PQ Bypass

The TORUS 2 IDE Clinical Study

Protocol Number: CLN 227 Rev. D

Statistical Analysis Plan

Version 2.0

Version History

Version	Version Date	Author/Title	Summary of Key Changes
<1.0>	<28Aug2020>	Tyson Rogers, Senior Product Development Strategist, Biostatistics	Initial Release
<2.0>	<11Oct2020>	Tyson Rogers, Senior Product Development Strategist, Biostatistics	Updates based on October 2, 2019 Letter for G190226

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1 Introduction

The primary objective of the TORUS 2 IDE Clinical Study is to evaluate the safety and effectiveness of the TORUS Stent Graft System in the treatment of obstructive atherosclerotic lesions of the native SFA or the superficial femoral and/or proximal popliteal arteries.

The safety and effectiveness of the PQ Bypass Torus Stent Graft System will be established by comparing the primary safety and effectiveness endpoints to safety and effectiveness Performance Goals (PG) from the published literature.

This statistical analysis plan (SAP) describes the planned statistical methods to be used during the reporting and analysis of data collected under the TORUS 2 IDE Clinical Study. This SAP should be read in conjunction with the study protocol/clinical investigation plan (CIP) and case report forms (CRFs). This version of the SAP has been developed with respect to Version 2.0 of the protocol. Any revisions to the protocol or CRFs that impact the planned analyses may require updates to the SAP.

Detailed definitions of endpoints assessed by the Clinical Events Committee (CEC) are available in the CEC charter held at Syntactx. Additional analyses, beyond those described in this SAP, are anticipated as requested by the CEC for oversight of the study.

2 Abbreviations

Abbreviation/Term	***Definition***
IDE	Investigational Device Exemption
SFA	Superficial femoral artery
PG	Performance Goal
MAE	Major Adverse Event
SSED	Summary of Safety and Effectiveness Data
PSVR	Peak Systolic Velocity Ratio
CD-TLR	Clinically-Driven Target Lesion Revascularization
ITT	Intention-To-Treat

mITT	Modified Intention-To-Treat
PP	Per-Protocol

3 Study Objectives

The objectives of the TORUS 2 IDE Clinical Study are to evaluate the safety and effectiveness of the PQ Bypass Torus Stent Graft System in patients with femoral popliteal arterial disease. The safety and effectiveness of the PQ Bypass Stent Graft System will be established by comparing the primary safety and effectiveness endpoints to safety and effectiveness Performance Goals (PG).

- The primary safety endpoint will compare freedom from Major Adverse Event (MAE) at 30 days to a safety Performance Goal (PG) derived from literature, including an aggregate of published trial data and the Summary of Safety and Effectiveness Data (SSED) of the PMAs of approved devices.

- The primary effectiveness endpoint will compare primary patency at 12 months to an effectiveness PG derived from literature, including an aggregate of published trial data and the Summary of Safety and Effectiveness Data (SSED) of the PMAs of approved devices.

Secondary and additional endpoints are defined in the protocol.

3.1 Study Endpoints

3.1.1 Primary Effectiveness Endpoint

Primary patency as defined as a duplex ultrasound peak systolic velocity ratio (PSVR) of <2.5 in the absence of clinically-driven target lesion revascularization (CD-TLR).

3.1.2 Primary Safety Endpoint

Freedom from a major adverse event (MAE) at 30 days post-procedure defined as any occurrence of death, CD-TLR, and amputation of the treated limb.

4 Study Design

The design of the study is a global, prospective, single-arm, multi-center, clinical investigation to evaluate the safety and effectiveness of the Torus Stent Graft System in the treatment of obstructive atherosclerotic lesions of the native SFA or the superficial femoral and/or proximal popliteal arteries.

The study uses a group-sequential design for assessment of the primary effectiveness endpoint. A single analysis is planned for the primary safety endpoint, with timing of the analysis determined by the primary effectiveness analysis.

5 Sample Size Determination

Study sample size is calculated based on formal power calculations for the primary endpoint hypothesis tests. Assumptions used for sample size calculations and details of the calculations are provided below. R code and PASS 2019 screenshots are provided in the appendix to document the sample size calculations. Type I error is controlled overall at 2.5% since each primary endpoint is controlled at 2.5% and both primary endpoints must be passed for study success. A hierarchical alpha control is employed such that the primary safety analysis is only performed after the primary effectiveness endpoint is either successfully met or the final analysis is performed.

5.1.1 Primary Effectiveness Endpoint

The primary effectiveness endpoint sample size calculation is based on the specification below:

- One sample exact binomial hypothesis test
- Performance goal: 57%
- Alternative hypothesis: 70%
- Power: 90%
- Alpha: 2.5% (one-sided)
- Interim analysis information fractions: 16%, 75%, 100%
- Hwang-Shih-DeCani spending function (gamma = -6)

Table 1: Group-Sequential Interim and Final Analysis Success Criteria

Sample Size	Information Fraction	Nominal p-value	Alpha Spending	Power	Post 15% attrition	Minimum Observed Rate
30	16%	0.0001	<0.0001	0.0016	25	N/A
141	75%	0.0055	0.0051	0.6433	119	68.9%
188	100%	0.0239	0.0149	0.2671	159	65.4%
		Total:	0.0201 (one-sided)	0.912		

The sample size calculation is implemented using the gsDesign package with the gsDesign and gsBinomialExact functions.

A total of 30 subjects from the TORUS 1 study are planned to be included in the primary effectiveness endpoint analysis, since the primary effectiveness outcome data for these subjects has not yet been ascertained at the time of TORUS 2 study design. Given that the outcome results for these 30 patients are not known to the sponsor, there is no opportunity for bias in the overall study analysis due to including these patients. Subjects that did not yet complete a 12 month follow-up visit by the time of the pre-submission meeting with FDA to discuss the TORUS 2 study design (24 JUL 2019), will be included in the ITT analysis cohort (see Section 5.3 for the definitions of analysis sets).

To account for the fact that TORUS 1 results will be analyzed prior to the completion of the TORUS 2 study, an interim analysis after 30 patients is added to the interim analysis plan. Alpha spending is implemented to account for the early analysis of these 30 patients.

5.1.2 Primary Safety Endpoint

The primary safety endpoint sample size calculation is based on the specification below:

- One sample exact binomial hypothesis test
- Performance goal: 88%
- Alternative hypothesis: 96.5%

- Power: 90%
- Alpha: 2.5% (one-sided)

The sample size was calculated using PASS 2019 and results in a sample size of 106. See the appendix for details.

Since the timing of the analysis of the primary safety endpoint is determined by the primary effectiveness endpoint, it is anticipated that the final analysis of the primary safety endpoint will include either approximately 141 or 188 patients.

5.1.3 Study Sample Size

The overall study sample size is driven by the primary effectiveness endpoint and is 188 patients.

5.2 General Considerations

Except where otherwise specified, the following general principles apply to the planned statistical analyses. All statistical analysis will be conducted using SAS version 9.4 or later (SAS Institute Inc., Cary, NC) or other widely-accepted statistical or graphical software as required.

5.2.1 Descriptive Statistics

Continuous data will be summarized with mean, standard deviation, median, minimum, maximum, and number of evaluable observations. Categorical variables will be summarized with frequency counts and percentages. Confidence intervals may be presented, where appropriate, using the t-distribution for continuous data and Clopper-Pearson Exact method for categorical variables.

5.2.2 Study Day

Study day 0 is the date of the index procedure. Day in study will be calculated relative to the index procedure as follows:

Study Day = Assessment Date – Index Procedure Date

For each subject, duration in study will be based on last study contact date which is the latest date of all follow-up visits or assessments or study exit including date of death.

Duration variables will be calculated as follows:

Duration Days = Start Date – End Date

5.2.3 Visit Windows

Visit windows are defined in the CIP. Unless otherwise specified, visit based assessments will be analyzed for each analysis time point according to the nominal visit entered in the Case Report Form (CRF) regardless of if it is out of window.

5.2.4 Unscheduled Visits

If a scheduled visit is missed and there are protocol assessments obtained at an unscheduled visit, either before or after the scheduled visit date, the one closest to the scheduled visit date will be used for analysis. If more than one measurement satisfies this condition (i.e., they are both within the same number of days from the scheduled visit date), the later of the two measurements satisfying the condition will be used.

5.2.5 Statistical Significance

The primary safety and effectiveness endpoints are one-sided tests and are conducted with one-sided alpha (type 1 error) of 0.025. Unless otherwise specified, hypothesis testing will be performed at either the one-sided 0.025 alpha level or, equivalently, the two-sided 0.05 alpha level, depending on whether the hypothesis is one-sided or two-sided. P-values will be rounded to three decimal places. If a p-value is less than 0.001 it will be reported as "<0.001". If a p-value is greater than 0.999, it will be reported as ">0.999".

5.2.6 Precision

Unless otherwise specified, the following conventions will apply for data display. In general, percentages will be displayed to 1 decimal place. Percentages <0.05% will be reported to 2 decimal places. For continuous parameters, means and medians will be reported to 1 additional decimal place than the measured value while standard deviation will be reported to 1 additional decimal places than the measured value. Minimum and maximum values will be reported to the same precision as the measured value.

5.3 Analysis Sets

The study will use intention-to-treat (ITT), modified intention-to-treat (mITT) and per-protocol (PP) analysis sets. The primary endpoint hypothesis tests will be conducted based on the modified intention-to-treat analysis set in which patient endpoint outcomes are known. Analyses based on all other analysis sets are intended as supportive analyses.

Sensitivity analyses will be performed to account for missing data and explore hypothetical outcomes in the ITT analysis set. Analyses of the PP analysis set will serve as additional sensitivity analyses to explore the impact of protocol non-compliance on primary study endpoints.

Table 2: Analysis Set Definitions

Analysis Set	Definition
ITT	All enrolled subjects.
mITT	Subset of ITT set where primary safety and efficacy status are known. For primary safety endpoint, includes all ITT subjects evaluated at 30 days post-procedure or with failure prior to 30 days. For primary efficacy endpoint, includes all ITT subjects with 12 month duplex ultrasound obtained within the 12 month window or with failure prior to 12 months.
PP	Subset of mITT not found in violation of any inclusion or exclusion criteria post-procedure.

If a supportive analysis set (e.g. ITT or PP) is the same as the mITT set, the results will be the same and will not be regenerated for that supportive analysis set.

5.4 Handling of Missing Data

All attempts will be made to limit the amount of missing data. Unless otherwise specified, no attempt will be made to impute missing data. If a data point is missing, that data point will not contribute to that portion of the analysis. The number of evaluable observations will be reported in analysis so that extent of missing data can be assessed.

In the case of partial adverse event onset date or date of death, the unknown portion of the date of the event will be imputed. If the month and year are known, the 15th of the month will be used for analysis. If only the year is known, the event will be analyzed as if it occurred on June 30th of the known year. In the rare case that the date is fully unknown, the date will be imputed as the index procedure date. Imputation of partial dates is subject to the condition that it must occur on or after the index procedure date. In the case where the imputed date is prior to the index procedure date, the date of the index procedure will be used. As death cannot occur before any documented subject contact, for date of death the imputed date of death must occur on or after last known contact in study.

5.5 Subject Disposition

The number of subjects in each analysis population will be presented along with reason for any exclusions. Subject accountability will be summarized by visit. The number of subjects who are enrolled, eligible for follow-up, and number completing clinical follow-up will be summarized for each protocol-required visit. In addition, the number of subjects who complete the study or exit early will be summarized by reason.

5.6 Demographics and Baseline Characteristics

Descriptive statistics will be presented for all clinically-relevant baseline demographic, medical history, and clinical characteristic variables.

5.7 Analysis of Study Endpoints

5.7.1 Primary Effectiveness Endpoint

The primary effectiveness endpoint is defined as primary patency through 12 months as evidenced by a peak systolic velocity ratio (PSVR) ≤2.5 from DUS at the 12-month visit and no clinically-driven revascularization within the stented segment through 12 months of follow-up.

5.7.1.1 Primary Analysis

The statistical hypothesis test for the primary effectiveness endpoint is:

$$Ho: p^{effectiveness} \leq 57\%$$

$$Ha: p^{effectiveness} > 57\%$$

where $p^{effectiveness}$ is the primary patency rate at 12 months, and 57% is the pre-specified performance goal (PG). The rationale for the PG is provided in the protocol.

The hypothesis will be evaluated with an exact binomial test including all patients in the mITT analysis set with demonstrated lack of primary patency through 12 months or with follow-up through 12-month duplex ultrasound assessment in the denominator. The timing of the interim analysis is addressed in Section 5.11.

The endpoint is met if the p-value from the one-sided exact test of whether $p^{effectiveness}$ exceeds 57% is less than the nominal p-value in ***Table 1*** corresponding to the timing of the analysis that was performed.

5.7.1.2 Handling of Missing Data

Handling of missing data is described in Section 5.4. Sensitivity analyses that address missing data for the primary effectiveness endpoint are defined below in Section 5.7.1.3

5.7.1.3 Sensitivity Analysis

Sensitivity analyses for missing data are described in Section 5.4.

In addition to analyzing the endpoint as a binomial proportion, patients with partial follow-up will be included in an additional Kaplan-Meier analysis. Freedom from loss of patency through 12 months will be summarized and presented using Kaplan-Meier graphs. Survival estimates with 95% confidence limits at 12 months will be presented. Subjects without event will be censored at the date of the last follow-up assessment for follow-up assessments prior to 12 months. If a 12-month assessment was performed, the patient will be censored at the close of the 12 month visit window to prevent staggered censoring and unstable risk sets at the 12 month timepoint. Estimated patency at the end of the 12-month visit window will be presented as the 12-month rate to include any loss of patency noted at any 12-month visit that occur during the 12-month visit window.

Additional sensitivity analyses will be performed to explore the potential impact of missing data on the primary effectiveness endpoint. The planned missing data sensitivity analyses are:

1. Worst case analysis

   This analysis analyzes all patients that are enrolled but not part of the mITT analysis set as failures for the primary effectiveness endpoint. If the endpoint is passed under this worst case scenario, no further missing data sensitivity analyses will be performed.

2. Tipping point analysis

   This analysis iterates over all patients that are enrolled but not part of the mITT analysis set and explores the range of potential outcomes based on assuming that 0% to 100% of the patients with missing data failed the primary effectiveness endpoint (i.e. had a non-patent vessel at 12 months or had a CD-TLR prior to 12 months)

3. Multiple imputation analysis

   Whereas the Worst Case and Tipping Point analyses focus on the potential for missing data to differ substantially from the observed data, a multiple imputation analysis is performed to estimate the expected analysis results assuming that the missing data follows the same distribution as the observed data conditional on baseline covariates. A multiple imputation analysis will be performed using a logistic regression model to impute hypothetical binary patency outcomes for patients with missing data with the following baseline covariates: age, gender, diabetes, Rutherford class, lesion length. A total of 100 imputations will be performed and the results summarized with the estimated 12-month patency and 95% confidence interval obtained using PROC MIANALYZE to implement Rubin's method of decomposing the variance into within-imputation and between-imputation components with the imputed proportion and asymptotic standard error as inputs.

5.7.2 Primary Safety Endpoint

The primary safety endpoint is freedom from a major adverse event (MAE) at 30 days post-procedure defined as any occurrence of the following events: all-cause death, clinically-driven target lesion revascularization and amputation of the index limb.

5.7.2.1 Primary Analysis

The statistical hypothesis test for the primary safety endpoint is:

$$Ho: p^{safety} \leq 88\%$$

$$Ha: p^{safety} > 88\%$$

where p^{safety} is the freedrom from MAE event rate at 30 days and 88% is the pre-specified performance goal (PG). The rationale for the PG is provided in the protocol.

The hypothesis will be evaluated with an exact binomial test including all patients in the mITT analysis set with an MAE through 30 days or with follow-up through 30 days in the denominator. The timing of the primary safety analysis is addressed in Section 5.11.

The endpoint is met if the p-value from the one-sided exact test of whether p^{safety} exceeds 88% is less than 0.025.

5.7.2.2 Handling of Missing Data

Handling of missing data is described in Section 5.4.

It is anticipated that all subjects will have adverse effect data collected through Day 30 post-procedure. Investigators will be advised that it is critical to obtain this information for all subjects.

If any 30-day follow-up data is missing, sensitivity analyses that address missing data for the primary effectiveness endpoint will also be performed to assess sensitivity to missing data for the primary safety endpoint, as defined in Section 5.7.1.3. These sensitivity analyses will be modified to use 30-day MAE rather than 12-month primary patency as the outcome of interest.

5.7.2.3 Sensitivity Analysis

In addition to analyzing the endpoint as a binomial proportion, patients with partial follow-up will be included in an additional Kaplan-Meier analysis. Freedom from MAE through 30 days will be summarized and presented using Kaplan-Meier graphs. Survival estimates with 95% confidence limits at 30 days will be presented. Subjects without event will be censored at the date of the last follow-up assessment.

5.7.3 Secondary Endpoints

Binary endpoints will be analyzed with frequency counts and proportions. Exact binomial 95% confidence intervals will be used as descriptive measures. Time-to-event analyses may be employed as an additional descriptive analysis to account for partial follow-up, as applicable.

5.8 Poolability Analyses

All investigational sites will follow the requirements of a common protocol and standardized data collection procedures and forms. The primary endpoints will be presented separately for each site using descriptive statistics. Poolability of the primary endpoints across investigational sites will be evaluated using a logistic regression model with site as a main effect. Since sites with a small number of enrollments may prevent this model from converging, several methods may be employed to assess poolability in the event that the model with all sites does not obtain convergence.

Sites enrolling less than 5 subjects will be combined to form one-quasi site. If the quasi-site exceeds the maximum enrollment allowed per investigational site, centers will be combined based on geographical proximity to form multiple quasi-sites until at least 5 subjects are included in each quasi-site.

If the p-value for the test of whether the site effect is non-zero is < 0.15, additional exploratory analyses will be performed to understand any variations in outcomes by site.

Assessment of poolability by geography (US vs. outside of US) will be performed using the same methods as described for poolability across sites.

5.9 Safety Analyses

Adverse events (AE) will be reported for the ITT population. AEs will be tabulated with the number of events and subjects with event for each event type and overall. Rates will be reported as the number of subjects who experience at least one event during the analysis interval out of the total number of subjects with follow-up to the beginning of the analysis interval. Serious adverse events will also be tabulated. The rate of all AEs and SAEs reported in the study will be reported as well as the rates at 0-30 days and 0-12 months.

All AEs and SAEs will also be summarized by relatedness as described above. Adverse events leading to death or study discontinuation will be provided in listing format.

All device deficiencies will be reported in listing format.

5.10 Subgroup Analyses

Subgroup analysis of the primary safety and efficacy endpoints will be performed for the following subgroups:

- Gender
- History of diabetes
- Lesion length (cm)
- Rutherford classification

These analyses are intended to demonstrate consistency of results across subgroups.

A multivariable logistic regression model will be fit with independent variables (unique for safety and effectiveness analyses) for the subgroup levels as well as additional baseline characteristics. Separate sets of baseline characteristics to be included in subgroup logistic regression models will be defined for safety and effectiveness analyses.

Subgroup analyses will be performed using the mITT analysis set. Additional exploratory analysis may be performed to understand any variations in outcomes by subgroup.

For each subgroup analysis, the p-value for the sub-group main effect will be presented. Additionally, at each level of the subgroup of interest, frequency counts and percentages will be presented. Furthermore, the odds ratio versus an identified reference group will be presented with a two-sided 95% profile confidence interval. The Firth option to implement penalized maximum likelihood regression will be used in any of the cells in the logistic regression analysis has a result of 0% or 100% that prevents convergence of the maximum likelihood regression analysis.

5.11 Interim Analyses

One group-sequential interim analysis is planned after 159 subjects (75%) have been followed through 12 months. The primary effectiveness endpoint analysis will be conducted and the nominal p-value compared to the nominal

p-value threshold in Table 1. The analysis is anticipated to have at least 119 subjects with 12-month data available for analysis, but will be conducted with all available 12-month data for the first 159 enrolled subjects, regardless of the missing data/attrition rate.

If the group sequential nominal p-value boundary is met, the primary safety endpoint analysis will be conducted. If both primary endpoints are met, the results at the time of the interim analysis may be used for a PMA submission.

It is anticipated that all subjects will have been enrolled at the time of the interim analysis. All enrolled subjects will be followed through completion and analysis of all study data may be conducted at a later date as an additional supporting analysis.

5.12 Protocol Deviations

Deviations from the procedures outlined in the CIP will be reported by investigational sites on the CRF. Protocol deviations will be summarized for all deviations and by type with event counts and number of subjects with at least one deviation.

6 Changes from Planned Analyses

Any changes to planned statistical analyses determined necessary prior to performing the analyses will be documented in an amended Statistical Analysis Plan and approved prior to the analysis when possible. Any other deviations or changes from the planned analyses deemed necessary due to violation of critical underlying statistical assumptions, data characteristics, or missing data will be clearly described in the clinical study report with justification and rationale.

7 Subject Listings

Subject listings will be provided for the primary endpoints and adverse events.

8 References

[1] Rocha-Singh, K.J., et al., Performance goals and endpoint assessments for clinical trials of femoropopliteal bare nitinol stents in patients with symptomatic peripheral arterial disease. [with editorial comment]. Catheterization & Cardiovascular Interventions, 2007. 69(6): p. 910-9.

9 Appendices

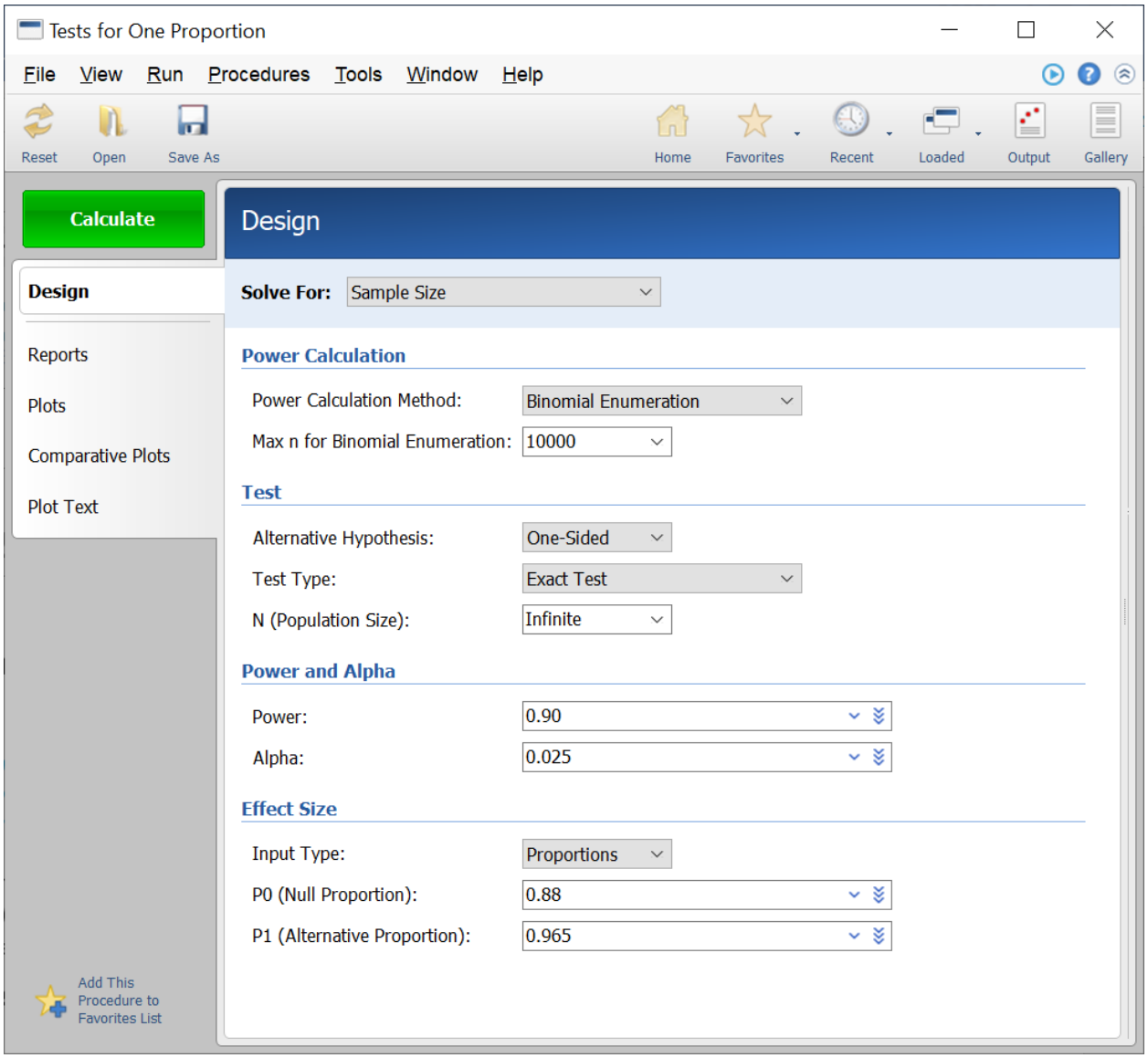
Appendix A. Sample Size Calculation

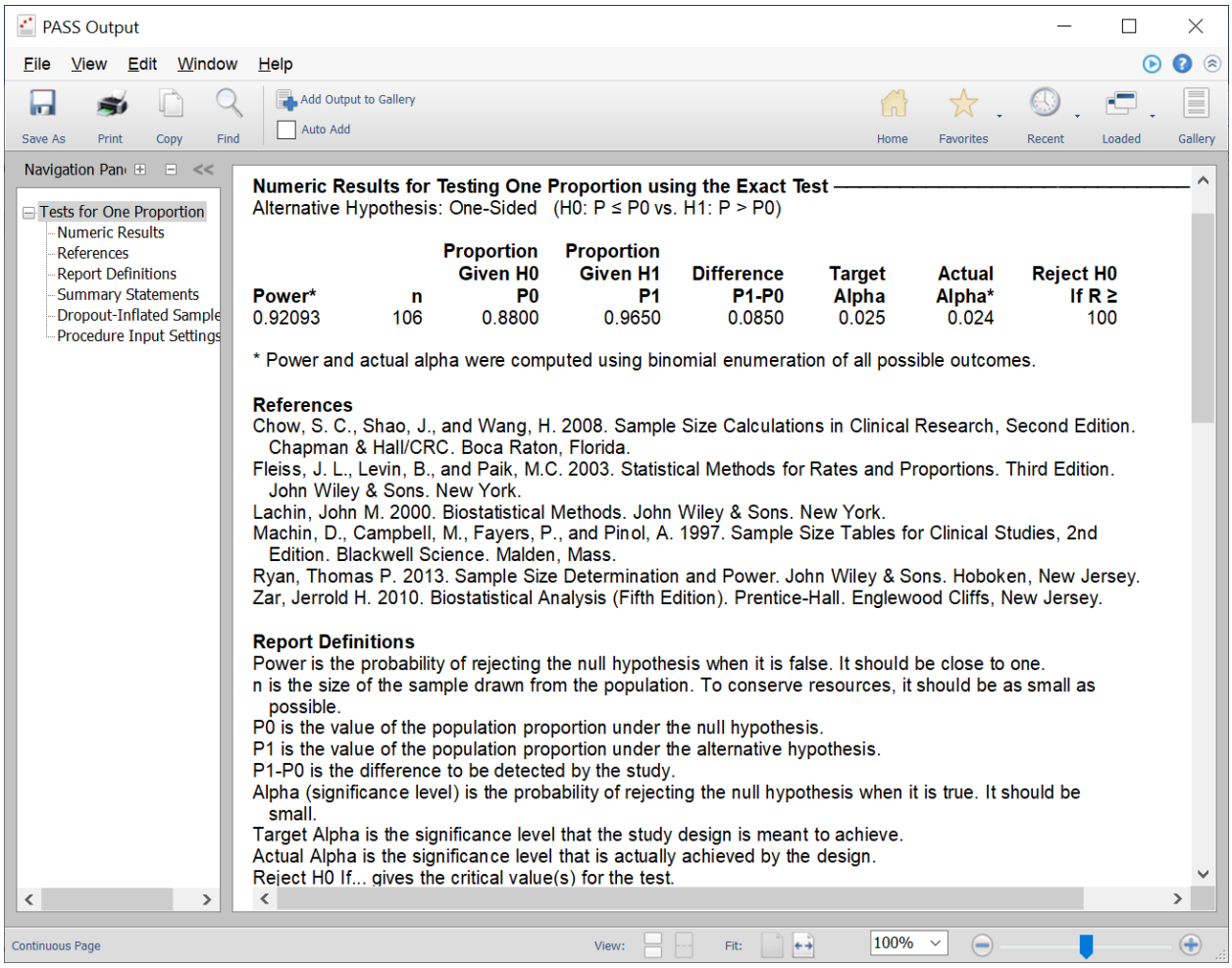
A.1 Primary Effectiveness Analysis

```
# R Code

library(gsDesign)

n.I <- 158.1  # Fractional fixed n selected such that group-sequential design yields target power

HSD <- gsDesign(k=3, test.type=2, alpha=0.025, n.fix = n.I, beta=0.1, timing=c(30/188, 141/188, 188/188),
sfu=sfHSD, sfupar=-6)

HSD$n.I

ceiling(HSD$n.I/0.85)

HSD$upper$bound

1-pnorm(HSD$upper$bound)

# [1] 9.970937e-05 5.451247e-03 2.393048e-02

# nominal p-value thresholds of 0.0001, 0.0055, 0.0239

floor(10**5*(1-pnorm(HSD$upper$bound)))/10**5


# Smallest numerator that results in passing nominal p-value boundaries

# 30 patients (30/188) -> 25 patients after 15% attrition

binom.test(24, 25, alternative="greater", p=0.57) # p-value = 1.566e-05

# 24/25 is lowest results with p-values < 0.0001

binom.test(82, b1, alternative="greater", p=0.57) # p-value = 0.005147

# 82/119 is lowest results with p-values < 0.0055

binom.test(104, 159, alternative="greater", p=0.57) # p-value = 0.01886

# 104/159 is lowest results with p-values < 0.0239
```

```
# After attrition of up to 15%, sample sizes of b0=25, b1=119, and 159 expected
b0 <- 25
b1 <- round(0.75*159)
b2 <- 159

# Calculate exact type I error and power
gsTorus2 <- gsBinomialExact(k=3, theta=c(.57, .70), n.I=c(b0, b1, b2), a=c(-1, -1, -1), b=c(24, 82,104))
gsTorus2



# Demonstrate that type I error is controlled across full range of possible attrition rates

type1 <- cbind(159:188, sapply(159:188, function(n1) {

  b0 <- round(0.1595745*n1)
  b1 <- round(0.75*n1)
  denom <- c(b0, b1, n1)

  p.thresholds <- c(0.0001, 0.0055, 0.0239) # approximate bounds

  x.thresholds <- sapply(1:3, function(i) {

  min((1:denom[i])[sapply(1:denom[i], function(x) { binom.test(x, denom[i], alternative="greater",
p=0.57)$p.value}) < p.thresholds[i]])

  })
  x <- gsBinomialExact(k=3, theta=c(.57, .70), n.I=denom, a=c(-1, -1, -1), b=x.thresholds)
  sum(x$upper$prob[,1])
}))

type1
plot(type1[,2] ~ I((1-type1[,1]/188)), xlim=c(0, 0.15), ylim=c(0, 0.03), xlab="Attrition Rate", ylab="Type 1 Error")
abline(h=0.025, lty=2)
```

A.2 Primary Safety Analysis




PASS Output
File View Edit Window Help
Save As Print Copy Find
Add Output to Gallery
Auto Add
Home Favorites Recent Loaded Gallery
Navigation Pan
Tests for One Proportion
Numeric Results
References
Report Definitions
Summary Statements
Dropout-Inflated Sample
Procedure Input Settings
Numeric Results for Testing One Proportion using the Exact Test
Alternative Hypothesis: One-Sided (H0: P ≤ P0 vs. H1: P > P0)
Power* n Proportion Given H0 P0 Proportion Given H1 P1 Difference P1-P0 Target Alpha Actual Alpha* Reject H0 If R ≥
0.92093 106 0.8800 0.9650 0.0850 0.025 0.024 100
* Power and actual alpha were computed using binomial enumeration of all possible outcomes.
References
Chow, S. C., Shao, J., and Wang, H. 2008. Sample Size Calculations in Clinical Research, Second Edition. Chapman & Hall/CRC. Boca Raton, Florida.
Fleiss, J. L., Levin, B., and Paik, M.C. 2003. Statistical Methods for Rates and Proportions. Third Edition. John Wiley & Sons. New York.
Lachin, John M. 2000. Biostatistical Methods. John Wiley & Sons. New York.
Machin, D., Campbell, M., Fayers, P., and Pinol, A. 1997. Sample Size Tables for Clinical Studies, 2nd Edition. Blackwell Science. Malden, Mass.
Ryan, Thomas P. 2013. Sample Size Determination and Power. John Wiley & Sons. Hoboken, New Jersey.
Zar, Jerrold H. 2010. Biostatistical Analysis (Fifth Edition). Prentice-Hall. Englewood Cliffs, New Jersey.
Report Definitions
Power is the probability of rejecting the null hypothesis when it is false. It should be close to one.
n is the size of the sample drawn from the population. To conserve resources, it should be as small as possible.
P0 is the value of the population proportion under the null hypothesis.
P1 is the value of the population proportion under the alternative hypothesis.
P1-P0 is the difference to be detected by the study.
Alpha (significance level) is the probability of rejecting the null hypothesis when it is true. It should be small.
Target Alpha is the significance level that the study design is meant to achieve.
Actual Alpha is the significance level that is actually achieved by the design.
Reject H0 If... gives the critical value(s) for the test.
Continuous Page
View:
Fit:
100%