# Supplementary Material for "Bayesian Statistics for Medical Device: Progress Since 2010" in the journal Theoretical and Innovative Regulatory Science

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## 1. Annotated list of publicly available PMA Summaries of Safety and Effectiveness (SSEDs) for PreMarket Approval Applications (PMAs) and PMA Supplements (PMASs) approved by FDA 1998-2021 that used Bayesian statistics

S1. P970033
Multi-frequency Impedance Breast Scanner
T-Scan 2000 by TransScan Medical, Inc.
Approved April 16, 1999 after a panel August 17, 1998.
SSED describes a Bayesian model to combine three studies.
https://www.accessdata.fda.gov/cdrh_docs/pdf/P970033b.pdf
(accessed August 23, 2022).

S2. P970015
Intervertebral Body Fusion Device
INTER FIX™ Threaded Interbody Fusion Device by Sofamor-Danek
Approved May 14, 1999 after a Bayesian panel December 11, 1997.
Bayesian predictive probabilities
https://www.accessdata.fda.gov/cdrh_docs/pdf/P970015b.pdf
(accessed August 23, 2022).

S3. P980048
Cervical Interbody Fusion System Instrumentation
BAK/Cervical Interbody Fusion System by Sulzer SpineTech approved April 20, 2001 after a Bayesian panel meeting January 19, 2001.
Bayesian success criterion; credible intervals
https://www.accessdata.fda.gov/cdrh_docs/pdf/P980048b.pdf
(accessed August 23, 2022).

S4. P000053
Implanted Mechanical/hydraulic Urinary Continence Device
AMS Sphincter 800™ Urinary Prosthesis by American Medical Systems
Approved June 14, 2001 with no panel meeting.
Hierarchical Bayesian model
https://www.accessdata.fda.gov/cdrh_docs/pdf/P000053b.pdf
(accessed August 23, 2022).

S5. P000036
Interactive Wound Dressing
DERMAGRAFT® by Advanced Tissue Sciences, Inc.
Approved September 28, 2001 with no panel meeting.
Interim analysis
https://www.accessdata.fda.gov/cdrh_docs/pdf/P000036b.pdf
(accessed August 23, 2022).

S6. P000028
Intervertebral Cervical Cage
AFFINITY™ Anterior Cervical Cage System by Medtronic Sofamor Danek approved June 13, 2002 with no panel meeting.
Credible intervals were reported in SSED.
https://www.accessdata.fda.gov/cdrh_docs/pdf/P000028b.pdf
(accessed August 23, 2022).

S7. P000058
filler, recombinant human bone morphogenetic protein, collagen scaffold with metal prosthesis, osteoinduction
InFUSE™ Bone Graft /LT CAGE™ Lumbar Tapered Fusion device approved July 02, 2002 after a January 10, 2002 panel meeting.
Bayesian predictive probabilities
https://www.accessdata.fda.gov/cdrh_docs/pdf/P000058b.pdf
(accessed August 23, 2022).

S8. P020014
Contraceptive Tubal Occlusion Device and Delivery System
Essure by Conceptus Inc.
Approved November 4, 2002 after a July 22, 2002 panel meeting.
Because of the similarity of the Phase II Study and Pivotal Study, contraceptive effectiveness results from the two studies were combined using Bayesian statistics.
https://www.accessdata.fda.gov/cdrh_docs/pdf2/P020026b.pdf
(accessed August 23, 2022).

S9. P020026
Drug-Eluting Coronary Stent System
CYPHER™ Sirolimus-Eluting Coronary Stent by Cordis approved April 24, 2003.
Interestingly there is no report in the SSED of the Bayesian analysis but there is in the FDA presentation at the October 22, 2002 panel meeting:
http://www.fda.gov/ohrms/dockets/ac/02/slides/3905s1.htm
(accessed August 23, 2022).

S10. P040021
Replacement Heart Valve
SJM Biocor® Valve by St Jude Medical

Approved August 5, 2005 with no panel meeting. There is a Bayesian treatment of missing data in SSED.
https://www.accessdata.fda.gov/cdrh_docs/pdf4/P040021b.pdf
(accessed August 23, 2022).

S11. P060018
Artificial Cervical Disc System
PRESTIGE® Cervical Disc System by Medtronic Sofamor Danek
Approved July 16, 2007 after a September 16, 2006 panel meeting.
The study was designed to use Bayesian methods with non-informative or uniform priors to analyze the primary endpoint.
Bayesian predictive probabilities
https://www.accessdata.fda.gov/cdrh_docs/pdf6/P060018b.pdf
(accessed August 23, 2022).

S12. P040021/S004
Replacement Heart Valve
SJM Epic Valve by St Jude Medical approved November 15, 2007 with no panel meeting.
This statistical methodology provides a framework for "borrowing' historical data.
Bayesian posterior means are the event rates modeled from a Bayesian hierarchical model.
https://www.accessdata.fda.gov/cdrh_docs/pdf4/P040021s004b.pdf
(accessed August 23, 2022).

S13. P080007
Iliac Stent
Bard® E-LUMINEXX™ Vascular Stent by Bard® _
Approved December 4, 2008 with no panel meeting.
Bayesian statistical models, using non-informative prior probabilities for the parameters of interest, were used to evaluate whether there was at least a 96% probability that the MACE rate would be less than a maximum threshold of 25% at nine months post-procedure.
https://www.accessdata.fda.gov/cdrh_docs/pdf8/P080007b.pdf
(accessed August 23, 2022).

S14. P030031/S011
Irrigated Diagnostic Ablation Catheter
Navistar ThermoCool RF Ablation Catheter by Biosense Webster
Approved February 6, 2009 after a November 20, 2008 panel meeting.
The critical results of the Bayesian analysis are the predictive probability of success for 230 patients and the posterior probability of superiority for the THERMOCOOL group.
https://www.accessdata.fda.gov/cdrh_docs/pdf3/P030031s011b.pdf
(accessed August 23, 2022).

S15. P060023
Artificial Cervical Disc
BRYAN® Cervical Disc by Medtronic Sofamor Danek
Approved May 12, 2009 after a July 17, 2007 panel meeting.
Bayesian statistical methods were planned to determine whether the investigational device is non-inferior to the control with respect to the overall success rate at 24 months. A non-inferiority margin of 10% was selected.
Non-informative priors are used for all prior distributions.
https://www.accessdata.fda.gov/cdrh_docs/pdf6/P060023b.pdf
(accessed August 23, 2022).

S16. P080032
Bronchial Thermoplasty System
Alair Bronchial Thermoplasty System by Asthmatx
Approved April 27, 2010 after October 28, 2009 panel meeting.
Primary Effectiveness Endpoint -Integrated AQLQ Score:
For the ITT population, the difference between the groups had a Posterior Probability of Superiority of 96.0%, and for the PP population, the difference between the groups had a Posterior Probability of Superiority of 97.9%, demonstrating an improvement in the Asthma Quality of Life in the Alair group compared to Sham.
https://www.accessdata.fda.gov/cdrh_docs/pdf8/P080032b.pdf
(accessed August 23, 2022).

S17. P100018
Intracranial Aneurysm Flow Diverter
Pipeline™ Embolization Device by ev3 Inc.
Approved April 6, 2011 after a March 18, 2011 panel meeting.
The primary safety and effectiveness endpoints were analyzed using a Bayesian statistical approach. Although prior information regarding safety and effectiveness of the Pipeline™ Embolization Device from a preceding feasibility study was used to power the study, a non-informative prior distribution was assumed.
The study was to be considered successful if, using a Bayesian analysis, the posterior probability that the effectiveness rate (pE) exceeded 50% given trial data was at least 0.975 and the posterior probability that the safety rate (pS) given trial data was less than 20% was at least 0.975.
Posterior probability, credible intervals
https://www.accessdata.fda.gov/cdrh_docs/pdf10/P100018b.pdf
(accessed August 23, 2022).

S18. P100046
Electrosurgical device
AtriCure Synergy Ablation System by AtriCure, Inc.
Approved Dec. 15, 2011
This pivotal study was based on a Bayesian adaptive design. The performance goal

endpoints for the study were based on historical data reported in the clinical literature and the applicant's data from a previous study.
Bayesian adaptive design with interim monitoring, posterior probabilities, credible intervals
https://www.accessdata.fda.gov/cdrh_docs/pdf10/P100046b.pdf
(accessed August 23, 2022).

S19. P100003
Cervical artificial disc
SECURE®-C Cervical Artificial Disc by Globus Medical, Inc.
Approved Sept. 28, 2012
Bayesian predictive posterior probabilities and credible intervals were used.
https://www.accessdata.fda.gov/cdrh_docs/pdf10/P100003b.pdf
(accessed August 23, 2022).

S20. P110008
Interlaminar Stabilization Device
coflex® Interlaminar Technology by Paradigm Spine, LLC
Approved October 17, 2012
A Bayesian statistical plan utilizing Jeffries non-informative priors and a single late-information time interim analysis was used to analyze the success of the device. After 70% of patients were evaluable for month 24 composite clinical success, the Bayesian statistical methods were used to obtain the posterior probabilities of non-inferiority and superiority.
Bayesian credible intervals and posterior probability of non-inferiority and superiority
https://www.accessdata.fda.gov/cdrh_docs/pdf11/P110008b.pdf
(accessed August 23, 2022).

S21. P040043/S051
Endovascular Graft
GORE® TAG® Thoracic Endoprosthesis by W.L. Gore & Associates, Inc.
Approved Sept. 10, 2013
The study used Bayesian adaptive design methodology, which allowed sample size to vary based on observed outcomes.
https://www.accessdata.fda.gov/cdrh_docs/pdf4/P040043s051b.pdf
(accessed August 23, 2022).

S22, S23. P010015/S205 + P010031/S381
Family of Cardiac Resynchronization Therapy Pacemaker (CRT-P) and Cardiac Resynchronization Therapy Defibrillator (CRT-D) by Medtronic. Inc.
Panel Oct 8, 2013, Approved April 10, 2014
The prespecified statistical approach for the primary objective and stopping rules for data collection and trial completion was an adaptive Bayesian statistical design. Posterior probabilities and 95% credible intervals were the metrics generated.
https://www.accessdata.fda.gov/cdrh_docs/pdf/P010015s205b.pdf

https://www.accessdata.fda.gov/cdrh_docs/pdf/P010031s381b.pdf
(accessed August 23, 2022).

S24. P090029
Artificial cervical disc
PRESTIGE LP™ Cervical Disc by Medtronic Sofamor Danek
Approved July 24, 2014
A Bayesian logistic model was used to assess qualitative response outcomes, including success status, adverse event data, and additional surgical event data. A Bayesian linear model was used for assessment of surgery data. The propensity score was used as the single covariate in the Bayesian models.
https://www.accessdata.fda.gov/cdrh_docs/pdf9/P090029b.pdf
(accessed August 23, 2022).

S25. P140004
Prosthesis, Spinous Process Spacer/Plate
Superion® InterSpinous Spacer (ISS)
by VertiFlex®, Incorporated
Approved Feb. 20. 2015
This clinical study was designed as a Bayesian adaptive trial.
A Bayesian approach was used to test for non-inferiority. If the posterior probability of the alternative hypothesis was at least 95.8%, using non-informative uniform (Beta[1,1]) priors for each success rate then the claim of non-inferiority would be made.
https://www.accessdata.fda.gov/cdrh_docs/pdf14/P140004b.pdf
(accessed August 23, 2022).

S26. P130013
Left Atrial Appendage Closure System
WATCHMAN® LAA Closure Technology by Boston Scientific Corp.
Dates of Panel Recommendation: December 11, 2013 and October 8, 2014
Approval: March 13, 2015
The primary analysis was according to intent-to-treat (ITT) principles, and a Bayesian adaptive design with discounted historical priors was used for the statistical analysis.
A Bayesian approach based on a piecewise exponential model was used to evaluate the first and second primary endpoints based on time to first event. In addition, this approach included prior PROTECT AF historical data from subjects with the same CHADS2 enrollment criteria as the PREVAIL subjects with a discounting weight of 50%.
The sponsor and FDA developed a Bayesian study for PREVAIL in which a portion of the PROTECT AF data would be used as an informative prior.
This study design methodology allowed the sponsor to collect additional safety and effectiveness data on the WATCHMAN device in a least burdensome manner. In addition to new data collected in PREVAIL, continued follow-up of PROTECT AF subjects was collected to provide critical insights into long-term device safety and

effectiveness.
https://www.accessdata.fda.gov/cdrh_docs/pdf13/P130013b.pdf
(accessed August 23, 2022).

S27. P150010
Intra-articular Hyaluronic Acid
HYMOVIS® by Fidia Farmaceutici S.p.A.
Approved Aug. 28, 2015
A Bayesian regression analysis was undertaken in order to determine whether the effect of two injections of HYMOVIS® was non-inferior to the effect of 5 injections of HYALGAN®, with a delta of 5mm, when WOMAC A Pain scores for HYMOVIS® and HYALGAN® from baseline up to 180 days were compared under a non-inferiority test.
https://www.accessdata.fda.gov/cdrh_docs/pdf15/P150010b.pdf
(accessed August 23, 2022).

S28. P140005
Sodium Hyaluronate for Injection
GenVisc 850® by OrthogenRx, Inc.
Approved Sept. 2, 2015
The Bayesian longitudinal analysis included data from four randomized controlled trials, two of which included comparisons of GenVisc 850 to PBS and two of which included comparisons of Supartz/Supartz FX to PBS. The results of this Bayesian longitudinal analysis show an increasing trend in superiority of GenVisc 850 to a PBS control over time, up to 30 weeks.
https://www.accessdata.fda.gov/cdrh_docs/pdf14/P140005b.pdf
(accessed August 23, 2022).

S29, S30. P070015/S128 and P110019/S075
Drug eluting coronary stent system
Abbott Vascular
XIENCE family of everolimus eluting coronary stent system
Approved Sept. 23, 2015
A Bayesian hierarchical model with prior data from clinical trial databases was utilized to analyze the primary endpoint of target vessel failure (TVF) at 12 months). The TVF rate was tested against a prespecified performance goal (PG) of 14.8% (expected rate 8.6% plus a delta of 6.2%).
The primary endpoint of 1-year TVF rate was 8.04% based on the Bayesian binomial-normal hierarchical model where prior data from AV historical trials were taken into consideration.
Meta-Analysis of 4 Studies Using Bayesian Modeling To further support the clinical similarities between GenVisc 850 and Supartz/Supartz FX, a Bayesian analysis was performed.
https://www.accessdata.fda.gov/cdrh_docs/pdf7/P070015s128b.pdf
https://www.accessdata.fda.gov/cdrh_docs/pdf11/P110019s075b.pdf
(accessed August 23, 2022).

S31. P160050
Reherniation reduction device
Barricaid® Anular Closure Device (ACD)
Approved Feb. 19, 2016
The first co-primary endpoint required a subject to have no evidence of recurrent herniation at the index level at any time up to and including the 24-month follow-up. The purpose of this primary endpoint was to evaluate the Barricaid's purpose, function and principal benefit: retention of nucleus material. Barricaid was superior to Control (posterior probability >0.9999), with the Control group exhibiting a success rate that was 20.8 percentage points lower than Barricaid (Table 10-30).
The data demonstrate that, with regard to the composite co-primary endpoint, the Barricaid was better by a statistically significant superiority margin compared to Control discectomy (27.8% vs. 18.1%, posterior probability=0.9980).
https://www.accessdata.fda.gov/cdrh_docs/pdf16/P160050b.pdf
(accessed August 23, 2022).

S32. P090029/S003
Artificial Cervical Disc
PRESTIGE LP™ Cervical Disc by Medtronic Sofamor Danek
Approved July 7, 2016
Credible intervals, predictive probabilities of non-inferiority, superiority
At FDA's request, the applicant also conducted a Bayesian hierarchical model to assess the homogeneity of the primary endpoint across sites at 24 months.
https://www.accessdata.fda.gov/cdrh_docs/pdf9/P090029s003b.pdf
(accessed August 23, 2022).

S33. P970003/S207
Autonomic Nerve Stimulator for Epilepsy
VNS Therapy System by Cyberonics, Inc. (vagus nerve stimulator)
Approved June 23, 2017
Expansion of an indication for an implanted autonomic nerve simulator for epilepsy based on an OUS national registry data in a Bayesian Hierarchical Analysis
The main study was the Japanese PAS, from which there were 30 patients aged 4 – 11 years. The other studies served as prior information to be leveraged within a statistical Bayesian hierarchical model. The data were obtained from six studies/sources, which had varying sample sizes and age groups. The main study for the current indication was the Japanese PAS, from which there were 30 patients aged 4 – 11 years. The other studies served as prior information to be leveraged within a statistical Bayesian hierarchical model.
https://www.accessdata.fda.gov/cdrh_docs/pdf/P970003s207b.pdf
(accessed August 23, 2022).

S34. P130021/S033
Aortic valve, prosthesis, percutaneously delivered
Medtronic CoreValve™ System by Medtronic CoreValve LLC

Approved July 10, 2017
The trial employed Bayesian adaptive methods to allow for "early win" look when 1400 subjects reached 12 months of follow-up.
Credible intervals
https://www.accessdata.fda.gov/cdrh_docs/pdf13/P130021S033b.pdf
(accessed August 23, 2022).

S35. P150009
Acute coronary syndrome event detector
AngelMed Guardian System by Angel Medical Systems, Inc.
Implantable Cardiac Monitor with Patient Alerting (Advisory Committees Meeting Materials; available on Web)
Approved April 9, 2018
Bayesian adaptive design was selected so that sample size could be dynamically determined during the course of the trial. Posterior probability was used to assess the level of evidence in support of a hypothesis.
To account for this uncertainty, a Bayesian adaptive design was selected so that sample size could be dynamically determined during the course of the trial. The appropriateness of the sample size was to be evaluated at different time points during the trial, with Bayesian prediction of data values for subjects who had not yet reached their 6 month follow-up visit. Posterior probabilities were used to make decisions.
https://www.accessdata.fda.gov/cdrh_docs/pdf15/P150009b.pdf
(accessed August 23, 2022).

S36. P170013
Intracranial Neurovascular Stent
Low-Profile Visualized Intraluminal Support (LVIS) and LVIS Jr. (Intracranialneurovascular Stent) by MicroVention, Inc.
Approved May 30. 2018
Posterior probability that the primary effectiveness endpoint success rate exceeds the pre-specified PG at 12 months.
Posterior mean, posterior probability, credible intervals
https://www.accessdata.fda.gov/cdrh_docs/pdf17/P170013b.pdf
(accessed August 23, 2022).

S37. P180007
Endobronchial valve
Spiration® Valve System by Spiration, Inc.
Approved Dec. 3, 2018
Breakthrough Device Status
Superiority of the Spiration Valve System over Control was considered established if the posterior probability for the primary effectiveness endpoint was > 0.982, a pre-specified threshold.

The pre-specified primary analysis using Bayesian multiple imputation for missing values showed that the estimated difference between the two (2) study groups.
Credible intervals
https://www.accessdata.fda.gov/cdrh_docs/pdf18/P180007b.pdf
(accessed August 23, 2022).

S38. P170030

Coronary Stent
Orsiro Sirolimus Eluting Coronary Stent System by BIOTRONIK, Inc._

Approved Feb 22, 2019
Non-inferiority of the Orsiro stent compared to the Xience stent in the BIOFLOW-V study was assessed using a Bayesian approach employing hierarchical models to formally incorporate data from the BIOFLOW-II and BIOFLOW-IV trials.
Bayesian posterior probability of non-inferiority; credible intervals
https://www.accessdata.fda.gov/cdrh_docs/pdf17/P170030b.pdf
(accessed August 23, 2022).

S39. P180036

Implantable impulse generator

OPTIMIZER Smart System by Impulse Dynamics (USA), Inc

Approved Mar 21, 2019

Breakthrough Device Status
A Bayesian statistical approach was employed to leverage the data available from the FIX-HF5 trial, particularly the peak VO2 results.
For the primary effectiveness endpoint, longitudinal data from the prospective study was analyzed, borrowing of datafrom a previous study using a Bayesian modeling approach.
Bayesian posterior probability, credible intervals
https://www.accessdata.fda.gov/cdrh_docs/pdf18/P180036b.pdf
(accessed August 23, 2022).

S40. P170027
SuperSaturated Oxygen Therapy
TherOx DownStream System by TherOx, Inc.
Approved April 2, 2019
The AMIHOT II trial had a Bayesian statistical design that allows for the informed borrowing of data from the previously completed AMIHOT I trial.
The Bayesian posterior probability of superiority is 95.1% for study success based on an analysis of available data; when the study results for missing data were imputed using pre-specified methods, the posterior probability of superiority is 96.9%.
The primary safety endpoint evaluated for non-inferiority using a Bayesian hierarchical model that considered 30-day MACE data from two studies.
https://www.accessdata.fda.gov/cdrh_docs/pdf17/P170027b.pdf
(accessed August 23, 2022).

S41. P180050
Carotid sinus stimulator
BAROSTIM NEO® System by CVRx, Inc. (carotid sinus stimulator)
Approved Aug 16, 2019
Expedited Access Pathway -- Breakthrough device status
https://www.sciencedirect.com/science/article/pii/S0002870318302217
The BAROSTIM NEO® - Baroreflex Activation. Therapy® for Heart Failure (BeAT-HF) trial data is the basis for the PMA approval decision. A summary ...
Bayesian adaptive sample size but not mentioned in SSED.
https://www.accessdata.fda.gov/cdrh_docs/pdf18/P180050b.pdf
(accessed August 23, 2022).

S42. P190016
Lidocaine/Epinephrine Iontophoresis and Automated Tympanostomy Tube Insertion System
Tula® System by Tusker Medical
Approved November 25, 2019
Breakthrough Device Status
The Procedural Success endpoint was analyzed in a Bayesian hierarchical framework, with prospectively-designed borrowing of data between the younger and older pivotal cohorts, with the extent of borrowing dependent upon the similarity in results.
Each age group was tested separately, however, a prospectively designed Bayesian hierarchical model was implemented which enabled data borrowing between the groups, with the extent of borrowing dependent upon the similarity/dissimilarity in results.
The procedural success rate was compared to the performance goal of 68% using a Bayesian Hierarchical model.
https://www.accessdata.fda.gov/cdrh_docs/pdf19/P190016b.pdf
(accessed August 23, 2022).

S43. P180027
Intracranial Aneurysm Flow Diverter
Flow Re-Direction Endoluminal Device (FRED®) System by MicroVention, Inc.
Approved Dec. 16, 2019
With regard to success/failure criteria, the FRED study was designed to be successful if, using a Bayesian analysis, the two-sided 95% credible interval (CI) lower bound of the effectiveness rate exceeds the 46% PG and the two-sided 95% CI upper bound of the safety rate is below the 15% PG.
Posterior probability that the primary safety endpoint event rate is < 15%.
Bayesian analysis also allowed the computation of credible intervals for inference regarding primary endpoints.
https://www.accessdata.fda.gov/cdrh_docs/pdf18/P180027b.pdf
(accessed August 23, 2022).

S44, S45. P170019 and P160018
FoundationOne®CDx (F1CDx) by Foundation Medicine, Inc.
Approved December 19, 2016 and November 30, 2017
P170019 granted Breakthrough Device Status
Base substitution detection is performed using a Bayesian methodology, which allows for the detection of novel somatic alterations at low mutant allele frequency (MAF) and increased sensitivity for alterations at hotspot sites through the incorporation of tissue-specific prior expectations.
The imputation model was driven by a hierarchical Bayesian logistic regression.
https://www.accessdata.fda.gov/cdrh_docs/pdf16/P160018b.pdf
https://www.accessdata.fda.gov/cdrh_docs/pdf17/P170019b.pdf (accessed August 23, 2022).
(accessed August 23, 2022).

S46. P190019
Drug-Eluting Peripheral Transluminal Angioplasty Catheter
Device Trade Name: Ranger™ Paclitaxel-Coated PTA Balloon Catheter by Boston Scientific Corporation
Approved Oct. 30, 2020
Bayesian predictive modeling was used to estimate the 3-year mortality rate and compared to a performance goal (PG) of 12.9%.
https://www.accessdata.fda.gov/cdrh_docs/pdf19/P190019B.pdf
(accessed August 23, 2022).

S47. P210034
Device Generic Name: Implant, resorbable, for articular osteochondral repair
Device Trade Name: Agili-C™ by CartiHeal Ltd.
Approved March 29, 2022
Breakthrough Device Status
The primary goal of the trial was to demonstrate superiority of the Agili-C™ device relative to SSOC using Bayesian analysis. The trial would be considered a success if the posterior probability exceeds 0.98 at the final analysis.
The Bayesian analysis results were used for primary endpoint and confirmatory secondary endpoints
https://www.accessdata.fda.gov/cdrh_docs/pdf21/P210034B.pdf
(accessed August 23, 2022).

## 2. OpenBUGS code for the Intracranial Stent Data for Table 1 Analysis

```
#Model
model   {
for( i in 1 : N ) {
    r[i] ~ dbin(p[i],n[i])    #p[i]=success proportion for stent i
    logit(p[i]) <- mu[i]      #mu[i]=logit of p[i]
```

```
    mu[i] ~ dnorm(mu0,tau) }  #mu[i] is a random draw from a superpopulation
mu0 ~ dnorm(0.0,0.75)         #      with unknown mean mu0 and precision tau
tau ~ dgamma(0.11,0.09)       #mu0, tau given normal, gamma hyperpriors
 s2 <- 1 / tau                #s2=variance between mu[i]'s
  s <- sqrt(s2)               #s= standard deviation between mu[i]'s
       }

#Data
#N= 4 = number of  generations of intracranial  stents
#r= counts of successful stent placements for the 4  stents
#n= sample sizes for r; NA=indicates missing data
list(r = c(6,37,42,30),  n = c(8,59,56,60), N = 4)
list(r = c(6,37,42,40),  n = c(8,59,56,60), N = 4)
list(r = c(6,37,42,NA),  n = c(8,59,56,60), N = 4)

#Inits
list(mu=0, tau=1)   #initial value of parameters (or let OPENBugs determine)
```