institute on Addictions University
at Buffalo, The State University
of New York

"For my purposes, StatXact is state of the art. There are some cases where we can't live without it."

Paul Gibbs
Statistician

"I have found that Cytel Software Corp has consistently produced the best statistical software on the market. In addition, their manuals contain the technical information statisticians need, while being easy to understand and clearly illustrated with examples."

Gregory J. Stoddard
Dept. of Mathematics, University
of Utah and independent consultant
to the pharmaceutical industry

$$P_1(\bar{\mathcal{R}}_j^{opt}) \geq P_1(\bar{\mathcal{R}}_j) \text{ for all } j$$

StatXact Compared to SPSS Exact Tests and SAS Software

| | StatXact | SPSS Exact | SAS Version 9 |
|---|----------|------------|------------------|
| One-sample Goodness-of-Fit | | | |
| Chi-Square | YES | YES** | YES |
| Kolmogorov | YES | YES** | |
| Lilliefors | YES | | |
| Runs | YES | YES** | |
| Paired Samples | | | |
| Sign | YES | YES** | YES |
| Wilcoxon Signed-Rank | YES | YES** | |
| Hodges Lehman Estimates | YES | | |
| Permutation | YES | | |
| McNemar - Conditional | YES | YES** | YES |
| McNemar - Unconditional | Yes | | |
| Marginal Homogeneity | YES | YES** | |
| Two Independent Samples | | | |
| Wilcoxon-Mann-Whitney | YES | YES** | YES* |
| Hodges Lehman estimates | YES | | |
| Normal Scores | YES | | YES* |
| Savage Scores | YES | | YES* |
| Siegel-Tukey | YES | | YES |
| Ansari-Bradley | YES | | YES |
| Klotz | YES | | YES |
| Mood | YES | | YES |
| Conover | YES | | |
| Permutation | YES | | YES* |
| Logrank | YES | | |
| Wilcoxon-Gehan | YES | | |
| Kolmogorov-Smirnov | YES | YES** | YES |
| Wald-Wolfowitz Runs | YES | YES** | |
| K Related Samples | | | |
| Friedman | YES | YES** | |
| Kendall's W | YES | YES** | |
| Cochran's Q | YES | YES** | |
| Quade | YES | | |
| Page | YES | | |
| K Independent Samples | | | |
| Median | YES | YES** | YES |
| Kruskall-Wallis | YES | YES** | YES |
| Normal Scores | YES | | YES |
| Savage | YES | | YES |
| ANOVA with General Scores | YES | | YES |
| Jonckheere-Terpstra | YES | YES** | YES |
| Linear by Linear | YES | YES** | YES |
| Logrank | YES | | |
| Wilcoxon-Gehan | YES | | |
| Tarone and Ware Trend | YES | | |
| One-Sample Rates and Proportions | | | |
| Binomial | YES | YES** | YES |
| Multinomial | YES | | |
| Poisson | YES | | |

| | StatXact | SPSS Exact | SAS Version 9 |
|--|----------|------------|------------------|
| Poisson Rates | | | |
| Homogeneity of Relative Risks | YES | | |
| CI on Common Relative Risk | YES | | |
| Trend in C Ordered Poisson Rates | YES | | |
| Two Independent Binomials | | | |
| Fisher's Exact | YES | YES** | YES |
| Pearson's Chi-Square | YES | YES** | YES |
| Likelihood Ratio | YES | YES** | YES |
| CI on Odds Ratio | YES | | YES |
| Barnard's Test for Superiority | YES | | |
| Tests of Non-inferiority | YES | | |
| Tests of Equivalence | YES | | |
| CI on Difference of Proportions | YES | | |
| CI on Ratio of Proportions | YES | | |
| Two Related Binomials | | | |
| McNemar | YES | | YES |
| CI on odds Ratio | YES | | |
| Test for Superiority | YES | | |
| Tests of Non-inferiority | YES | | |
| Tests of Equivalence | YES | | |
| CI on Difference of Proportions | YES | | |
| Stratified 2x2 Tables | | | |
| Homogeneity of Odds Ratios | YES | | |
| CI on Common Odds Ratios | YES | | |
| C Ordered Binomials (with or without strata) | | | |
| Cochran-Armitage Trend | YES | | YES* |
| Permutation with General Scores | YES | | YES* |
| Trend Test for Clustered Data | YES | | |
| Test for Interaction Across Strata | YES | | |
| Two Ordered Multinomials (with or without strata) | | | |
| Wilcoxon-Mann-Whitney | YES | | YES* |
| Savage Scores | YES | | YES* |
| Normal Scores | YES | | YES* |
| Permutation with General Scores | YES | | YES* |
| Test for Interaction Across Strata | YES | | |
| Unordered RxC Table | | | |
| Pearson's Chi-Square | YES | YES** | YES |
| Likelihood Ratio | YES | YES** | YES |
| Fisher-Freeman-Halton | YES | YES** | YES |
| Single Ordered RxC Table | | | |
| Kruskal-Wallis | YES | YES** | YES |
| Normal Scores | YES | | YES |
| Savage | YES | | YES |
| ANOVA with Arbitrary Scores | YES | | YES |
| Doubly Ordered RxC Table | | | |
| Jonckheere-Terpstra | YES | YES** | YES |
| Linear by Linear Association | YES | YES** | YES |

| | StatXact | SPSS Exact | SAS Version 9 |
|--|----------|------------|------------------|
| Stratified RxC Tables | | | |
| Unordered RxC Table | YES | | |
| Single Ordered RxC Table | YES | | |
| Doubly Ordered RxC Table | YES | | |
| Measures of Association (nominal) | | | |
| Contingency Coefficients | YES | YES** | |
| Goodman-Kruskal-Tau | YES | YES** | |
| Uncertainty Coefficient | YES | YES** | |
| Measures of Association (ordinal) | | | |
| Pearson's Correlation | YES | YES** | YES |
| Spearman's Correlation | YES | YES** | YES |
| Kendall's Concordance | YES | YES** | |
| Kendall's Tau and Somers' D | YES | YES** | |
| Gamma Coefficient | YES | YES** | |
| Measures of Agreement | | | |
| Cohen's Kappa | YES | YES** | YES |
| Weighted Kappa | YES | | YES |
| Power & Sample Size | | | |
| One Binomial | YES | | YES |
| Paired Binomials:Difference | YES | | |
| Two Binomials:Difference (conditional) | YES | | |
| Two Binomials:Difference (unconditional) | YES | | |
| Two Binomials:Non-inferiority | YES | | |
| Two Binomials:Equivalence | YES | | |
| K ordered Binomials | YES | | |
| Two Ordered Multinomials (power) | YES | | |

* StatXact can handle Stratified or Unstratified data
SPSS, SAS can handle only unstratified data

** The exact algorithms in SPSS Exact Tests were developed by and are licensed from Cytel Software.



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