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2017

### Karl E. Peace Collection

Zach S. Henderson Library Special Collections

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## OVERVIEW OF COLLECTION

**Title:** Karl E. Peace papers

**Date:** 1941 - 2014

**Extent:** 38 boxes

**Creator:** Peace, Karl E., 1941-

**Accruals:** Further accruals expected.

**Language:** English

**Repository:** Zach S. Henderson Library Special Collections, Georgia Southern University, Statesboro, GA. [specolle@georgiasouthern.edu](mailto:specolle@georgiasouthern.edu). 912-478-7819. [library.georgiasouthern.edu](http://library.georgiasouthern.edu).

**Processing Note:** Finding aid revised in 2020.

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## INFORMATION FOR USE OF COLLECTION

**Conditions Governing Access:** The collection is open for research use.

**Physical Access:** Materials must be viewed in the Special Collections Reading Room under the supervision of Special Collections staff.

**Technical Access:** Special Equipment may be needed to view audiovisual materials

### **Conditions Governing Reproduction and Use:**

In order to protect the materials from inadvertent damage, all reproduction services are performed by the Special Collections staff. All requests for reproduction must be submitted using the Reproduction Request Form. Requests to publish from the collection must be submitted using the Publication Request Form. Special Collections does not claim to control the rights to all materials in its collection. In all instances, it is the researcher's responsibility

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**Preferred Citation:** [Item Identification], Karl E. Peace papers, Zach S. Henderson Library Special Collections, Georgia Southern University, Statesboro, GA

**Related Collections:** [Jiann Ping Hsu and Karl E Peace Art Collection](#)

**Separated Material:** [Journal of Biopharmaceutical Statistics](#)

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## ABOUT THE COLLECTION

**Biographical History:** Karl E. Peace was born into a family of southwest Georgia sharecroppers in Baker County, Georgia, on July 28, 1941. He overcame an impoverished background to become immensely successful, both academically and professionally. In 1959, with a loan of \$532 from a businessman in a neighboring county, he enrolled at Georgia Southern University, prepaying his tuition for the first two quarters. In the third quarter, he obtained a Georgia State Teacher's scholarship that, in addition to his seven part-time jobs, helped him complete his bachelor's degree in chemistry while supporting his siblings and cancer-stricken mother. He went on to earn a master's degree in mathematics from Clemson University, teach at several colleges and universities, and earn a PhD in biostatistics from the Medical College of Virginia (MCV).

Peace began to pursue a career in biostatistics in the pharmaceutical industry in 1978. After rising from an entry-level biostatistician position at Burroughs-Wellcome to vice president of worldwide technical operations at Parke-Davis/Warner Lambert, he started Biopharmaceutical Research Consultants Inc. in 1989. Dozens of international biotech and pharmaceutical companies relied on his expertise and he played a key role in the development and regulatory approval of dozens of medicines, including drugs used to treat Alzheimer's disease, hypertension, arthritis, anxiety, depression and panic attacks, and gastrointestinal ulcers. At the same time, Peace kept one foot in the classroom, serving as an adjunct faculty member at Duke University, the MCV, the University of Michigan, The University of North Carolina, Temple University, and Virginia Commonwealth University. Peace approached Georgia Southern University officials in 1998 with a plan to establish a biostatistics center at the university, a corresponding program of study in biostatistics at the graduate level, and a school of public health.

Peace returned to the Statesboro, Georgia, campus in the fall of 2000, when Georgia Southern began to offer the masters of public health degree in biostatistics that he and Charles Hardy developed. In 2004, his endowment to honor his late wife led to the creation

of the Jiann-Ping Hsu School of Public Health (JPHSOPH), the first school of public health in the University System of Georgia (USG). In creating the JPHSOPH, the board of regents also named the center for biostatistics the Karl E. Peace Center for Biostatistics. Peace made many contributions to the literature, publishing 10 books and more than 150 articles.

Peace was the recipient of dozens of honors, awards, and citations, and he was internationally known as an educator, researcher, author, humanitarian, and philanthropist. For example, he was the 1998 Distinguished Alumnus of GSU; the 2003 GSU Alumnus of the Year in private enterprise; the first recipient of the President's Medal at GSU in 2005; the 2009 recipient of the GSU Award for Excellence in Research and Scholarly Activity; the Georgia Cancer Coalition's Distinguished Cancer Scholar at GSU (a first for GSU) from 2002–2007; the first recipient at GSU of a grant from the Georgia Research Alliance; the endower of the first Eminent Scholar Chair at GSU; the endower of the Karl E. Peace/JP Hsu Eminent Scholar Chair in Public Health at GSU; the endower of 13 scholarships at GSU; and a benefactor of the GSU library, Center for Disabled Students, and the music and art departments. He was cited as Georgia Southern University's greatest benefactor in the 2004 Campaign for National Distinction.

Additionally, Peace was the 1991 Star Alumnus of the MCV; the 2005 recipient of the MCV Founder's Society Award; the 2007 recipient of the American Public Health Association (APHA) Statistics Section Award for his contributions to the pharmaceutical industry in drug research and development, the founder and editor-in-chief of the *Journal of Biopharmaceutical Statistics*; the founder of the Biopharmaceutical Applied Statistical Symposium (BASS); and the recipient of meritorious service awards from the American Society for Quality Control, Drug Information Association, BASS, Southwest Georgia Cancer Coalition, and Georgia Cancer Coalition.

Peace endowed two scholarships at the University of California at Berkeley, including the JiannPing Hsu/Karl E. Peace Chair in Biostatistics; three scholarships in biostatistics at MCV; one scholarship at Randolph-Macon College; and the Jiann-Ping Hsu Biopharmaceutical and Regulatory Sciences Session at the annual meeting of the International Chinese Statistical Association. He was also a major contributor to the growth of the Philippine Statistical Association and responsible for creating the Office of the International Chinese Statistical Association within the Jiann-Ping Hsu College of Public Health.

(Source: American Statistical Association)

**Scope and Content:** This collection consists of the personal and research papers of Karl E. Peace, Professor of Biostatistics at Georgia Southern University and namesake of the Karl E. Peace Center for Biostatistics and Survey Research. Materials span 1941 to 2018 and include, correspondence, teaching materials, published articles, and manuscripts. A small portion of

photographs and artists renderings are also included. This collection is still undergoing processing.

**System of Arrangement:**

The collection has been tentatively sorted into three main categories, manuscripts, teaching and research.

- |                       |                       |
|-----------------------|-----------------------|
| Box 1: 0200105948729  | Box 20: 0200106500115 |
| Box 2: 0200105948737  | Box 21: 0200106500123 |
| Box 3: 0200105948745  | Box 22: 0200106500131 |
| Box 4: 0200105948752  | Box 23: 0200106500149 |
| Box 5: 0200105948760  | Box 24: 0200106500156 |
| Box 6: 0200105948778  | Box 25: 0200106500164 |
| Box 7: 0200105948786  | Box 26: 0200106500172 |
| Box 8: 0200105948794  | Box 27: 0200106500180 |
| Box 9: 0200105948802  | Box 28: 0200106500198 |
| Box 10: 0200106500016 | Box 29: 0200106500206 |
| Box 11: 0200106500024 | Box 30: 0200106500214 |
| Box 12: 0200106500032 | Box 31: 0200106500222 |
| Box 13: 0200106500040 | Box 32: 0200106500230 |
| Box 14: 0200106500057 | Box 33: 0200106500248 |
| Box 15: 0200106500065 | Box 34: 0200106500255 |
| Box 16: 0200106500073 | Box 35: 0200106500263 |
| Box 17: 0200106500081 | Box 36: 0200106500271 |
| Box 18: 0200106500099 | Box 37: 0200106500289 |
| Box 19: 0200106500107 | Box 38: 0200106500297 |

**Acquisitions Info:** Donated by Karl E. Peace, 2012 - 2018.

**Access Points:**

- Biology -- Study and teaching -- Sources
- Biometry -- Study and teaching -- Sources
- Biopharmaceutics -- Study and teaching -- Sources
- Biology -- Study and teaching
- Biometry -- Study and teaching
- Sources
- Records (Documents)

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**CONTAINER LISTING**

**Box 1:** 0200105948729

<b><u>Items: BASS Symposium</u></b>	<b><u>Box Number</u></b>	<b><u>Folder Number</u></b>
BASS XI: Short Courses <ul style="list-style-type: none"> <li>● Lecture 00:               <ul style="list-style-type: none"> <li>○ Data Mining Introduction</li> </ul> </li> <li>● Lecture 01:               <ul style="list-style-type: none"> <li>○ All linear Statistical Methods are Special Cases of SVD</li> </ul> </li> <li>● Lecture 02:               <ul style="list-style-type: none"> <li>○ Data Mining of Large, Clinical Trials</li> </ul> </li> <li>● Lecture 04:               <ul style="list-style-type: none"> <li>○ Multiple Trees and Metabolomic Data</li> </ul> </li> <li>● Lecture 06:               <ul style="list-style-type: none"> <li>○ Multiple Blocks of Data rSVD and RP</li> <li>○ Subgroup Analysis of Clinical Trials</li> <li>○ Recursive Partitioning with a Multivariate Dependent</li> <li>○ Lecture Notes</li> <li>○ Design and Interim Monitoring of Flexible Clinical Trials</li> </ul> </li> </ul>	1	<b>1</b>
BASS XI: Tutorials <ul style="list-style-type: none"> <li>● BASS XI: "A Brief for Breaking our Rules"</li> <li>● Breast Cancer Chemotherapy Treatment, Design, and Recent Advances</li> <li>● Determination of the Best Linear Unbiased Estimates (Blue) of Incomplete Data For The Analysis of Repeated Measurements In Clinical Trials</li> <li>● Endpoints in HIV/AIDS Clinical Trials</li> <li>● Lecture 04:               <ul style="list-style-type: none"> <li>○ Multiple Trees and Metabolomic Data</li> </ul> </li> <li>● Lecture 06:               <ul style="list-style-type: none"> <li>○ Multiple Blocks of Data rSVD and RP</li> </ul> </li> <li>● Subgroup Analysis of Clinical Trials</li> <li>● Recursive Partitioning with a Multivariate Dependent</li> <li>● Lecture Notes</li> <li>● Design and Interim Monitoring of Flexible Clinical Trials</li> <li>● Statistical Considerations in Biomarker Method Development &amp; Validation</li> </ul>	1	<b>2</b>
BASS XI: Tutorials continued <ul style="list-style-type: none"> <li>● Non-inferiority Trials -Hypotheses and Analyses</li> <li>● Active Control Non-Inferiority Trial- The Hypothesis</li> <li>● Multiple Primary Endpoints in Clinical Trials</li> <li>● Optimal Adaptive vs. Optimal Group Sequential Designs</li> </ul>	1	<b>3</b>

<ul style="list-style-type: none"> <li>● Methods for Incorporating Flexibility in Clinical Trials</li> <li>● Using Robust Parameter Design In Industrial Experiments</li> <li>● Critical Path: An Overview</li> <li>● Emerging Issues and Considerations in Clinical Trial Design Strategy for Drug Development</li> <li>● Emerging Issues and Considerations in Manufacturing Quality Control and Assurance of Drug Products</li> </ul>		
<p>BASS XIII: Short courses, Nov. 06</p> <ul style="list-style-type: none"> <li>● Statistical Methods to Address Multiplicity: <ul style="list-style-type: none"> <li>○ Adaptive Designs and the One Study Paradigm versus the Two (or More) Studies Paradigm as the Primary Confirmatory Evidence for a New Medical Product Relative to a Control</li> </ul> </li> <li>● Statistical Methods to Address Multiplicity: <ul style="list-style-type: none"> <li>○ Statistical Considerations for the Conduct and Reporting of Interim Analyses</li> </ul> </li> <li>● Statistical Methods to Address Multiplicity: <ul style="list-style-type: none"> <li>○ Analyses for Sub-population Effects</li> </ul> </li> <li>● Statistical Methods to Address Multiplicity: <ul style="list-style-type: none"> <li>○ Discussion of Applications of SAS Macros for Multiplicity Adjustment</li> </ul> </li> <li>● Statistical Methods to Address Multiplicity: <ul style="list-style-type: none"> <li>○ Analysis of Covariance: Parametric and Nonparametric</li> </ul> </li> <li>● Statistical Methods to Address Multiplicity: <ul style="list-style-type: none"> <li>○ Methods for Multiple Group Comparisons Bass</li> </ul> </li> <li>● Statistical Methods to Address Multiplicity: <ul style="list-style-type: none"> <li>○ Overview for Issues and Methods for Multiple Endpoints</li> </ul> </li> <li>● Statistical Methods to Address Multiplicity: <ul style="list-style-type: none"> <li>○ Summary and Discussions for Points to Consider and Guidance for Multiplicity, Missing Data, and Adjustment for Baseline Covariates</li> </ul> </li> <li>● Adaptive Design Methods in Clinical Trials</li> <li>● Statistical Methods to Address Multiplicity: <ul style="list-style-type: none"> <li>○ Discussion of Application of the MULTTEST Procedure in SAS</li> </ul> </li> <li>● BASS XIII: Course Schedule</li> </ul>	1	<b>4</b>
<p>BASS XIII: Short courses continued Nov.06</p> <ul style="list-style-type: none"> <li>● Conditional Inference</li> <li>● Improving Statisticians' Consulting Effectiveness</li> <li>● Using The Myers-Briggs Type Indicator</li> <li>● Improving One-On-One Communications Skills</li> <li>● Improving Group Communications</li> <li>● Chapter 1. The Babel Problem, The Partnering Solution</li> </ul>	1	<b>5</b>

<p>BASS XIII: Stat Symposium, Nov. 06</p> <ul style="list-style-type: none"> <li>● BASS XIII Thirteenth Annual Biopharmaceutical Applied Statistics Symposium</li> <li>● Simulation for Designing and Analyzing Clinical Trials</li> <li>● Comparison of Statistical Analysis Methods Using Modeling and Simulation for Modern Protocol Design</li> <li>● Design of Dose Response Clinical Trials</li> <li>● Resampling Based Multiple Testing</li> <li>● BASS XIII Insightful</li> <li>● Model Based Adaptive Dose Ranging Designs</li> <li>● Bioequivalence trials designed using adaptive methodologies</li> </ul>	1	<b>6</b>
<p>BASS XIII: Stat Symposium continued</p> <ul style="list-style-type: none"> <li>● A Comparison of Methods for Longitudinal Data with Missing Due to Truncation</li> <li>● Rescue Behavior and Imputation Strategies in Analgesic Studies</li> <li>● Multivariate Assays with Values Below the Lower Limit of Quantitation: <ul style="list-style-type: none"> <li>○ Parametric Estimation by Imputation and Maximum Likelihood</li> </ul> </li> <li>● Variability in Gene Expression in Healthy Volunteers</li> <li>● Adaptive Design Methods in Clinical Trials</li> <li>● Considerations in Planning and Testing for Multiple Endpoints in Clinical Trials</li> <li>● Issues and Considerations in Composite Endpoints</li> <li>● Recent Results Concerning Multiplicities in Animal Carcinogenicity Studies</li> <li>● Tree-structured gatekeeping procedures in clinical trials with multiple objectives</li> <li>● BASS XIII Fellows</li> <li>● BASS XIII letter from Karl E. Peace</li> <li>● Our Keynote Speaker is Greg Campbell</li> <li>● Letter to BASS Committee Members from Laura H. Gunn</li> <li>● Adaptive Design Methods in Clinical Trials</li> <li>● Housekeeping</li> <li>● Program Abstracts Conference Sessions</li> </ul>	1	<b>7</b>
<p>BASS XIV: Stat Symposium, Nov. 07</p> <ul style="list-style-type: none"> <li>● An Adaptive Dose Finding Design (DOSEFIND) Using a Nonlinear</li> <li>● Dose Response Model</li> <li>● Dose Response Analysis for Combination Products</li> <li>● Parametric Bayesian Dose Response Modeling</li> <li>● Concordance Analysis in Biopharmaceutical Industry</li> <li>● Statistical Validation of Surrogate Markers</li> </ul>	1	<b>8</b>



<ul style="list-style-type: none"> <li>● An Introduction to Pathodynamics from the View of Liver Homeostasis Using the Ornstein-Uhlenbeck Process</li> <li>● On the Analysis of Longitudinal Clinical Lab Data with Latent Mixture Models</li> <li>● Some Thoughts on the Assessment of Pharmaceutical Safety Data</li> <li>● Statistical Modeling and Graphical Analysis of Safety Data in Clinical Trials</li> <li>● Absolute Risk: Clinical Applications and Controversies</li> </ul>		
<p>BASS XIV: Stat Symposium continued Nov.07</p> <ul style="list-style-type: none"> <li>● Adaptive Model-Based Designs in Clinical Drug Development</li> <li>● A Nonlinear Model Based Method for Steady-state Assessment</li> <li>● Moving Beyond QT...</li> <li>● Strategies for Meta-Analyses of Randomized Clinical Trials Based on Individual Patient Data</li> <li>● Statistical Issues in Predictive Toxicology</li> <li>● Enriching and Mining Missing Data: Design and Analysis Issues</li> <li>● Missing Data: The shape of things to come</li> <li>● An Overview of Causal Inference and its Application in Clinical Trials</li> <li>● Developing an Analytical Road Map for Incomplete Longitudinal Clinical Trial Data</li> </ul>	1	<b>9</b>
<p>BASS XIV: Stat methods for Biomarker Discovery, Nov. 07</p> <ul style="list-style-type: none"> <li>● Statistical Learning From Data</li> <li>● Prediction Methods</li> <li>● Super Learning</li> <li>● Super Learning in Prediction</li> <li>● Informative Censoring Addressing Bias in Effect Estimates Due To Study Drop-out</li> <li>● Assessing ETA Violations, and Selecting Attainable/Realistic Parameters</li> <li>● Targeted MLE for Variable Importance and Causal Effect with Clinical Trial/Randomized and Observational Data</li> <li>● Multiple Testing</li> <li>● Outline</li> <li>● Controlling FDR in Second Stage Analysis</li> <li>● Secondary Analysis</li> <li>● Resampling Based Multiple Testing</li> <li>● Targeted Maximum Likelihood Learning; Application to Realistic Variable Importance</li> </ul>	1	<b>10</b>

<p>BASS XIV: Stat Graph, Covariance Analysis, Nov. 07</p> <ul style="list-style-type: none"> <li>● Statistical Graphics</li> <li>● Statistical Problems to Document and to Avoid</li> <li>● How Should Change be Measured?</li> <li>● The Role of Covariable Adjustment in the Analysis of Clinical Trials</li> <li>● Bayesian Approaches to Design and Analysis of RCTs and Advantages over Frequentist Methods</li> </ul>	1	<b>11</b>
<p>BASS XV: Creating more effective graphs, Nov. 08</p> <ul style="list-style-type: none"> <li>● Creating More Effective Graphs</li> <li>● Creating More Effective Graphs with Applications to Clinical Trials and</li> <li>● Electronic Medical Records: <ul style="list-style-type: none"> <li>○ Use of Advanced Computer Methods and Visualization Tools to Simplify the Analysis of Complex Clinical Drug Safety Data</li> </ul> </li> </ul>	1	<b>12</b>
<p>BASS XV: Trial simulation, Nov. 08</p> <ul style="list-style-type: none"> <li>● Lecture 1: Mathematical Modeling And Trial Simulation In Medicine And Life Sciences</li> <li>● Lecture 2: Regulatory Aspects of Modeling And Simulation</li> <li>● Lecture 3: Simulation For Designing And Analyzing Clinical Trials – A Statistical Approach</li> <li>● Lecture 4: Simulation For Designing And Analyzing Clinical Trials – A Statistical Approach</li> <li>● Lecture 5: Simulation For Designing And Analyzing Clinical Trials – A Statistical Approach</li> <li>● Lecture 6: Simulation For Designing And Analyzing Clinical Trials – A Statistical Approach</li> <li>● Lecture 7: Simulation For Designing And Analyzing Clinical Trials – A Statistical Approach</li> <li>● Lecture 8: Simulation For Designing And Analyzing Clinical Trials – A Statistical Approach</li> <li>● Lecture 9: Simulation For Designing And Analyzing Clinical Trials – A Statistical Approach</li> <li>● Lecture 10: Simulation For Designing And Analyzing Clinical Trials – A Statistical Approach</li> <li>● Lecture 11: Pharmacokinetic &amp; Pharmacodynamic Concepts</li> <li>● Lecture 12: Pharmacology, Pharmacokinetics &amp; Pharmacodynamics</li> <li>● Lecture 13: Modeling In Biopharmaceutics, PK and PD</li> <li>● Lecture 14: Modeling In Biopharmaceutics, PK and PD</li> <li>● Lecture 15: Modeling In Biopharmaceutics, PK and PD</li> </ul>	1	<b>13</b>

<p>BASS XV: trial simulation continued</p> <ul style="list-style-type: none"> <li>● Lecture 16: Modeling In Biopharmaceutics, PK and PD</li> <li>● Lecture 17: Population Dynamics</li> <li>● Lecture 18: Population Dynamics</li> <li>● Lecture 18: Population Dynamics</li> <li>● Lecture 19: Population Dynamics</li> <li>● Lecture 20: Population Dynamics</li> <li>● Lecture 21: Epidemics</li> <li>● Lecture 22: Epidemics</li> <li>● Lecture 23: Epidemics</li> <li>● Lecture 24: Computational Neuroscience</li> <li>● Lecture 25: Computational Neuroscience</li> <li>● Lecture 26: Computational Neuroscience</li> <li>● Lecture 27: Computational Neuroscience</li> <li>● Lecture 28: Mathematical Modeling &amp; Simulation</li> <li>● Lecture 29: Mathematical Modeling &amp; Simulation</li> <li>● Lecture 30: Modeling Of the Human Heart</li> <li>● Lecture 31: Modeling Of the Human Heart</li> <li>● Lecture 32: Modeling Of the Human Heart</li> </ul>	1	<b>14</b>
<p>BASS XV: Cross-over Trials, Nov. 08</p> <ul style="list-style-type: none"> <li>● The Design and Analysis of Cross-over Trials</li> </ul>	1	<b>15</b>
<p>BASS XV: Fifteenth Annual Biopharmaceutical Applied Statistics Symposium</p>	1	<b>16</b>
<p>BASS XVI: Stat Symposium Nov.09</p> <ul style="list-style-type: none"> <li>● Controversial Issues in Clinical Trials</li> <li>● Dose-finding in oncology clinical trials based on unit probability mass</li> <li>● Implementing Response-Adaptive Randomization in Multi-Armed Survival Trials</li> <li>● Evaluating Probability of Success in Oncology Clinical Trials</li> <li>● Design and Analysis of a Cancer Prevention Trial: Plans and Results</li> <li>● Comparing Conditional and Predictive Power to Assess Futility in a Phase III Program with Two Studies</li> <li>● Comparing Conditional and Predictive Power to Assess Futility in a Phase III Program with Two Studies</li> <li>● Setting Alpha Levels for Testing Key Secondary Endpoints in Trials with Interim Assessments when the Primary and Secondary Endpoints are Correlated</li> <li>● Efficient Sampling of Inverse Correlation Matrices and its Applications in Bayesian Modeling of Gene Interaction in Early Phase Genomic Experiments</li> <li>● The Mean Ain't What It Used to Be</li> </ul>	1	<b>17</b>

<ul style="list-style-type: none"> <li>● Subgroup Data Analyses of Clinical Trials- Issues &amp; Methods</li> <li>● Analyses to Aid Dose Selection in Ph 2 Virology Clinical Trials Larry F. Leon</li> </ul>		
<p>BASS XVI: Stat Symposium cont. Nov. 09</p> <ul style="list-style-type: none"> <li>● Phase 2a "Power" Calculations: Comparisons with SOC</li> <li>● Statistical Graphics for Exploratory Review and Reporting in Clinical Trials</li> <li>● Statistical assessment and analyses of suicidality data in clinical trials: current challenges</li> <li>● Retrospective Look: Logistics of Implementing a Suicidality Analysis</li> <li>● Using Statistical Principles to Implement FDA Guidance on Cardiovascular Risk Assessment for Diabetes Drugs</li> <li>● Lifecycle Planning For Safety Evaluation In Support Of Benefit-Risk Activities</li> <li>● On Methodologies Associated with Meta-analysis</li> <li>● Targeted Maximum Likelihood Super Learning: Application to Causal Effects in Safety Analysis</li> <li>● Letter from Laura H. Gunn to Bass Attendees</li> <li>● Bass XVI Fellows</li> <li>● Housekeeping</li> <li>● Bass XVI Attendees</li> </ul>	1	<b>18</b>
<p>BASS XVI: Bayesian Methods, Nov. 09</p> <ul style="list-style-type: none"> <li>● Recent Developments in Practical Bayesian Methods for Clinical Trials</li> </ul>	1	<b>19</b>
<p>BASS XVI: Fundamental Training, Nov. 09</p> <ul style="list-style-type: none"> <li>● The Development and Execution of a Clinical Program</li> <li>● Design of Dose Response Clinical Trials</li> <li>● The Roles of the (Bio) Statistician in Clinical Trials</li> <li>● Data Monitoring in Clinical Trials Using Prediction</li> <li>● Data Monitoring Committees</li> <li>● Planning and Reporting Your Analyses</li> <li>● Noninferiority Trials</li> <li>● Analysis of Efficacy</li> <li>● Subgroup Analysis</li> <li>● Benefit: Risk Assessment</li> </ul>	1	<b>20</b>
<p>BASS XVI: Bioequivalence &amp; Statistics Nov. 09</p> <ul style="list-style-type: none"> <li>● Bioequivalence and Statistics in Clinical Pharmacology</li> </ul>	1	<b>21</b>
<p>BASS XVII: Genomics, Nov. 10</p> <ul style="list-style-type: none"> <li>● Introduction to Design of Genomic Clinical Trials</li> <li>● Targeted (Enrichment) Design</li> </ul>	1	<b>22</b>

<p>BASS XVII: Tutorials, Nov. 10</p> <ul style="list-style-type: none"> <li>● Multiplicity problems in clinical trials A regulatory perspective</li> <li>● A Process View of Statistics for Clinical Trials: ANOVA, Product-Limit, and Adaptive Design</li> <li>● Covariate-Adjusted Response-Adaptive Randomization Designs for Phase III Survival Trials</li> <li>● Sample Size Re-estimation Using Adaptive Tests and Generalized Likelihood Ratio: A Comparative Study</li> <li>● Failure-Time Mixture Models for Analyzing Time to Response</li> <li>● Statistical Considerations in Multi-Regional Clinical Trials</li> <li>● Enrollment and Event Projection in Oncology Trials</li> <li>● Implementing the Continuous Reassessment Method (CRM) in a Phase I Oncology Trial</li> <li>● Scaled Average Bioequivalence: An Approach to Resolve A Difficult Program</li> <li>● Design of Non-inferiority Trials-Problems, Current Approaches and Applications of Inferiority Index</li> <li>● Methodological Considerations in Comparative Effectiveness Research</li> <li>● Estimation Issues for High Throughput Data</li> <li>● Multiple Testing in a Partitioning framework</li> <li>● Recent Development in Addressing Multiplicity Issues In Clinical Trials</li> <li>● Decomposition of a Composite Endpoint for Assessing Treatment Benefits for its Components</li> </ul>	1	<b>23</b>
<p>BASS XVII: Koch &amp; Stocks, Nov. 10</p> <ul style="list-style-type: none"> <li>● Categorical Data Analysis Using SAS</li> <li>● Quantal Bioassay Analysis</li> <li>● The 2 x 2 Table</li> <li>● The Final Session: Recent Topics in Categorical Data Analysis</li> <li>● Biomarker Adaptive Threshold Design</li> <li>● Development and Validation of Predictive Classifiers using High Dimensional Data</li> <li>● Proportional Odds and Generalized Logits Models</li> <li>● Weighted Least Squares for Mean Scores</li> <li>● Sets of 2 x r and s x 2 Tables</li> <li>● Poisson Regression</li> <li>● Generalized Estimating Equations</li> </ul>	1	<b>24</b>

**Box 2: 0200105948737**

<b><u>Clinical Trials</u></b>	<b><u>Box Number</u></b>	<b><u>Folder Number</u></b>
Clinical trials methodology (graduate course)	2	<b>1</b>
Clinical trials methodology (graduate course) continued	2	<b>2</b>
Clinical trials methodology <ul style="list-style-type: none"> <li>● Intro to methodology papers</li> <li>● Analysis of Ratios and Decision Rules in Bioequivalence Studies</li> <li>● Bioavailability and Bioequivalence of Pharmaceutical Formulations</li> <li>● Design and Analysis of Pivotal Trials to Assess Efficacy of Drugs to Treat Panic</li> <li>● Tagamet: Repairing Ulcers Without Surgery (excerpt)</li> <li>● Analysis of Ratios and Decision Rules in Bioequivalence Studies</li> <li>● Clinical Trials in the Prevention of NSAID Induced Gastric Ulceration</li> <li>● Biostatistical Aspects of the Development of H2-Receptor Antagonist Drugs to Treat Duodenal Ulcers</li> <li>● A Single Nocturnal Dose of Cimetidine in Active Duodenal Ulcer</li> <li>● Cimetidine Single-Dose Active Duodenal Ulcer Trial</li> <li>● Effects of Two Cimetidine Dosage Regimens on Serum Theophylline Levels</li> <li>● Efficacy of a Single Nocturnal Dose of Cimetidine in Active Duodenal Ulcer</li> </ul>	2	<b>3</b>
Folder 4: Clinical trials methodology continued <ul style="list-style-type: none"> <li>● Biostatistical Aspects of the Development of Anti-Anginal Drugs: a Phase II Trial Incorporating an Equiradial Hexagonal Design with RSM</li> <li>● The Importance of Numbers (of Patients) in Clinical Trials</li> <li>● The Pooling of Data from Multicentre Clinical Trials</li> <li>● Nonsequential Analysis of Time to Event Data</li> <li>● Additional Examples of Time-To-Event Analyses</li> <li>● Design Aspects of Cancer Clinical Trials</li> <li>● FDA Requirements for Approval of New Drugs</li> <li>● Guidelines for the Clinical Evaluation of Antineoplastic Drugs, February 1981</li> </ul>	2	<b>4</b>
Clinical trials methodology (Grad course for MPH Biostat)	2	<b>5</b>
Clinical trials methodology (Grad course for MPH Biostat) continued	2	<b>6</b>

<ul style="list-style-type: none"> <li>• Statistical Principles for Clinical Trials</li> <li>• Guideline for Good Clinical Practice</li> <li>• Choice of Control Group and Related Issue in Clinical Trials</li> <li>• Principles for Clinical Evaluation of New Antihypertensive Drugs</li> <li>• FDA Organization Charts</li> <li>• ICH Press Reports, 1997-2000</li> <li>• User Fee Correspondence from the FDA, 1997</li> <li>• Federal Register, 1999</li> </ul>		
Clinical trials & Biostatistics	2	<b>7</b>
Biostatistical aspects of clinical research programs	2	<b>8</b>
Cancer clinical investigation review committee, Apr. 1978 <ul style="list-style-type: none"> <li>• Bayesian Approach to Design of Clinical Trials</li> </ul>	2	<b>9</b>
Clinical trials talk at Duke, 03/26/2008 <ul style="list-style-type: none"> <li>• Interesting Pharmaceutical Clinical Trial Applications</li> </ul>	2	<b>10</b>
Interval-censoring in Biopharmaceutical clinical trials, 07/14/2010 <ul style="list-style-type: none"> <li>• Interval-Censoring in Biomedical and Biopharmaceutical Clinical Trials Presentation</li> <li>• Interval-Censoring in Biomedical and Biopharmaceutical Clinical Trials Journal Article</li> </ul>	2	<b>11</b>
Education of clinical trial statisticians <ul style="list-style-type: none"> <li>• The Education of Clinical Trial Statisticians: Do we need to change with the time? Presentation</li> <li>• DIA program, 1991</li> <li>• Scott Evans Email, 2008</li> <li>• Scott Evans Email, 2007</li> <li>• Title page of the program for The Education of Clinical Trial Statisticians</li> <li>• Some Comments on the Biopharmaceutical Section and Statistics, 1989</li> <li>• The Future of the Education of Clinical Trial Statisticians: What Changes are Needed?</li> <li>• XXIVth International Biometric Conference sheet</li> </ul>	2	<b>12</b>
Clinical trial protocol	2	<b>13</b>
Workshop on clinical trials <ul style="list-style-type: none"> <li>• Statistical Aspects of Clinical Drug Development</li> </ul>	2	<b>14</b>
Clinical trial workshop S.K.& F.	2	<b>15</b>

<ul style="list-style-type: none"> <li>Smith Kline and French In House Biostatistical Educational Program; A Two Day Session on the Clinical Trials Workshop and Seminar Series; Presentation 1983</li> </ul>		
Workshop on clinical trials, Dec. 8-9, 1983	2	<b>16</b>
Introduction to S.K.& F. clinical trials <ul style="list-style-type: none"> <li>Papers and microfiche</li> </ul>	2	<b>17</b>
RAPS 1992 <ul style="list-style-type: none"> <li>Sample Size Considerations in Clinical Trials Premarket Approval, 1992</li> </ul>	2	<b>18</b>
Clinical trial transparencies	2	<b>19</b>
Multicenter trials	2	<b>20</b>
Numbers of patients in clinical trials	2	<b>21</b>
S.K.& F. protocol (transparencies)	2	<b>22</b>
Statistics & clinical trials	2	<b>23</b>
Miscellaneous	2	<b>24</b>

**Box 3: 0200105948745**

<b>Transparencies</b>	<b><u>Box Number</u></b>	<b><u>Folder Number</u></b>
Design Aspects of Cancer Clinical Trials	<b>3</b>	<b>1</b>
Bioavailability & Bioequivalence	<b>3</b>	<b>2</b>
Nonsequential Analysis of Time to Event Data	<b>3</b>	<b>3</b>
Sequential Methods	<b>3</b>	<b>4</b>
Sequential Methods continued	<b>3</b>	<b>5</b>
Biostatistical Aspects of Clinical Drug Development <ul style="list-style-type: none"> <li>Includes microfiche</li> </ul>	<b>3</b>	<b>6</b>
Statistics Issues Course handouts <ul style="list-style-type: none"> <li>The Importance of Numbers (of Patients) in Cancer Clinical Trials</li> </ul>	<b>3</b>	<b>7</b>



<ul style="list-style-type: none"> <li>• Additional Examples of Time-To-Event Analyses</li> </ul>		
Statistical Issues Course continued (Photocopied Transparencies) <ul style="list-style-type: none"> <li>• Active Control Equivalence Studies</li> <li>• Dosing in the Elderly</li> <li>• The Pooling of Data from Multi-Centre Clinical Trials</li> <li>• Design, Monitoring, and Analysis Issue Relative to Adverse Events</li> <li>• Summarization, Analysis, and Monitoring of Adverse Experiences, REFERENCES/Chapter 2</li> <li>• Two Treatment Crossover Designs References/Chapter 3</li> <li>• Active Control Equivalence Studies REFERENCES/Chapter 4</li> <li>• Optimization in Clinical Trials and Combination Drug Development References/Chapter 5</li> <li>• Meta-Analyses in Ulcer Disease</li> <li>• An Evaluation of Triprolidine and Pseudoephedrine in the Treatment of Allergic Rhinitis</li> <li>• Summarization, Analysis, and Monitoring of Adverse Experiences, REFERENCES/Chapter 2</li> </ul>	<b>3</b>	<b>8</b>
Graduate course in Biostatistics for Medical Personnel <ul style="list-style-type: none"> <li>• Clinical Trials Methodology (name of Biostatistics course)</li> </ul>	<b>3</b>	<b>9</b>
Canda Guidance Manual 2 nd Edition, October 1994 <ul style="list-style-type: none"> <li>• FDA Organization Charts</li> <li>• Canda Manual</li> <li>• FDA Organization Charts</li> </ul>	<b>3</b>	<b>10</b>
The Assessment of Drug Safety, 05/10/1988	<b>3</b>	<b>11</b>
Monitoring Adverse Experiences in Clinical Drug Development	<b>3</b>	<b>12</b>

**Box 4: 0200105948752**

Courses	<b><u>Box Number</u></b>	<b><u>Folder Number</u></b>
Institute for Professional Education, 1989-1990	4	1
Courses: Drug Information Association, 1989 <ul style="list-style-type: none"> <li>• Correspondence</li> </ul>	4	2
Courses: Beaumont Hospital, 1989 <ul style="list-style-type: none"> <li>• Correspondence</li> </ul>	4	3

Courses: Statistical Aspects of Clinical Research Programs	4	4
<p>Short Course on Analysis of Cancer Clinical Trials</p> <ul style="list-style-type: none"> <li>• Nonsequential Analysis of Time to Event Data</li> <li>• Additional Examples of Time-To-Event Analyses</li> <li>• <b>INCLUDES A Short Course on the Design of Cancer Clinical Trials</b></li> <li>• Design Aspects of Cancer Clinical Trials</li> <li>• Guidelines for the Clinical Evaluation of Antineoplastic Drugs</li> </ul>	4	5
<p>Short Course on Analysis of Cancer Clinical Trials continued</p> <ul style="list-style-type: none"> <li>• Design Aspects of Cancer Clinical Trials</li> <li>• Nonsequential Analysis of Time to Event Data</li> <li>• The Importance of Numbers (of Patients) in Cancer Clinical Trials</li> </ul>	4	6
<p>Guide for Biostatistical clinical trials methodology course</p> <ul style="list-style-type: none"> <li>• Course Overview</li> <li>• Biostatistical Aspects of the Development of Drugs to Treat Alzheimer's Disease based upon 'Enrichment Designs'</li> </ul>	4	7
Binder of an Overview of the Regulation of Pharmaceuticals presentation I	4	Binder
Binder of an Overview of the Process of Discovery, Basic Research, Clinical Development & Manufacturing in Pharmaceutical Development presentation II	4	Binder
Binder of Biostatistical Aspects of Clinical Drug Development presentation III	4	Binder
Binder of Bioavailability and Bioequivalence of Pharmaceutical Formulations presentation IV-a	4	Binder
Binder of Analysis of Ratios and Decision Rules in Bioequivalence Studies presentation IV-b	4	Binder
Binder of The Design and Analysis of Pivotal Clinical Trials to Assess the Efficacy of Drugs to Treat Panic Disorder presentation V	4	Binder
Binder of Clinical Trials in the Prevention of NSAID Induced Gastric Ulceration presentation VI	4	Binder
Binder of Biostatistical Aspects of the Development of H-2 Receptor Antagonist Drugs in the Treatment of Duodenal Ulcer	4	Binder

presentation VII		
Binder of Biostatistical Aspects of the Development of Anti-Anginal Drugs: a Phase II Clinical Trial Incorporating an Equiradial Hexagonal Design with Response Surface Methodology presentation VIII	4	Binder
Binder of The Importance of Numbers (of Patients) in Cancer Clinical Trials presentation IX	4	Binder
Binder of Biostatistical Aspects of the Design of Cancer Clinical Trials presentation X	4	Binder
Binder of Biostatistical Aspects of the Analysis and Interpretation of Cancer Clinical Trials presentation XI	4	Binder
Binder of Monitoring Adverse Experiences in Clinical Drug Development presentation XII	4	Binder
Binder of The Pooling of Data from Multicentre Clinical Trials presentation XIII	4	Binder
Binder of Interim Analyses: p-Value and Power Computations in Multiple Look Trials presentation XIV	4	Binder
Binder of Biostatistical Aspects of Development of Drugs to Treat Alzheimer's Disease Based Upon Enrichment Designs presentation XV	4	Binder
J & J Course, 1990 (Johnson & Johnson)	4	8
Lectures (Oncology studies) <ul style="list-style-type: none"> <li>● Statistical Input into the Design, Analysis and Interpretation of Oncology Studies</li> <li>● Nonsequential Analysis of Time to Event Data</li> <li>● Additional Examples of Time-To-Event Analyses</li> <li>● Non-sequential Analysis of Time To Event Data</li> <li>● Survival Analysis Articles x5</li> <li>● Analysis of Survival Data Articles x4</li> <li>● Multivariate Survival Analysis Articles and Articles on Competing Risks</li> </ul>	4	9
Lectures (Oncology studies) continued <ul style="list-style-type: none"> <li>● Design Aspects of Cancer Clinical Trials</li> <li>● Connection Between the Mantel-Haenszel and Cox Procedures for the Two Sample Case, 1979</li> <li>● A Parametric Model with Covariates or Cox's Procedure? 1984</li> </ul>	4	10

Clinical trials & Biostatistics lecture <ul style="list-style-type: none"> <li>• Thank You Card</li> <li>• Clinical Trials and Biostatistics presentation</li> <li>• Real Problems Call for Statistical Solutions presentation</li> </ul>	4	11
Biostatistical aspects of development of drugs lecture <ul style="list-style-type: none"> <li>• Biostatistical Aspects of Development of Drugs to Treat Alzheimer's Disease Based Upon Enrichment Designs</li> </ul>	4	12
Prevention of NSAID lecture <ul style="list-style-type: none"> <li>• Clinical Trials in the Prevention of NSAID Induced Gastric Ulceration</li> </ul>	4	13
Interesting Applications from Three Decades of Biostatistic Consulting lecture	4	14

**Box 5: 0200105948760**

Case Studies	<b>Box Number</b>	<b>Folder Number</b>
Matched pair design in controlling confounding factors in spontaneous duodenal ulcer relapse, 1987	5	1
Study design for the assessment of misoprostol in the treatment & prophylaxis of NSAID induced peptic ulcer, 1987	5	2
A blind endoscopic comparative study of misoprostol vs. sucralfate & placebo in the prevention of aspirin-induced gastric & duodenal ulceration, 1987	5	3
A blind endoscopic comparative study of misoprostol vs. sucralfate & placebo in the prevention of aspirin-induced gastric & duodenal ulceration (continued), 1987	5	4
Duodenal ulcer- what comes after healing? 1987	5	5
Prevention of gastric ulceration upon reinstating NSAID therapy in Osteo-Arthritic patients, 1987-1988 <ul style="list-style-type: none"> <li>• Meta-analysis of Duodenal Ulcer Relapses Using Actual Patient Data: A Comparison of the Effect of Acute Treatment with Cimetidine, Misoprostol and Placebo</li> </ul>	5	6
NEJM manuscript, 1985-1986 <ul style="list-style-type: none"> <li>• Acid Suppression – How Much and When for Acute Duodenal Ulcer Healing?</li> <li>• Nocturnal Cimetidine Therapy to Treat Duodenal Ulcers;</li> </ul>	5	7

<p>a Dose Response Study</p> <ul style="list-style-type: none"> <li>• One Article by John Romankiewicz</li> <li>• Effectiveness of Cimetidine in Doses of 400 mg, 800 mg and 1600 mg Given at Bedtime for the Acute Treatment of Duodenal Ulcers</li> </ul>		
<p>Maxzide clinical manuscript 11/1987</p> <ul style="list-style-type: none"> <li>• Comparative Bioavailability of Two Pharmaceutical Formulations Containing Hydrochlorothiazide and Triamterene</li> <li>• Influence of Tablet Dissolution on Furosemide Bioavailability: A Bioequivalence Study by McNamara, Foster, Digenis, Patel, Craig, Welling, Rapaka, Prasad, and Shah</li> </ul>	5	8
<p>A double-blind crossover comparison of equal daily doses, 1987</p> <ul style="list-style-type: none"> <li>• Two Abstracts for the American College of Cardiology</li> <li>• Comparison of Equivalent Oral Doses of Verapamil and Diltiazem in Patients with Mild to Moderate Hypertension</li> <li>• A Double Blind Crossover Comparison of Equivalent Doses of Oral Verapamil and Diltiazem in Patients with Mild to Moderate Hypertension</li> </ul>	5	9
<p>Betaxolol Vs. Atenolol serum level Fluetuatron study, 1987-1988</p> <ul style="list-style-type: none"> <li>• Comparison of Steady State Plasma Profiles of Betaxolol and Atenolol</li> <li>• Betaxolol/Atenolol Studies</li> <li>• Preliminary Studies</li> <li>• The Steady State Plasma Profile of Betaxolol as Compared to Atenolol</li> </ul>	5	10
<p>Bioequivalency of controlled release &amp; sustained release formulations of verapamil HCL following multiple dosing in normal healthy male volunteers, 1987</p> <ul style="list-style-type: none"> <li>• Comparative Steady State Bioavailability of Conventional and Controlled- Release Formulations of Albuterol by Powell, Weisberger, Dowdy, Gural, Symchowicz, and Patrick (1987)</li> </ul>	5	11
<p>Estimation of survival parameters</p>	5	12
<p>Some results in the estimation of survival parameters</p>	5	13
<p>A brief review of correlation, 10/1976</p>	5	14
<p>Statistical report of Searle protocol, 1988</p>	5	15

<ul style="list-style-type: none"> <li>● Abstract to the American College of Cardiology: Variability of Left Ventricular Mass Measurements by Ultrafast Computed Tomography</li> <li>● Abstract to the American College of Cardiology: Measurement of Myocardial Blood Flow After Transdermal Nitroglycerin by Ultrafast Computed Tomography</li> </ul>		
<p>Sequential analysis book visuals, 04/1986</p> <ul style="list-style-type: none"> <li>● P-Value and Power Computation in Multiple Look Trials transparency</li> <li>● Mathematical Statistics by Thomas Ferguson</li> <li>● Sequential Tests of Hypotheses for the Reliability of a 2-Parameter Weibull System by Harter, Moore, and Wiegand</li> <li>● Notes</li> <li>● Correspondence</li> <li>● Effect of Antilyphocyte-Globulin Potency on Survival of Cadaver Renal Transplants, 1977</li> <li>● Performing a Survival Analysis Instead of an Endpoint Analysis</li> <li>● The Design of a Sequential Clinical Trial for the Comparison of Two Lung Cancer Treatments by Jones, Newman, and Whitehead (1982)</li> <li>● Sequential Analysis of Survival Data in Clinical Trials by Gordon Lan (1984; handwritten)</li> <li>● Discrete Sequential Boundaries for Clinical Trials by Lan and DeMets (1983)</li> <li>● More Flexible Sequential and Non-Sequential Designs in Long-Term Clinical Trials by Lan, DeMets, and Halperin</li> <li>● Temple University program for Gordon Lan's Sequential Analysis of Survival Data in Clinical Trials</li> <li>● Exact Confidence Intervals Following a Group Sequential Test by Tsiatis, Rosner, and Mehta (1983)</li> </ul>	5	16
<p>Sequential analysis book visuals continued</p> <ul style="list-style-type: none"> <li>● Notes</li> <li>● A Generalized Wilcoxon Test for Comparing Arbitrarily Singly-Censored Samples by Edmund Gehan (1965)</li> <li>● 'Lecture 6' Notes</li> <li>● Evaluation of Survival Data and Two New Rank Order Statistics Arising in its Consideration by Nathaniel Mantel (1966)</li> <li>● Evaluation of Response-Time Data Involving Transient States: An Illustration Using Heart-Transplant Data by Mantel and Byar (1974)</li> <li>● The Effect of 6-Mercaptopurine on the Duration of</li> </ul>	5	17

<p>Steroid-induced Remissions in Acute Leukemia: A Model for Evaluation of Other Potentially Useful Therapy by Freireich, Gehan, Frei, Schroeder, Wolman, et al.</p> <ul style="list-style-type: none"> <li>• Notes</li> </ul>		
Exposure analysis of Dichotomous response measures in long-term studies, 1993	5	18
Summary of BRCl analyses of ADAS-Cog & CGIC from protocols CI-970-01, 04, and 06; 11/1992	5	19
<p>Ulcer papers, 80's &amp; one 2011</p> <ul style="list-style-type: none"> <li>• Meta-Analyses in Ulcer Disease</li> <li>• Effects of Two Cimetidine Dosage Regimens on Serum Theophylline Levels by Seaman, Randolph, Peace, Frank, Dickson, Putterman, and Young (1985)</li> <li>• The Treatment of Gastric Ulcer with Antisecretory Drugs: Relationship of Pharmacological Effect to Healing Rates by Howden, Jones, Peace, Burget, and Hunt (1988)</li> <li>• Case Study in Optimal Dosing in Duodenal Ulcer</li> <li>• Info on the 'Peptic Ulcer Disease' book</li> <li>• Early Termination of Two Trials of Misoprostol in the Prevention of NSAID- Induced Gastric Ulceration (1992)</li> <li>• Efficacy of a Single Nocturnal Dose of Cimetidine in Active Duodenal Ulcer by Valenzuela, Dickson, Dixon, Peace, Putterman, and Young (1985)</li> <li>• A Single Nocturnal Dose of Cimetidine in Active Duodenal Ulcer by Peace, Dickson, Dixon, Putterman, and Young (1985)</li> <li>• Cimetidine Single-Dose Active Duodenal Ulcer Trial by Dickson, Dixon, Peace, Putterman, and Young (1985)</li> <li>• Determining the Optimal Dosage Regimen for H<sub>2</sub>-Receptor Antagonist Therapy – a dose validation approach by Young, Frank, Dickson, Peace, Braverman, and Mounce (1989)</li> <li>• Slideshow presentation on Cimetidine and Duodenal Ulcers</li> <li>• Notes</li> </ul>	5	20
A brief review of correlation, 1/77	5	21
Time to event data, 1988-2006	5	22
Prediction probabilities in stability studies, 11/83	5	23
Monitoring & analysis issues relative to adverse events, 1985-1987	5	24

Appendix g. Methodology for the computation of partial areas under the Nar time curves	5	25
Size & power assessments of tests of hypotheses on survival parameters, 1978-1980	5	26
Second revision of size & power assessments of tests of hypotheses on survival parameters, 1977-1978 <ul style="list-style-type: none"> <li>Size and Power Assessments of Tests of Hypotheses on Survival Parameters by Peace and Flora (1977 &amp; 1978 printed copy)</li> </ul>	5	27
Efficiency assessments of tests of hypotheses on survival parameters, 1976-1977	5	28

**Box 6: 0200105948778**

<b>Manuscripts</b>	<b><u>Box Number</u></b>	<b><u>Folder Number</u></b>
Size & power assessments of tests of hypotheses on survival parameters	<b>6</b>	<b>1</b>
Exposure analysis of Dichotomous data <ul style="list-style-type: none"> <li>Exposure Analysis of Dichotomous Data draft and transparencies</li> <li>On the Analysis of a Combination of Two Primary Efficacy Measures</li> </ul>	<b>6</b>	<b>2</b>
Estimating the probability of the superiority of one treatment to another, 8/9/85	<b>6</b>	<b>3</b>
A brief review of correlation, 11/19/76 <ul style="list-style-type: none"> <li>Includes transparencies</li> </ul>	<b>6</b>	<b>4</b>
Connection between the Mantel-Haenszel & Cox procedures for the two sample case, 12/17/79	<b>6</b>	<b>5</b>
Some results in the estimation of survival parameters, 4/30/76	<b>6</b>	<b>6</b>
Proceedings of the National Academy of Sciences (PNAS) miscellaneous, 1992 <ul style="list-style-type: none"> <li>Methodological Aspects of a Population Pharmacodynamic Model for Cognitive Effects in Alzheimer Patients Treated with Tacrine by Holford and Peace (1992)</li> <li>Results and Validation of a Population Pharmacodynamic Model for Cognitive Effects in Alzheimer Patients Treated</li> </ul>	<b>6</b>	<b>7</b>



<ul style="list-style-type: none"> <li>with Tacrine by Holford and Peace (1992)</li> <li>• A Double-Blind, Placebo-Controlled Multicenter Study of Tacrine for Alzheimer's Disease by Davis, Thal, Gamzu, Davis, Woolson, Gracon, et al.</li> <li>• Controlled Trial of Tacrine by Farlow et al</li> </ul>		
<p>Proceedings of the National Academy of Sciences (PNAS) miscellaneous continued, 1992</p> <ul style="list-style-type: none"> <li>• A Controlled Trial of Tacrine in Alzheimer's Disease by Farlow, Gracon, Hershey, Lewis, Sadowsky, and Dolan-Ureno (1992)</li> <li>• Methodological Aspects of a Population Pharmacodynamic Model for Cognitive Effects in Alzheimer Patients Treated with Tacrine by Holford and Peace (1992)</li> <li>• Results and Validation of a Population Pharmacodynamic Model for Cognitive Effects in Alzheimer Patients Treated with Tacrine by Holford and Peace (1992)</li> </ul>	<b>6</b>	<b>8</b>
<p>Final Proceedings of the National Academy of Sciences (PNAS) manuscripts, 1992</p> <ul style="list-style-type: none"> <li>• Methodological Aspects of a Population Pharmacodynamic Model for Cognitive Effects in Alzheimer Patients Treated with Tacrine by Holford and Peace <ul style="list-style-type: none"> <li>◦ Draft of this article too</li> </ul> </li> <li>• Results and Validation of a Population Pharmacodynamic Model for Cognitive Effects in Alzheimer Patients Treated with Tacrine by Holford and Peace <ul style="list-style-type: none"> <li>◦ Draft of this article too</li> </ul> </li> </ul>	<b>6</b>	<b>9</b>
<p>Proceedings of the National Academy of Sciences (PNAS) manuscripts: reviewer/revisions, 1992</p> <ul style="list-style-type: none"> <li>• Tacrine in Alzheimer's Disease: A Population Pharmacodynamic Model for Cognitive Effects parts I and II <ul style="list-style-type: none"> <li>◦ Includes a set of drafts</li> </ul> </li> </ul>	<b>6</b>	<b>10</b>
<p>Proceedings of the National Academy of Sciences (PNAS) manuscripts: reviewer/revisions continued, 6/29/92</p> <ul style="list-style-type: none"> <li>• Tacrine in Alzheimer's Disease: A Population Pharmacodynamic Model for Cognitive Effects parts I and II Drafts</li> </ul>	<b>6</b>	<b>11</b>
<p>Determining type I &amp; type II errors in multiple trials, 1980</p> <ul style="list-style-type: none"> <li>• Size of the Type I Error at which to Conduct an Interim Analysis in Order that the Results of the Interim and Final Analyses are Significant, 1980</li> </ul>	<b>6</b>	<b>12</b>
<p>Letters to the editor</p>	<b>6</b>	<b>13</b>

Letters to the editor: NEJM (New England Journal of Medicine), 1984	<b>6</b>	<b>14</b>
Letters to the editor: Lancet, 11/10/84	<b>6</b>	<b>15</b>
Letters to the editor: journal of chronic diseases, 1987	<b>6</b>	<b>16</b>
JBS subgroup paper, 2009-2010 <ul style="list-style-type: none"> <li>• Analysis of Subgroup Data of Clinical Trials by Tsai and Peace</li> </ul>	<b>6</b>	<b>17</b>
Duodenal ulcers paper, 1/2010 <ul style="list-style-type: none"> <li>• Clinically Optimal Dosing in the Treatment of Duodenal Ulcers: A Case Study of a Phase III SNDA Clinical Program</li> </ul>	<b>6</b>	<b>18</b>
DIA sample size, 11/19/91 <ul style="list-style-type: none"> <li>• Sample Size Considerations in Clinical Trials Premarket Approval</li> </ul>	<b>6</b>	<b>19</b>
Manuscripts with Kao-Tai Tsai, 2005 <ul style="list-style-type: none"> <li>• Multivariate Dose Response Test by Kao-Tai Tsai and Karl Peace</li> </ul>	<b>6</b>	<b>20</b>
Multivariate dose response JMS; Peace & Tsai, 2007 <ul style="list-style-type: none"> <li>• o Multivariate Dose Response Test by Kao-Tai Tsai and Karl PeaceIncludes Drafts and a powerpoint</li> <li>• Correspondence</li> <li>• Nonparametric Two-Sample Comparisons of Changes on Ordinal Responses by Bajorski and Petkau (1999)</li> </ul>	<b>6</b>	<b>21</b>
A brief introduction to survival curve estimation, 10/31/75	<b>6</b>	<b>22</b>
Some results in the estimation of survival parameters, 4/30/76	<b>6</b>	<b>23</b>
Estimation & tests of hypotheses on survival parameters, 5/17/79	<b>6</b>	<b>24</b>
A brief review of correlation	<b>6</b>	<b>25</b>
Bivariate plot paper JBS, 2008-2009 <ul style="list-style-type: none"> <li>• Bivariate or Composite Plots of Endpoints by Peace and Tsai</li> <li>• Bivariate or Composite Plots of Primary Endpoints by Peace and Tsai</li> </ul>	<b>6</b>	<b>27</b>
Multivariate dose response test, 2008-2009 <ul style="list-style-type: none"> <li>• Multivariate Dose Response Test by Tsai and Peace Various versions</li> <li>• Article comments from reviewers</li> <li>• The Fibroblast Growth Factor Receptor Gene Arg 388 Allele</li> </ul>	<b>6</b>	<b>28</b>

<p>is not Associated with Early Lymph Node Metastasis of Breast Cancer by Becker, Nieters, and Chang-Claude (2003)</p> <ul style="list-style-type: none"> <li>• Analysis of Dose-Response Relationships on Complex Survey Data by Judkins, Zador, and Nadimpalli (2002)</li> </ul>		
<p>The use of response surface methodology in the development of antianginal drugs (handout), 5/29/86</p>	<b>6</b>	<b>29</b>
<p>Lipid manuscripts: HHS I: exposure analysis, 11/23/91</p> <ul style="list-style-type: none"> <li>• Statistical Analysis Methods for Providing Inferences between Primary Response Measures and Exposure to Study Medication in the Helsinki Heart Study: Double Blind and Open Label Periods by Peace and Haber (1991)</li> </ul>	<b>6</b>	<b>30</b>
<p>Lipid manuscripts: HHS II: exposure analysis, 1991-1992</p> <ul style="list-style-type: none"> <li>• Exposure Analysis of Dichotomous Response Measures in Long Term Studies, 1992</li> <li>• Statistical Analysis Methods for Providing Inferences Between Primary Response Measures and Exposure to Study Medication in Long Term Studies</li> <li>• Drafts, Revisions, and Reviews</li> <li>• Compliance as an Explanatory Variable in Clinical Trials by Efron and Feldman (1991)</li> <li>• Exposure Analysis of Dichotomous Response Measures in Long-Term Studies by Peace and Carter Jr. (1992)</li> </ul>	<b>6</b>	<b>31</b>
<p>Lipid manuscripts: Zweig &amp; Urquhart, 92-93</p> <ul style="list-style-type: none"> <li>• Correspondences</li> <li>• Xerox Telecopied Compliance as an Explanatory Variable in Clinical Trials by Efron and Feldman (1991)</li> <li>• Medication Compliance and Serum Lipid Changes in the Helsinki Heart Study by Maenpaa, Heinonen, and Manninen (1991)</li> </ul>	<b>6</b>	<b>32</b>
<p>Life time learning publications, 1/10/83</p>	<b>6</b>	<b>33</b>
<p>Miscellaneous papers from Biopharmaceutical research consultants, INC.</p> <ul style="list-style-type: none"> <li>• Biostatistical Aspects of the Development of Anti-anginal Drugs: a Phase II Trial Incorporating an Equiradial Hexagonal Design with RSM notes</li> <li>• Design and Analysis of Pivotal Trials to Assess Efficacy of Drugs to Treat Panic notes</li> <li>• Biostatistical Aspects of the Development of Drugs to Treat Alzheimer's Disease based upon 'Enrichment Designs'</li> <li>• Monitoring Adverse Experiences in Clinical Drug Development</li> </ul>	<b>6</b>	<b>34</b>

Miscellaneous papers from Biopharmaceutical research consultants, INC. continued <ul style="list-style-type: none"> <li>Monitoring Adverse Experiences in Clinical Drug Development</li> <li>Bioavailability and Bioequivalence of Pharmaceutical Formulations</li> <li>Analysis of Ratios and Decision Rules in Bioequivalence Studies</li> <li>Biostatistical Aspects of the Development of H2-Receptor Antagonist Drugs to Treat Duodenal Ulcers</li> </ul>	6	35
SJS (Steven Johnson Syndrom) research, 2004 <ul style="list-style-type: none"> <li>(Re)Assessing the Co-Administration of Steroids and Antibiotics in the Management of Patients with Metastatic Brain Cancer research proposal</li> <li>Correspondence</li> <li>Notes</li> <li>Intention-to-Treat Analysis and Accounting for Missing Data in Orthopaedic Randomized Clinical Trials by Herman, Botser, Tenenbaum, and Chechick (2010)</li> </ul>	6	36
Drug information journal: articles, 87 & 93 <ul style="list-style-type: none"> <li>Design, Monitoring, and Analysis Issues Relative to Adverse Events, 1987</li> <li>Discussion for Interim Analysis and Sample Size Reestimation, 1993</li> </ul>	6	37
Analysis of efficacy data on IBS patients, 6/9/81 <ul style="list-style-type: none"> <li>Analysis of Efficacy Data on IBS Patients, in AHR Study 4523/03, Who Presented at Entry With Both Day Pain and Night Pain; Patients Who Did Not Complete Study Are Carried Through With the Rating at Time of Dropout Assigned to Post-Dropout Visits. Supplement 2 to "Statistical Report of the Multi-Investigator Study of Donnatal, Belladonna Alkaloids, Phenobarbital and Placebo, at a Dosage of 3-8 Tablets for Four Weeks, in Patients With Irritable Bowel Syndrome</li> </ul>	6	38

**Box 7: 0200105948786**

	<u>Box Number</u>	<u>Folder Number</u>
To The Editor: Giles Robertson, 1975 <ul style="list-style-type: none"> <li>Math notes</li> <li>The Hypocalcemia of Acute Pancreatitis</li> </ul>	7	1

<ul style="list-style-type: none"> <li>• Giles Robertson</li> <li>• To the Editor</li> </ul>		
Chapter 3: Section 1-3 deleted <ul style="list-style-type: none"> <li>• 3.1.1.1.2 : The Weibull Density</li> </ul>	7	2
Note concerning Fishers Method for Combining P-values <ul style="list-style-type: none"> <li>• Notes</li> </ul>	7	3
Letter about Journals 10/1/82 <ul style="list-style-type: none"> <li>• Notes</li> </ul>	7	4
Analysis & interpretation of log transformed DATA 8/15/85 <ul style="list-style-type: none"> <li>• On The Analysis and Interpretation of log Transformed DATA</li> <li>• Background</li> <li>• Theory and Methods</li> <li>• Simulation</li> <li>• Results</li> <li>• Discussion</li> <li>• Strategy</li> </ul>	7	5
Hale's Problem 2/05/79 <ul style="list-style-type: none"> <li>• Math Notes</li> <li>• The Teacher's Corner</li> <li>• Designs for Estimating Variance Components</li> <li>• Introduction</li> <li>• Variances of Estimated Variance Components for a Three Stage Nested Classification</li> <li>• Optimal Designs for Estimating Parameters for a Three Stage Nested Classification</li> <li>• Some Aspects of the Simultaneous Estimation of Variance Components For a Three Stage Nested Classification</li> </ul>	7	6
Goodness of Fit Test for Survival Models 10/3/79 <ul style="list-style-type: none"> <li>• Goodness of Fit Test For Failure Time Models utilizing covariates</li> <li>• Goodness of Fit Test For Model</li> <li>• Comparing Observed Life Table Data with a Known Survival Curve in the Presence of Random Censorship</li> <li>• Math notes</li> <li>• Letter from Karl E. Peace to Dr. Carol Redmond</li> </ul>	7	7
GCM analysis of Quantal data, 11/8/85	7	8
Folder 9: Endpoint Analysis of DATA from trial of cyclical Disease <ul style="list-style-type: none"> <li>• Endpoint Analysis of Data</li> <li>• Weighting Proportions</li> </ul>	7	9

<ul style="list-style-type: none"> <li>• Math Notes</li> </ul>		
Analysis of F & Z data, Freireich data & T.P. data, 2/3/76	7	10
Analysis of F & Z data, Freireich data & T.P. data continued, 2/3/76	7	11
Yvonne efficiency article <ul style="list-style-type: none"> <li>• Efficiency Assessments of Tests of Hypotheses on Survival Parameters</li> </ul>	7	12
RPB	7	13
Dose response problem, 10/15/91 <ul style="list-style-type: none"> <li>• Medical College of Virginia</li> </ul>	7	14
Iterative solutions of F & Z normal equations, 12/65 <ul style="list-style-type: none"> <li>• Program For The Iterative Solution Of The Normal Equations of Feigl and Zelen</li> <li>• Estimation of Exponential Survival Probabilities with Concomitant Information: Feigl and Zelen</li> </ul>	7	15
Survival curve anthology idea <ul style="list-style-type: none"> <li>• An Anthology of Survival Curve Estimation</li> <li>• Chapter 3: The Actuarial Method</li> </ul>	7	16
Contrasting linear additive model with YIJ	7	17
Parameter estimation LDIO, LDSO, etc, 1/9/85 <ul style="list-style-type: none"> <li>• Pinhole Tester (Densok)</li> </ul>	7	18
Nature of the Difference Between The Mantel-Haenszel	7	19
Parameter Estimating LD10,LD50, ETC 1/9/85 <ul style="list-style-type: none"> <li>• Northwest Orient</li> </ul>	7	20
Europa distribution related book	7	21
Guide to decision making involving human experimentation (C.K. Himmelsback), 12/30/76 <ul style="list-style-type: none"> <li>• Letter to Chif</li> <li>• Guide to Decision Making in Human Experimentation</li> </ul>	7	22
Consulting project: Giles, 9/10/75 <ul style="list-style-type: none"> <li>• The Hypocalcemia of Acute Pancreatitis</li> <li>• Letter to the Editor</li> <li>• Letter to Giles from Karl</li> <li>• Final Letter to the Editor From Karl</li> </ul>	7	23
Study proposals for generics, 1982	7	24

<ul style="list-style-type: none"> <li>• Study Proposites For Generies Existing Indications</li> <li>• Clinical Research Protocol</li> </ul>		
Design, Analysis & Interpretation of Oncology Trials 1/9/84 1. Note concerning Fishers method for combining P-values 2. Letter about journals, 10/1/82 3. Analysis & interpretation of log transformed data, 8/15/85 4. Hale's problem, 2/05/79 5. Goodness of fit test for survival models, 10/3/79 7. Endpoint analysis of data from trial of cyclical disease 8. Analysis of F & Z data, Freireich data & T.P. data, 2/3/76 9. Analysis of F & Z data, Freireich data & T.P. data continued, 2/3/76 10. Yvonne efficiency article 11. RPB 12. Dose response problem, 10/15/91 13. Iterative solutions of F & Z normal equations, 12/65 14. Survival curve anthology idea 15. Contrasting linear additive model with YIJ 16. Pinhole testing problem, 6/6/79 17. On the nature of the difference between the Mantle-Haenszel, PETO & PETO tests 18. Parameter estimation LDIO, LDSO, etc, 1/9/85 19. Europa distribution related book 20. Guide to decision making involving human experimentation (C.K. Himmelsback), 12/30/76 21. Consulting project: Giles, 9/10/75 22. Study proposals for generics, 1982 23. Design, Analysis & Interpretation of Oncology trials, 1/9/84	7	25
Mathematical Physiology ( Finite Markov chains & stochastic processes with applications), 1976	7	26
A brief introduction to survival curve estimation, 10/31/1975	7	27
Marginal likelihoods based on Cox's regression & life model, 1972	7	28
Marginal likelihoods based on Cox's regression & life model continued, 1972	7	29

**Box 8: 0200105948794**

<b>Manuscripts</b>	<b><u>Box Number</u></b>	<b><u>Folder Number</u></b>
One-sided or Two-sided? 8/16/1988	8	1

One-sided or Two-sided? Continued, 8/16/1988	8	2
Some thoughts on One-tailed tests (letter to the editor), 1988	8	3
Technometrics letter to the editor, 10/1/1980	8	4
The treatment of gastric ulcer with antisecretory drugs, 10/86	8	5
What hypothesis is being addressed in the analysis of change scores? 6/10/80	8	6
A characterization of the effect of varying sample sizes, subject to a fixed total, on detecting a difference in two means, 1/7/80	8	7
Tests of hypothesis in two by two tables, 1980	8	8
Connection between the Mantel-Haenszel & Cox procedures for the two sample case, 3/14/80	8	9
The Statistician Article: A two-treatment, two-period, crossover design permitting assessment of direct & carry-over effects, 8/23/83	8	10
P-value & power computations in multiple look trials, 1987	8	11
P-value & power computations in multiple look trials, 4/3/86	8	12
P-value & power computations in multiple look trials continued, 4/3/86	8	13
Charts P-value & power computations, 4/3/86	8	14
Design, analysis & interpretation of Oncology trials, 12/14/84	8	15
Copies of articles by K.E.P., 1988-2006	8	16
Copies of articles by K.E.P. continued, 1988-2006	8	17
Copies of articles by K.E.P. continued, 1988-2006	8	18
Statistics handouts by K.E.P.	8	19
Statistics handouts by K.E.P. continued	8	20
PSA papers ( Panic trials 06, Survival analysis instead of an end point analysis for antibiotic data 06, Statistical analysis methods for providing inferences between primary response measures 06)	8	21
ASA articles, 1989 & 2008	8	22



Copies of articles, 1979-2007	8	23
Copies of articles continued, 1979-2007	8	24

**Box 9: 0200105948802**

<b>MISC</b>	<b><u>Box Number</u></b>	<b><u>Folder Number</u></b>
Berkeley Wellness Letters	9	1
Jiann-Ping Hsu College of Public Health	9	2

**Box 10: 0200106500016**

<b>MISC</b>	<b><u>Box Number</u></b>	<b><u>Folder Number</u></b>
Loose Items	10	<b>1</b>
Car calendars- pictures from the private collection of Dr. Karl E. Peace <ul style="list-style-type: none"> <li>• 1. (white binder) <ul style="list-style-type: none"> <li>○ -Biopharmaceutical Research Consultants, Inc. Standard Operating Procedures</li> </ul> </li> </ul>	10	<b>2</b>
(black binder) <ul style="list-style-type: none"> <li>• Health Systems Plan 1979-1980 (items not in folder)</li> <li>• Speaker and Brochure Information- Optimizing Dose and Exposure-Response Studies to Reduce Drug Development Time and Expense</li> <li>• The Summer Meeting in Eugene</li> </ul>	10	<b>3</b>
1986 Munice Meetings 5/29/86 and The 1986 Midwest Biopharmaceutical Workshop	10	<b>4</b>
"Issues Concerning the Dose Comparison Trail" PMA 1983 Annual Meeting	10	<b>5</b>
APHA Meeting (7/25-27, 2010)	10	<b>6</b>
APHA Meeting – December 11, 2010	10	<b>7</b>
Inter-Sectional Council (ISC) Agenda –APHA (transparent folder)	10	<b>8</b>
APHA- Philly 11/10-11/12 2009 \	10	<b>9</b>

(loose item) <ul style="list-style-type: none"> <li>• The History of the Biopharmaceutical Section of the American Statistical Association (ASA), 1966-1988</li> </ul>		
Column for PSA Newsletter	10	<b>10</b>
PSA Column 1: Q or A? Importance of the Research Questions relative to Analyses	10	<b>11</b>
Letter to the Editor <ul style="list-style-type: none"> <li>• Is it better to have many small trials or few large trials?</li> <li>• Observations</li> <li>• Some Thoughts on Confirmatory Evidence (CE) to Support a Single Clinical Trial as a Basis for Drug Approval</li> <li>• Clinical Development Program</li> <li>• On the Need for Placebo in Combination Drug Development</li> <li>• Combination Drugs</li> <li>• Placebo is needed to Establish Efficacy in Combination Drug Development</li> <li>• Response</li> <li>• letter from Karl E. Peace to Dr. Alvan R. Reinstein Jan 22, 1990</li> <li>• letter to the Editor</li> <li>• letter from Karl E. Peace to Dr. Alvan R. Reinstein Jan 17, 1990</li> <li>• letter from Alvan R. Reinstein and Walter O. Spitzer to Karl E. Peace</li> <li>• handwritten pages – stapled</li> <li>• The Impact of Investigator Heterogeneity in clinical Trials on Detecting Treatment Differences</li> <li>• Some Comments on the Biopharmaceutical Section and Statistics</li> </ul>	10	<b>12</b>
PSA Column 2: Validity of Statistical Inferences from Medical Experiments (PSA Newsletter)	10	<b>13</b>
PSA Column 3: "Fixed Combination..."	10	<b>14</b>
PSA Column 4: "Bio statistical Aspects of NSAID and Gastric Ulcers"	10	<b>15</b>
Manuscripts for PAS <ul style="list-style-type: none"> <li>• email correspondence between Joselito C. Magadia and Karl E. Peace</li> <li>• mathematical update and clarification</li> <li>• email correspondence between Jose Ramon G. Albert and Karl Peace</li> </ul>	10	<b>16</b>
Talk to PSA	10	<b>17</b>

<ul style="list-style-type: none"> <li>● receipts including hotel bill</li> <li>● email correspondence between William I. Griffis and Karl E. Peace</li> <li>● email correspondence between Dalsay Maligalig and Karl E. Peace</li> <li>● travel agent invoice</li> <li>● email correspondence between Robert Vogel and Karl E. Peace</li> <li>● email correspondence between Jose Ramon G. Albert and Dalisay</li> </ul>		
<p>Combination GSU and UP Los Banos</p> <ul style="list-style-type: none"> <li>● email correspondence between Nancy Shumaker and Karl E. Peace</li> <li>● email correspondence between Dr. Carter and Karl E. Peace</li> <li>● background</li> </ul>		<b>18</b>
Related to PSA Newsletter	10	<b>19</b>
PS column: statistics in medical science	10	<b>20</b>
PS Column: Statistics in medical science	10	<b>21</b>
ASA Summer Meeting – 1994	10	<b>22</b>
Comparative Advertising Claim Poop (loose items)	10	<b>23</b>
Efficacy	10	<b>24</b>
Analysis of Survival Data Course (browned accordion folder)	10	<b>25</b>
<p>Unlabeled</p> <ul style="list-style-type: none"> <li>● Assessment of Drug Safety</li> <li>● PMA Education and Research Institute (PERI) Third Annual Training Course for New Clinical Statisticians March 11 -13, 1990</li> <li>● The FDA and the IND/NDA Statistical Review Process</li> <li>● Bioavailability/ Bioequivalence Trials Design and Evaluation</li> <li>● Protocol Development –A Statistician's Point of View</li> <li>● Planning of Clinical Studies</li> <li>● Acceleration of the Drug Approval Process</li> <li>● Investigational New Drug, Antibiotic, and Biological Drug Product Regulations: Procedures for Drugs Intended to Treat Life- Threatening and Severely –Debilitating Illnesses</li> <li>● Efficacy Analysis with Missing Data</li> <li>● Interim Analysis</li> <li>● Multicenter Studies</li> </ul>	10	<b>26</b>

<ul style="list-style-type: none"> <li>• General Linear Models Procedure</li> </ul>		
Statistical Services Seminar (loose items) <ul style="list-style-type: none"> <li>• Pharmacometrics Impact on FDA Decisions and Recommendations: Past, Present, and Future</li> </ul>	10	<b>27</b>
Unlabeled <ul style="list-style-type: none"> <li>• letter from Drug Information Association</li> <li>• two sheets of slides – statistical Considerations in the design and Analysis of LOPID-MR Placebo –Controlled Study (loose items)</li> <li>• regulatory affairs</li> <li>• Clinical Studies: how to Successfully Resolve Clinical Problems to Achieve FDA Approval</li> </ul>	10	<b>28</b>
Graybill Conference VII	10	<b>29</b>

**Box 11: 0200106500024**

<b>Slides</b>	<b><u>Box Number</u></b>	<b><u>Folder Number</u></b>
Teaching	11	1
MIS	11	2

**Box 12: 0200106500032**

<b>MISC</b>	<b><u>Box Number</u></b>	<b><u>Folder Number</u></b>
Stats -Statistical Analysis Methods for Providing Inferences between Primary Response Measures and Exposure to Study Medication <ul style="list-style-type: none"> <li>• A Survival Analysis Instead of an Endpoint Analysis for Antibiotic Data</li> <li>• Statistical Computing and Graphics – Word from Computing Section Chair</li> <li>• Statistical Methods for a Three-Period Crossover Design in Which High Dose Cannot Be Used First</li> <li>• Statistical Input into the Design, Analysis and Interpretation of Clinical Trails</li> <li>• Assessing the Validity of Statistical Inferences in Public</li> </ul>	12	1

<p>Health Research: an Evidence-Based, 'Best Practices' Approach</p> <ul style="list-style-type: none"> <li>● Statistical Methods for a Three-Period Crossover Design in Which High Dose Cannot Be Used First</li> <li>● Statistics in Medical Science-Importance of Research Question Relative to Analyses</li> </ul>		
<p>Stats (cont'd)</p> <ul style="list-style-type: none"> <li>● Some Comments on the Biopharmaceutical Section and Statistics</li> <li>● Some Thoughts on the Development of Combination Drugs</li> <li>● The history of the Biopharmaceutical Section of the American Statistical Association (ASA), 1966-1988</li> <li>● Introduction of the Bass XVIII Keynote Speaker Dr. Marvin Zelen</li> <li>● Making Informed Consent More Ethical</li> <li>● A Call to Action</li> <li>● Safety of Drugs, indeed, a Lifecycle Exercise</li> <li>● An Evaluation of Triprolidine and Pseudoephedrine in the Treatment of Allergic Rhinitis</li> <li>● Discussion for Interim Analysis and Sample Size Reestimation</li> <li>● Statistical Tests for Indirectly Standardized Rates</li> <li>● Appendix 1 Statistical Test</li> <li>● (Loose items)</li> <li>● Resampling Stats- Probability and Statistics a Radically Different Way User Guide IBM Version 3.0 (w/2 floppy disks)</li> <li>● Journal of Biopharmaceutical Statistics</li> <li>● Purpose of Experimentation or Observation (transparent slides)</li> <li>● Resampling Stats – Probability and Statistics a Radically Different Way Ibm Version 2.0 (in blue folder)</li> <li>● Biotechnology and the Biostatistician</li> <li>● Keynote Address, Preliminary Comments: by Karl Peace, BASS Chair, GCC Distinguished Cancer Scholar, Senior Research Scientist, JPHCPH, GSU.</li> <li>● Summary of Linear Models Analyses of ADAS-COG and CGIC Scores from Three Placebo Controlled, Enrichment Studies of Tacrine</li> <li>● Discussion: Linear Models and Population PK/PD Models</li> <li>● Statistical Issues in the Pharmaceutical Industry: Design, Analysis and Interpretation Issues in Clinical Trails</li> <li>● The Effect of Tacrine on Alzheimer's Disease</li> <li>● Analysis of Menstrual Data from Contraceptive Trials</li> <li>● Comparing Treatment Groups on the Basis of Slopes, Areas-Under-The-Curve, and Other Summary Measures</li> <li>● Maximum Likelihood Assessment of Clinical Trials based on an Ordered Categorical Response Variable</li> </ul>	12	2

<ul style="list-style-type: none"> <li>● Reducing the Cost of Clinical Trials</li> <li>● Statistical Issues in the Pharmaceutical Industry: Design, analysis and Interpretation Issues in Clinical Trials</li> </ul>		
<p>Wyeth Ayerst</p> <ul style="list-style-type: none"> <li>● Hotel receipt</li> <li>● Wyeth-Ayerst Biostatistical Seminar</li> <li>● Handwritten note on Biopharmaceutical Research Consultants Inc. letterhead</li> <li>● Letter from Richard Entsuah, Ph.D to Karl Peace about Wyeth-Ayerst seminar</li> <li>● Some Statistical Issues in Pharmaceutical Applications</li> <li>● Memo to Dr. Richard Entsuah from Karl Peace – Abstract of Presentation</li> <li>● Handwritten note</li> <li>● Note from Dr. Richard Entsuah from Karl Peace</li> </ul>	12	3
<p>Barnett Educational Services: Drug Development</p> <ul style="list-style-type: none"> <li>● Applying FDA's Critical Path Initiative to Oncology Drug Development</li> <li>● Drug Development: Changing the Paradigm outline</li> <li>● Speaker and Brochure Information- Drug Development: the Changing Paradigm</li> <li>● Karl E. Peace, Ph. D. Biographical Sketch</li> <li>● Sample Size Considerations in Clinical Trials Pre-Market Approved.</li> </ul>	12	4
<p>Three-Period Crossover</p>	12	5
<p>Placebo v. Tacrine</p> <ul style="list-style-type: none"> <li>● Study 4</li> <li>● Study 5</li> <li>● Study 6</li> <li>● Comparisons of Improvement vs. No Improvement for ADAS-COG, CGIC, and combined</li> <li>● Summary of Dose Response Analyses ADAS-COG at End of DB Treatment</li> <li>● Summary of Life Table Analyses of Time to First Clinical Response</li> <li>● Summary of Linear Model Analyses of ADAS-COG and CIBI Scores from Parallel, Placebo-Controlled Phases of Protocol CI-970-61</li> <li>● Summary of Linear Models Analyses of ADAS-COG and CGIC Scores from Three Placebo Controlled, Enrichment Studies of Tacrine</li> <li>● Clinical Pharmacology</li> <li>● Life Table Analysis of Time to First Clinical Response</li> </ul>	12	6

<p>Protocol CI-970-61</p> <ul style="list-style-type: none"> <li>• Comparisons of Improvement vs. No Improvement for ADAS-COG (4 or More Point Reduction over Baseline) Protocols CI-970-01, -04, and -06</li> <li>• Life Table Analysis of Time to First Clinical Response Protocol CI-970-26</li> <li>• Experimental Design</li> </ul>		
Carl Peck's Oncology	12	7
<p>Georgetown University Medical School Center for Drug Development Science</p> <ul style="list-style-type: none"> <li>• handwritten notes on Georgetown letterhead</li> <li>• Carl Peck's Oncology papers</li> <li>• email from Karl Peace to Carl Peck on Intrinsic Efficacy</li> <li>• email from Karl Peace to Carl Peck on combination Drug Development</li> <li>• Clinical Development of Oncologic Agents: Challenging the Tradition</li> <li>• Speaker Biographies</li> <li>• Clinical Development of Oncologic Agents: challenging the Tradition</li> </ul>	12	8
<p>Presentation at Princeton-Trenton chapter (loose items)</p> <ul style="list-style-type: none"> <li>• handwritten notes on Marriott Hotels and Resorts letterhead</li> <li>• Welcome to "Dose Response Clinical Trials" November 15-16, 2004</li> <li>• Abstract From: American College of Gastroenterology</li> <li>• list of names</li> <li>• email from Joe Mason to Karl Peace about Barnett Internationals "optimizing Dose..." conference information (BI-443)</li> </ul>	12	9
<p>Dose Response Meeting</p> <ul style="list-style-type: none"> <li>• not in folder- Dose response papers</li> <li>• not in folder</li> <li>• PMA Education and Research Institute (Peri) Training Course in Non- Clinical Statistics January 9-11, 1991</li> </ul>	12	10
Dose Titration	12	11

**Box 13: 0200106500040**

<b>Meetings</b>	<b><u>Box Number</u></b>	<b><u>Folder Number</u></b>
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1986 Session on Draft Guideline	13	1
Chicago Session on Content and Format of the Application <ul style="list-style-type: none"> <li>Research/Meetings –ASA Chicago Session</li> </ul>	13	2
1986 Annual Joint Meeting, Chicago August 17-21 <ul style="list-style-type: none"> <li>Empty</li> </ul>	13	3
1986 Joint Meeting, Continuing Ed Subcommittee Meeting <ul style="list-style-type: none"> <li>ASA-Annual Joint Meetings</li> </ul>	13	4
Executive Committee Meeting-1986 Joint Meeting <ul style="list-style-type: none"> <li>ASA-Annual Joint Meeting</li> </ul>	13	5
1986 Joint Meeting, Session on the Clinical Guidelines <ul style="list-style-type: none"> <li>ASA-Annual Joint Meetings</li> </ul>	13	6
DIA BA/BE Workshop/ 1991 August	13	7
Time to Event ADTE Methods	13	8
Design and Analysis of Bioavailability Studies 11/16/83	13	9
Design and Analysis of Bioavailability Studies 11/16/83	13	10
Safety Data Book Chapter	13	11
PMA Med Section Training Seminar <ul style="list-style-type: none"> <li>Pharmaceutical Manufacturers</li> </ul>	13	12
PMA Biostatistics Committee	13	13
1986 ENAR-ALL <ul style="list-style-type: none"> <li>(loose items)</li> </ul>	13	14
ENAR-3/18/86 Combination Drug Trials	13	15
1986 Spring ENAR Meetings, Atlanta <ul style="list-style-type: none"> <li>Empty</li> </ul>	13	16
1987 Spring ENAR Meetings	13	17
Unlabeled <ul style="list-style-type: none"> <li>Continuous form stationary</li> </ul>	13	18
1989 Spring ENAR Meetings Lexington, KY	13	19

**Box 14:0200106500057**



<b>MISC</b>	<b><u>Box Number</u></b>	<b><u>Folder Number</u></b>
(loose items) <ul style="list-style-type: none"> <li>● Handwritten note on Courtyard Marriott Stationary</li> <li>● Flash drive –Jiann-Ping Hsu College of Public Health</li> <li>● The Promise of Berkley Spring 2010</li> <li>● Punch cards</li> <li>● Clinical Trial Methodology CD</li> </ul>	14	
Dr. Peace-APHA (loose items) <ul style="list-style-type: none"> <li>● Paid in Full: Baker county Native Releases New Book of Memoirs</li> <li>● Ga Southern Scholar Receives Award from Philippine Statistical Association</li> <li>● Drug information Journal Author Guidelines AIMS and SCOPE</li> <li>● Journal of Epidemiology and Community Health –printout</li> <li>● Statistical Methods in Medical Research</li> <li>● Instructions for Authors “What AJPH authors Should Know”</li> <li>● Submission Guidelines for ICSA Bulletin</li> <li>● Protecting the Health of the Public – Institute of Medicine Recommendations on Drug Safety</li> <li>● Applied Clinical Trials</li> <li>● Email about Regulatory Affairs in Drug and Device Development – Gall for Manuscripts</li> <li>● Renowned Scholar and Pharmaceutical Researcher Endows chair in Biostatistics at UC Berkeley</li> <li>● Bioinformatics Internet Sites</li> <li>● Proteinuria in Gold-Treated Rheumatoid Arthritis</li> <li>● Safety of Drugs Is Indeed a Life Cycle Exercise</li> <li>● The Role of Vasopressin in Maternal Separation-Induced Short- Term Consequences and Adult Depressive Profile</li> <li>● Southeast (Waycross) Public Health District Perinatal and Premature Mortality Measures By Census Tract With County Commission Districts, 1998-2002</li> <li>● Baseline Cumulative Hazards Graphs</li> <li>● The Ten Commandments of Good Health-book</li> <li>● The Claxton Enterprise</li> <li>● Regents Launch Public Health Initiative To meet Increased Demand</li> <li>● BookFinder4u.com page- Design and Analysis of Clinical Trials with Time-to-Event Endpoints (Chapman &amp; Hall/ Crc Biostatistics Series)</li> </ul>	14	1
Citations of K.E. Peace papers	14	2

(loose items ) <ul style="list-style-type: none"> <li>● Parke Davis Optical envelope</li> <li>● Current Board of Visitors 1986-87</li> <li>● Members of Board of Visitors Whose Terms Expire This Year and Are Not Eligible for Re-election</li> <li>● Suggestions for Membership on the Board of Visitors form</li> <li>● Letter form Katie Burkett PHSA President to Jiann-Ping Hsu College of Public Health Faculty and Staff</li> <li>● Top 50 Georgia Foundations by Assets, circa 2003</li> <li>● emails from Karl Peace –some links of interest re philanthropy</li> <li>● Biostatistics</li> <li>● Hot Topics in Clinical Trials-white binder</li> <li>● Meta-Analysis: fundamentals to Recent Developments-blue binder</li> <li>● Klonopin Dose Optimization Study – white binder</li> <li>● Klonopin Dose Titration Study</li> <li>● (loose items)</li> <li>● Statistics News printout</li> <li>● Update on the Jiann-Ping Hsu College of Public Health</li> </ul>		
McNeil Course <ul style="list-style-type: none"> <li>● (loose items)</li> <li>● Determining the Optimal Dosage Regimen for H2-Receptor Antagonist Therapy-A Does Validation Approach</li> <li>● The Pooling of Data from Multicentre Trials</li> <li>● The Pooling of Data from Multi-Centre clinical Trials</li> <li>● Sample size Considerations in Clinical Trials Pre-Market Approval</li> <li>● The Impact of investigator Heterogeneity in Clinical Trials on Detecting Treatment Differences</li> <li>● Statistical Section of a Clinical Trial Protocol</li> <li>● TMO: the Trial Management Organization – A New System for Reducing the Time for Clinical Trials</li> </ul>	14	3
DIA 1991	14	4
Institute For Health, Policy And Evaluation Research	14	5
Clinical Trial Methodology Book	14	6
Kidney T.P. Data (L1970, 71970) and ATG Study Data <ul style="list-style-type: none"> <li>● (loose items)</li> <li>● Letter from Murl T. Wilson –attached – information regarding switch from RX to OTC marketing of Actifed, NDA's 11-935 and 11-936</li> </ul>	14	7
Artifacts/Book Reviews	14	8

Intrinsic Efficacy to Greg Campbell and Sue-Jane Wang	14	9
Unlabeled (grey folder) <ul style="list-style-type: none"> <li>Correspondence between "Brother Kao-Tai" and "Brother Karl" regarding joint research</li> </ul>	14	10
TAS <ul style="list-style-type: none"> <li>Continuous form stationary</li> </ul>	14	11
1990 Princeton Conference	14	12
Calan Site Change Study	14	13
Articles Needed	14	14
John Marshall Article <ul style="list-style-type: none"> <li>(loose items)</li> <li>Past and Present Regulatory Aspects of Drug Development</li> <li>An Overview of the Processes of Discovery, Basic Research, Clinical Development, &amp; Manufacturing, In Pharmaceutical Development With Attention to Bio statistical Considerations</li> </ul>	14	15

**Box 15: 0200106500065**

<b>Biology</b>	<b><u>Box Number</u></b>	<b><u>Folder Number</u></b>
Bioinformatics/Genomes <ul style="list-style-type: none"> <li>(loose items)</li> <li>Statistical Considerations in the Design and Analysis of H.R.T. Study 376-368</li> <li>Drug Development Strategies For Subpopulations</li> <li>Introduction to SAS</li> </ul>	15	1
Problem with Harsi Patel	15	2
Special issue of JASA Radio Paper	15	3
Bioequivalence	15	4
CIBA Vision Talk	15	5
History of Biopharmaceutical Section of ASA	15	6
A Pharmaceutical Model with Covariates or Cox's Procedure? July 16, 1984	15	7

Statistical Services Department Agenda <ul style="list-style-type: none"> <li>• (loose items)</li> <li>• Biopharmaceutical Report Fall 1992</li> <li>• Biopharmaceutical Report Fall 2000</li> </ul>	15	8
FDA Bio equivalency Workshop on Solid Oral Dosage Forms 9/29, 30, 10/1/86	15	9
On the Analysis of Ratios in Bioequivalence Testing 10/5/85	15	10
Course: George Washington University	15	11

**Box 16:0200106500073**

<b>Teaching</b>	<b>Box Number</b>	<b>Folder Number</b>
Unlabeled <ul style="list-style-type: none"> <li>• Overview of Clinical Research Data Processing</li> </ul>	16	1
Workshop on Clinical Trials 12/8-9/83	16	2
Clinical Trials Workshop for U.K. And European Participants May 31, 1984	16	3
Cumulative Risk Index Seminar Sept 26, 1985	16	4
Aspects of the Clinical Trials Workshop at Smith Kline and French Labs April 19,1983	16	5
Finite Markov Chains and Stochastic Processes with Applications: Sibbing Gas Diffusion And Chemical Kinetics <ul style="list-style-type: none"> <li>• (loose items)</li> <li>• Survey of Frequency of statistical Analyses</li> </ul>	16	6
Parke Davis: Biometric Standards	16	7
Educational Materials for Individual Instruction June 1, 1984	16	8
Biometric Standards Poo <ul style="list-style-type: none"> <li>• (loose items)</li> <li>• Statistical Analysis</li> <li>• References</li> <li>• A Characterization of the Effect of Varying Sample Sizes, Subject to a Fixed Total, on Detecting a Difference in Two Means</li> <li>• Coding/Supply Memo</li> </ul>	16	9

<ul style="list-style-type: none"> <li>• Statistical Analysis Plans (SAP)</li> <li>• Issues in Data Monitoring And Interim Analysis In The Pharmaceutical Industry</li> <li>• Searle Memorandum</li> <li>• A Test For Differences Between Treatment Means When Several Dose Levels Are Compared With A Zero Dose Control</li> <li>• The comparison of Several Dose Levels With A Zero Dose Control</li> <li>• A Non-Parametric Equivalent of Williams' Test for contrasting Increasing Dose Levels of a Treatment</li> <li>• Analysis of Data from Multiclinic Trials</li> <li>• Statistical Input into the Design and Analysis of Bioavailability Studies</li> <li>• Organization of Ann Arbor Statisticians Proceedings</li> <li>• Sample Compare Program</li> <li>• Memo to Biometrics staff from Wayne about Multicenter Studies- Are More Subjects Always Better? (Or, What's the Effect of Centers with Few Patients)</li> <li>• Standard Analyses - Basic Hypotheses, CLs, and Type 1 Error Rates</li> </ul>		
Experimental Design by Box & Hunter	16	10
Biostatistics	16	11
Meta-analysis Chapter Correspondence	16	12
Meta-analysis Manuscripts-Peace	16	13
Unlabeled <ul style="list-style-type: none"> <li>• Methods for Interpreting and Combining Experimental Results</li> </ul>	16	14
On Combining P-U Alues	16	15
Meta-Analysis Literature Search (loose items) <ul style="list-style-type: none"> <li>• Ulcer Disease: Investigation and Basis for Therapy</li> <li>• Correspondence between Edward A. Swabb to Karl E. Peace</li> <li>• Correspondence between Tom Teal and Karl E. Peace</li> <li>• Cost-Effectiveness in treatment of Peptic Ulcer Disease</li> <li>• Meta-analyses in Ulcer Disease</li> </ul>	16	16
Bioavailability (loose items) <ul style="list-style-type: none"> <li>• Report of The Workshop on Controlled Release Dosage Forms: Issues and Controversies</li> </ul>	16	17

<ul style="list-style-type: none"> <li>• Slides on bioavailability</li> </ul>		
Karl Peace	16	18
Parke-Davis Highlights	16	19

**Box 17:0200106500081**

<b>Manuscripts</b>	<b>Box Number</b>	<b>Folder Number</b>
Perry, M : Health and Wellness in Residents Who Matriculate into Physician Training Programs acknowledgement paper (loose items) <ul style="list-style-type: none"> <li>• Summary of Gart's Paper</li> <li>• Division of Clinical Pharmacology</li> </ul>	17	1
Medical College of VA Seminar 2/17/95	17	2
Clinical Research <ul style="list-style-type: none"> <li>• Hard copies of slides</li> </ul>	17	3
AJPH Paper: Validity of PH Intervention	17	4
TTE: Permission verification	17	5
Contributor Agreements	17	6
TTE	17	7
Making Informed consent More Ethical DIA Forum	17	8
Letter to Editor PHARMA DD	17	9
Degrees of Freedom in a Nonparametric Test (Letter to Editor-Biometrics)	17	10
Racial Differences in Perception of Breast Cancer Risk in Rural Southeast Georgia (JGPHA)	17	11
Nonclinical Statistics Course (loose items) <ul style="list-style-type: none"> <li>• Research Ethics Timeline</li> <li>• The New England Journal of Medicine</li> <li>• The New England Journal of Medicine Special Report</li> <li>• Teaching Statistics to Medical Students Using Problem-based learning: The Australian Experience</li> <li>• Fundamentals of Clinical Trials</li> </ul>	17	12

<ul style="list-style-type: none"> <li>• Chapter 3 Sample Size Considerations in Clinical Trials Pre-market Approval</li> <li>• Chapter 8 Clinical Trials in the Treatment of Panic Disorder</li> <li>• Taylor and Francis Books, Inc.</li> </ul>		
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**Box 18: 0200106500099**

<b>Manuscripts</b>	<b><u>Box Number</u></b>	<b><u>Folder Number</u></b>
GPHA "Validity" (loose items) <ul style="list-style-type: none"> <li>• Biostatistical Aspects of the Analysis and Interpretation of Cancer Clinical Trials</li> <li>• Monitoring Adverse Experiences in Clinical Drug Development</li> <li>• The Pooling of Data from Multicentre Clinical Trials</li> <li>• Interim Analyses: p-Value and Power Computations in Multiple Look Trials</li> <li>• Biostatistical Aspects of Development of Drugs to Treat Alzheimer's Disease Based Upon enrichment Designs</li> </ul>	18	1
Pharmaceutical Classification of Bipolar Disorder" – MCG Seminar	18	2
MCG MTG re Bipolar	18	3
Equilibrium-Based Bipolar Neurological Modeling (loose items) <ul style="list-style-type: none"> <li>• Practice Guideline for the Treatment of Patients with Bipolar Disorder</li> <li>• Letter from Karl E. Peace to David J. Kupfer about Equilibrium-based Bipolar Dynamic Model</li> </ul>	18	4
Bio.IT Word	18	5
DIA	18	6
Bipolar Conference Pittsburgh 6/8-9/07	18	7
ICSA – 2007	18	8
Cancer Survivorship Conference 9/27-28/2007 Peachtree Conference Center	18	9

**Box 19: 0200106500107**

<b>Meetings</b>	<b><u>Box Number</u></b>	<b><u>Folder Number</u></b>
American Society of Hospital Pharmacist (ASHP) Meetings	19	1
Society for Pharmaceutical Medicine August- September 1988	19	2
Regulatory Affairs Professionals Society (RAPS) Meetings	19	3
BRCI Computer Manual	19	4
Clinical Research Data Processing Book Project	19	5
American Association of Pharmaceutical Scientist (AAPS) 1989	19	6
Princeton Conference 1974	19	7
American Society of Clinical Oncology (ASCO) Meeting 1978	19	8
Pharmaceutical Manufacturers Association (PMA) Meetings 1978 and 1989	19	9
Gynecologic Oncology Group (GOG) (Phoenix) 1980	19	10
Second International Conference on Adjuvant Therapy of Cancer 1979	19	11
SUGI (SAS Users Group International) Conference 1981	19	12
Midwest Biopharmaceutical Statistic Workshop-Muncie Meeting	19	13
Regional Meeting of Pharmaceutical Statisticians and Data Processors	19	14
The Scientist Newspaper	19	15
Pulmonary –Allergy Drugs Advisory Committee 18 th Meeting	19	16
Third Annual Society For Clinical Trials Meetings	19	17
Society for Clinical Trials Meetings May 2-5, 1982	19	18
Society for Clinical Trials May 9-13, 1981	19	19
Society for Clinical Trails Workshop Proposals for 4 th Annual Meeting	19	20
American Society for Quality Control (ASQC) TAPPAN ZEE Section April 22, 1983	19	21



Pharmaceutical Industry Statisticians (PIS)	19	22
American Society for Clinical Pharmacology and Therapeutics Booklets March 13-16, 1984	19	23
American Society for Clinical Pharmacology and Therapeutics (ASCPT) 1984	19	24
1984 Spring ENAR Meetings and Orlando American Statistical Association (ASA) Meetings Scientific Affairs	19	25
1984 Joint Meeting, Philadelphia ASA Annual Joint Meeting Scientific Affairs	19	26
1985 Spring ENAR Meetings, Raleigh ASA ENAR Meetings Scientific Affairs	19	27
1985 Annual Joint Meeting, Las Vegas ASA	19	28
Summary of ASA Biopharmaceutical Section 1985	19	29
American Statistical Association (ASA) Background and Etiology	19	30
1985 ASA Meeting	19	31

**Box 20:0200106500115**

<b>Manuscripts</b>	<b>Box Number</b>	<b>Folder Number</b>
Equilibrium-Based Bipolar Neurological Modeling	20	1
Ying-Yang Papers and Research	20	2
Tacrine/ Alzheimer Papers	20	3
Summary of the effectiveness of Tacrine	20	4
ANCOVA Analyses	20	5
Food and Drug Administration and Peripheral and Central Nervous System Drugs Advisory Committee	20	6
Population PD/PK	20	7
Tacrine Meeting 1993	20	8
Yin Yang Papers and Research 2	20	9

Ying-Yang Modeling of Bipolar Disorder	20	10
Yin Yang Dynamic Neurological Modeling and Diagnostic Analysis of Major Depressive and Bipolar Disorders	20	11
Statistical Methodology of Drug Receptor Theory July 18, 1986	20	12
Analytical/ Physical Chemistry Seminar March 1983	20	13

**Box 21:0200106500123**

<b>Meetings</b>	<b><u>Box Number</u></b>	<b><u>Folder Number</u></b>
1987 Annual Joint Statistical Meetings	21	1
An Analysis of Data on spontaneous Duodenal Ulcer Recurrence and Template	21	2
Federal Drug Administration Papers	21	3
Drug Information Association Workshops	21	4
Statistical Analysis of Protocol: U20-86-02-005: Comparison of In the Treatment of Hypertensive Patients	21	5
San Francisco: ASA Joint Seminar Meeting 1987 Workshop: Mechanics of Preparing an Integrated Statistical Dual Clinical Summary	21	6
Draft Guide For the Format and Content of the Statistical Section of An Application June 1985 and January 1986	21	7
Handbook of Biopharmaceutical Statistics in Human Drug Development	21	8
Handbook of Biopharmaceutical Statistics in Human Drug Development Chapter Contents	21	9
Correspondences and Papers 1 1985-1987 <ul style="list-style-type: none"> <li>● Correspondences on Chapters in Biopharmaceutical Statistics in Handbook of Biopharmaceutical Statistics and Drafts</li> <li>● American Statistical Association 1984 Proceedings of Biopharmaceutical Section</li> <li>● Statistics in the Pharmaceutical Industry</li> <li>● Letter to Volker W. Rahlfs from Karl E. Peace</li> </ul>	21	10

<p>Correspondences and Papers 2 1981-1990</p> <ul style="list-style-type: none"> <li>● a. Includes Articles and Drafts of papers with Correspondences</li> <li>● b. Statistical Issues in Drug Research and Development Letters from Sandra Beberman March 22, 1990 <ul style="list-style-type: none"> <li>○ i. To Joan Godbee</li> <li>○ ii. To Elsie Peace</li> <li>○ iii. To Christopher Peace</li> <li>○ iv. To Nora Coury</li> <li>○ v. To M. T. Roberson</li> <li>○ vi. To Mickey Peace</li> <li>○ vii. To Karl Johnson</li> <li>○ viii. To Ronald Moore</li> <li>○ ix. To Walter Lynch</li> <li>○ x. To Tom Semler</li> <li>○ xi. To Peggy Phillips</li> <li>○ xii. To Steve Hutcherson</li> <li>○ xiii. To Martha Watson</li> <li>○ xiv. Michael Dey</li> </ul> </li> <li>● c. Statistical Issues for Drug Research and Development No. 106</li> <li>● d. Statistical Issues in Drug Research and Development Letter from Marcel Dekker to Karl Peace December 12, 1989</li> <li>● e. Statistical Issues in Drug Research and Development Letter from Sylvan Wallenstein to Sandra Beberman September 5, 1989</li> <li>● f. Statistical Issues in Drug Research and Development Letter from Sylvan Wallenstein to Rebecca Bernstein August 20, 1989</li> <li>● g. List September 18, 1989</li> <li>● h. Statistical Issues in Drug Research and Development Fax to Sylvan Wallenstein from Sandra Beberman and Preface September 18, 1989</li> <li>● i. Package Receipt September 6, 1989</li> <li>● j. Statistical Issues in Drug Research and Development fax to Sylvan Wallenstein from Sandra Beberman August 30, 1989</li> <li>● k. Statistical Issues in Drug Research and Development fax to Rebecca Bernstein from Sylvan Wallenstein August 20, 1989</li> <li>● l. Letter to Sylvan Wallenstein from Karl Peace August 14, 1989</li> <li>● m. A Critique of the Grizzle, Balaam, and White Designs August 16, 1983</li> <li>● n. A Two Treatment, Two-Period, Crossover Design Permitting Assessment of Direct and Carry-Over Effects May 26, 1981</li> <li>● o. Letter to Sylvan Wallenstein from Karl Peace December 29, 1988</li> </ul>	21	11
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<ul style="list-style-type: none"> <li>● p. Letter to Harji Patel from Karl Peace December 29, 1988</li> <li>● q. Statistical Issues in Pharmaceutical Drug Development American Statistical Association Sesquicentennial Celebration August 6-10, 1989</li> <li>● r. Letter to Karl Peace from Harji Patel</li> <li>● s. Package Receipt August 14, 1989</li> <li>● t. Letter to Rebecca Bernstein from Karl Peace June 22, 1989</li> <li>● u. Letter to Karl Peace from Rebecca Bernstein June 21, 1989</li> <li>● v. Letters Concerning Statistical Issues in Drug Research and Develop <ul style="list-style-type: none"> <li>○ i. To Karl Peace from Rebecca Bernstein August 2, 1989</li> <li>○ ii. To Sylvan Wallenstein from Rebecca Bernstein August 2, 1989</li> <li>○ iii. To Karl Peace from Rebecca Berstein July 12, 1989</li> <li>○ iv. To Karl Peace from henry Boehm July 20, 1989</li> <li>○ w. Letter to Karl Peace from Bill July 25, 1989</li> </ul> </li> <li>● x. Letter to Karl Peace from Donald M. Stablein July 18, 1989</li> <li>● y. Letter to Karl Peace from Martha S. Hearron July 21, 1989</li> <li>● z. Letter to Karl Peace from Gerald M. Fava</li> <li>● aa. Letter to Karl Peace from Morris Meisner July 17, 1989</li> <li>● bb. Letter to Karl Peace from Joseph K. Haseman July 25, 1989</li> <li>● cc. Letter to Karl Peace from Lloyd Fisher July 25, 1989</li> <li>● dd. Letter July 31, 1989</li> <li>● ee. Letter to Karl Peace from Robert Makuch</li> <li>● ff. Package Receipt August 2, 1989</li> <li>● gg. Analysis of Crossover Designs When the Errors Are Not Independent</li> <li>● hh. Contract between Marcel Dekker, INC and Karl Peace November 17, 1989</li> <li>● ii. Contract between Marcel Dekker, INC and Karl Peace January 12, 1988</li> <li>● jj. Hypothesis Testing for Combination Treatments May 9, 1989</li> <li>● kk. Testing Whether an Identified Treatment is Best May 5, 1989</li> <li>● ll. Statistical Assessment of Combination Drugs</li> <li>● mm. Analysis of Crossover Designs When the Errors are Not Independent January 30, 1989</li> <li>● nn. Loyld Fisher Floppy Disc</li> </ul>		
Pharmaceutical Drug Development Statistical Consideration and Art July 31, 1989	21	12
Correspondence of Results of the ASA Biopharmaceutical Work Groups May 1985	21	13

Correspondence Pertaining to the Publication of ASA Workshop Volumes Sesquicentennial Celebration December 29, 1988	21	14
Presentations and Guidelines <ul style="list-style-type: none"> <li>• ASA Continuing Education Workshop Preparing the Statistical Section Under the New Drug Application (NDA) Rewrite August 15, 1987</li> <li>• An Outline of the Statistical Section of a New Drug Application August 15, 1987</li> <li>• Preparing the Statistical Section Under the NDA Rewrite</li> <li>• Objective</li> <li>• Draft Guideline for the Format and Content of the Statistical Section of an Application June 1985</li> <li>• Draft Guideline for the Format and Content of the Clinical Data Section of an Application January 1986</li> </ul>	21	15
Correspondences 1986-87	21	16
Integrated Report	21	17
Correspondences and Papers 3 <ul style="list-style-type: none"> <li>• Correspondences 1985-1990</li> <li>• Biopharmaceutical Statistics for Drug Development October 1987</li> <li>• Guide for Authors and Editors</li> </ul>	21	18

**Box 22:0200106500131**

<b>Transparencies</b>	<b><u>Box Number</u></b>	<b><u>Folder Number</u></b>
Transparencies 1 <ul style="list-style-type: none"> <li>• Biostatistical Aspects of Development of H2 Receptor Antagonist Drug to Treat Duo Denal Ulcers</li> <li>• Biostatistical Aspects of Clinical Research Programs</li> <li>• Design and Analysis of Pivotal Trails to Assess Efficacy of Drugs to Treat Panic</li> <li>• Clinical Trials in Prevention of NSAID Induced Gastric Ulceration</li> </ul>	22	1
Transparencies 2 <ul style="list-style-type: none"> <li>• Biostatistical Input to the Design, Analysis and Interpretation of Cancer Clinical Trials</li> <li>• A Short Course on the Design analysis and Interpretation of Cancer Clinical Trials</li> </ul>	22	2
Transparencies 3	22	3

<ul style="list-style-type: none"> <li>● Drug Development Type of Trails</li> <li>● Biological Test Systems</li> <li>● Clinical Development Biostatistics Tutorial</li> <li>● Preclinical Safety Development</li> <li>● Characterization of a Drug and Its Doses</li> </ul>		
Transparencies 4 <ul style="list-style-type: none"> <li>● a. Bioassay, Drugs, and Doses</li> <li>● b. Clinical Efficacy Trial with Quantitative Data</li> <li>● c. Pharmaceutical Lead Discovery and Optimization Drug Research October 29-31, 1990</li> <li>● d. Placebo Comparisons inactive-Controlled Trials Notes for Princeton Conference Tutorial December , 1987</li> <li>● e. Draft <ul style="list-style-type: none"> <li>○ i. Biotechnology and Biostatistician</li> </ul> </li> </ul>	22	4
Transparencies 5 <ul style="list-style-type: none"> <li>● Genetics and the Future of Medicine</li> </ul>	22	5
Transparencies 6 <ul style="list-style-type: none"> <li>● Course Outline: Statistical Issues in Drug Research and Development</li> <li>● Dual Control Groups in Rodent Carcinogenicity Studies</li> <li>● Statistical Methods for a Three-Period Crossover Design in Which High Dose Cannot be Used First</li> <li>● Active Control Equivalence Studies</li> <li>● Biostatistical Aspects of the Development of Anti-anginal Drugs: A Phase II Trial Incorporating an Equiradial Hexagonal Design with RSM</li> <li>● Intention to Treat In Clinical Trials</li> <li>● Dosing in the Elderly</li> </ul>	22	6
Julie Achatz/ Klugh	22	7
Emily Clark/ Klugh	22	8
Shawna Hedin/ Klugh	22	9
Rachel Hemberger/ Klugh	22	10
Olivia McCallum	22	11
Jon Mann Protocol	22	12
Diet Product Development	22	13
Request to Industry	22	14
Lan-DeMets PGM	22	15

<p>Integrated Research</p> <ul style="list-style-type: none"> <li>• Contains correspondence</li> <li>• The Center for Rural Health and Research</li> <li>• The Use of Nuclear Protein-encoding Genes, RNA Polymerase II Tick Molecular Systematics</li> </ul>	22	16
<p>Correspondences, Schedules, and Check</p> <ul style="list-style-type: none"> <li>• Correspondences 2003</li> <li>• Schedules</li> <li>• Check from Johnson and Johnson</li> <li>• List of names</li> </ul>	22	17
<p>Transparencies 7</p> <ul style="list-style-type: none"> <li>• Biostatistical Aspects of Development of Drugs to Treat Alzheimer's Disease Based upon Enrichment Designs</li> <li>• Analysis and Summarization of Safety Data Collected in Clinical Trails</li> <li>• The Polling of Data from Multicentre Trials</li> <li>• Monitoring Adverse Experiences in Clinical Drug Development</li> </ul>	22	18
<p>Transparencies 8</p> <ul style="list-style-type: none"> <li>• Includes Correspondence September 15, 2000</li> <li>• Department of Health and Human Services</li> <li>• Preclinical Safety Development</li> <li>• Pharmaceutical Formulation Development</li> <li>• Biopharmaceutical Statistics for Clinical Drug Development</li> </ul>	22	19
<p>Papers</p> <ul style="list-style-type: none"> <li>• Clinical Efficacy Trials with Quantitative Data</li> <li>• Analysis of Ratios and Decision Rules in Bioequivalence Studies</li> <li>• Additional Topics</li> <li>• Mini Course-Drug Metabolism and Pharmacokinetics</li> </ul>	22	20

**Box 23:0200106500149**

<b>Data</b>	<b><u>Box Number</u></b>	<b><u>Folder Number</u></b>
<p>Paris NSAID Meeting December 5-8, 1987</p> <ul style="list-style-type: none"> <li>• Correspondence December 3, 1987</li> <li>• CYTOTOEC (MISOPROSTIL) NSAID Etude Rapport Qualite-Prix Cost Effectiveness Study</li> <li>• Tables</li> </ul>	23	1

<ul style="list-style-type: none"> <li>• Slides</li> </ul>		
Deerhurst Symposium Administration Meeting <ul style="list-style-type: none"> <li>• Comparative Assessment of Spontaneous Relapse Rates after Healing Active duodenal Ulcers with Misoprostol or Other Agents: A Literature Survey Draft February 16, 1987</li> <li>• Acute D.U.</li> <li>• Cytotoec Advisory Board meeting November 19-22, 1987</li> <li>• The Treatment of Gastric Ulcer with Antisecretory Drug: Relationship of Pharmacological Effect to Healing Rates Manuscript</li> <li>• Duodenal Ulcer What Comes After Healing</li> <li>• Smoking and Ulcer Healing Charts</li> <li>• Map of Toronto</li> <li>• Receipt</li> <li>• Correspondence 1986-1987</li> <li>• Baseline Description G. D. Searle and Co. Table 1-a</li> <li>• Baseline Description G. D. Searle and Co. Table 1-b</li> </ul>	23	2
Relapse Poop Slides	23	3
Rheumatologist Symposium <ul style="list-style-type: none"> <li>• Correspondences 1987</li> </ul>	23	4
Cytotoec Advising Board Meeting November 18-23, 1987 <ul style="list-style-type: none"> <li>• Slides</li> <li>• Slides Print Outs</li> </ul>	23	5
Capability of Analyzing Time to Response Data at Burroughs Wellcome Co. <ul style="list-style-type: none"> <li>• Seminar March 6, 1980 <ul style="list-style-type: none"> <li>◦ Printout and Charts</li> </ul> </li> <li>• Survival Data Analysis User's Guide</li> <li>• BMDPIL Life Tables and Survival Functions Health Sciences Computing Facility November 1978</li> </ul>	23	6
VCU Career Day March 19, 1982 <ul style="list-style-type: none"> <li>• Schedule</li> <li>• Careers in Statistics</li> <li>• Slides Careers in Statistics</li> </ul>	23	7
PMA Seminars <ul style="list-style-type: none"> <li>• Framed Congratulatory Letters <ul style="list-style-type: none"> <li>◦ University of California, Berkeley September 3, 2009</li> <li>◦ North Georgia College and State University October 21, 2009</li> </ul> </li> </ul>	23	8
Basic Statistics Course for Clinical R and D May 1983	23	9



<ul style="list-style-type: none"> <li>● Correspondence 1983</li> <li>● Transparencies <ul style="list-style-type: none"> <li>○ Basic Statistics Course</li> </ul> </li> <li>● Contents</li> <li>● Schedule</li> </ul>		
Midwest Biopharm. Stat. Workshop May 23-25, 1983 1 <ul style="list-style-type: none"> <li>● General Information on the Workshop at Ball State University</li> <li>● Correspondence 1983</li> <li>● Job Request</li> <li>● The PHGLM Procedure</li> <li>● Data set for MBSW Example of Repeated Significance Testing March 2, 1983</li> <li>● Gold Data Salt Lake for Protocol 20</li> <li>● Uni-Coll Corporation Expansion of Networking Services</li> </ul>	23	10
Midwest Biopharm Stat. Workshop May23-25, 1983 2 <ul style="list-style-type: none"> <li>● Transparencies <ul style="list-style-type: none"> <li>○ Munclife Study May 24, 1983</li> </ul> </li> </ul>	23	11
Midwest Biopharm Stat. Workshop May23-25, 1983 3 <ul style="list-style-type: none"> <li>● Reprographic Services Quality Control Checklist</li> <li>● Tables</li> <li>● Appendix 2</li> <li>● Stepwise Proportional Hazards General Linear Model Procedure 1975- 1978</li> <li>● Patient Accountability 1973-1983</li> </ul>	23	12
Analysis of Survival Data Course	23	13
Non-Sequential Analysis of Time to Event Data Seminar March 1984 <ul style="list-style-type: none"> <li>● Now. Parametric Methodology</li> <li>● Distribution Lists</li> <li>● Memos 1984</li> </ul>	23	14
Non-Sequential Analysis of Time to Event Data	23	15
Non-Sequential Analysis of Time to Event Data Seminar	23	16
Transparencies <ul style="list-style-type: none"> <li>● Also has paper print form</li> </ul>	23	17
Survival Data Analysis Methodology 4-25-1984	23	18
Transparencies <ul style="list-style-type: none"> <li>● User Guide</li> </ul>	23	19

Reducing Sample Size Through Sequential Analysis <ul style="list-style-type: none"> <li>Reducing Sample Size Through Sequential Analysis Transparencies</li> </ul>	23	20
Notes on Owner Guide	23	21
Analysis of Survival Data Course	23	22
Survival Data Analysis Methodology April 25, 1984 <ul style="list-style-type: none"> <li>NTP Carcinogenesis Bioassay</li> <li>Carcinogenesis Bioassay of L-ASCORBIC Acid (Vitamin C) (CAS NO. 50- 81-7) in F344/N Rats and B6C3F1 Mice (Feed Study)</li> </ul>	23	23
Correspondence and Manuscripts <ul style="list-style-type: none"> <li>Correspondence 1987</li> <li>Manuscript</li> <li>Statistical Analysis of Protocol U81-86-02-001: Comparison of Two Dosing Regimens of Misoprostol as Therapy for Duodenal and/or Gastric Ulcer Disease</li> </ul>	23	24
Statistical Report Outline Administration <ul style="list-style-type: none"> <li>Integrated Report</li> <li>Correspondence 1986</li> <li>Manuscript <ul style="list-style-type: none"> <li>Statistical Analysis of Protocol: U20-86-02-005: Comparison of Calan Sr, Tenormin and Capoten in the Treatment of Black Hypertensive Patients</li> </ul> </li> <li>Statistical Report Outlines</li> <li>Integrated Report 2</li> <li>Integrated Report 3</li> </ul>	23	25
Research Reports of Clinical Investigation	23	26
Technical Operations Type Org. <ul style="list-style-type: none"> <li>Corporate Medical and Scientific Affairs Department of Clinical Data Information Management</li> <li>Manager, Clinical Efficiency and Safety Coordination</li> <li>Correspondence 1987</li> <li>Corporate Medical and Scientific Affairs Biometrics</li> <li>1988 Goals and Strategies</li> <li>1988 Operating Plan Corporate Medical and scientific Affairs</li> <li>Examination of the Information Management and Analysis Requirements of the Scientific Affairs Division of G.D. Searle</li> <li>G. D. Searle and Company Definitions of Performance Rating Executive/Exempt</li> </ul>	23	27

Box 24: 0200106500156

<b>MISC</b>	<b><u>Box Number</u></b>	<b><u>Folder Number</u></b>
2x2 Crossover Design	24	1
Correspondences and Papers <ul style="list-style-type: none"> <li>● Papers <ul style="list-style-type: none"> <li>○ The Treatment of Gastric Ulcer with Antisecretory Drugs: Relationship of Pharmacological Effect to Healing Rates</li> <li>○ Protocol Effect of Sleep Reversal on Gastric Secretion Before and After a Two Week Period of Night-Shift</li> <li>○ A Model for Definition of Optimal Dose Size and Frequency of Antisecretory Drugs in Duodenal Ulcer</li> </ul> </li> <li>● Correspondence 1986</li> <li>● Directions to Deerhurst, Ontario, Canada</li> <li>● Deerhurst Vacation Villas <ul style="list-style-type: none"> <li>○ i. Pamphlets</li> <li>○ ii. Map</li> <li>○ iii. Correspondence 1986</li> <li>○ iv. The condominium and Timesharing Magazine</li> <li>○ v. Information Sheet</li> </ul> </li> </ul>	24	2
Clinical Guideline DIA Workshop May 5-6, 1986 <ul style="list-style-type: none"> <li>● Correspondence 1986</li> </ul>	24	3
DDW San Francisco May 17-22, 1986 <ul style="list-style-type: none"> <li>● Correspondence 1986</li> <li>● Cimetidine 800mg h. s. in the Treatment of Gastric Ulcer</li> <li>● Digestive Disease Week May 18-21, 1986</li> <li>● Programs</li> </ul>	24	4
Influencing Colonoscopy Screening in Rural Southwest Georgia: A Pilot Study	24	5
Dose Proportions MS.	24	6
Papers <ul style="list-style-type: none"> <li>● Alternate Solution</li> <li>● To the Readers of the American Statisticians</li> </ul>	24	7
Southwest Georgia Cancer Coalition <ul style="list-style-type: none"> <li>● Agenda</li> <li>● Baker County Cancer Screening and Navigation Pilot Program Evaluation</li> <li>● Baker County Cancer Screening and Navigation Program</li> </ul>	24	8

<p>Evaluation Executive Summary</p> <ul style="list-style-type: none"> <li>● Baker County Screening and Navigation Project Client Demographics January 2006- July 2007 Tables</li> <li>● Criteria Rubric for Replication of Baker County Screening and Navigation Project</li> <li>● Baker County Cancer Screening and Navigation Program Evaluation Report</li> </ul>		
<p>Size and Power Assessments of Tests of Hypotheses on Survival Parameters</p>	24	9
<p>Course Director</p> <ul style="list-style-type: none"> <li>● Correspondence 1989</li> <li>● Linear Regression Analysis of Censored Data April 11, 1990</li> </ul>	24	10
<p>Publications AY 07-08 Yin Yang</p> <ul style="list-style-type: none"> <li>● MentalSquare- An Equilibrium-Based System for Biopolar Neurobiological Pattern Classification and Analysis</li> <li>● JSM 2007 Online Preliminary Program</li> <li>● Some Thoughts on the Assessment of Pharmaceutical Safety Data</li> <li>● List</li> <li>● Georgia Public Health Association (GPHA) 78 th Annual Meeting and Conference</li> </ul>	24	11
<p>SAS PC Table Programming</p> <ul style="list-style-type: none"> <li>● Floppy Disks (5 ¼") <ul style="list-style-type: none"> <li>○ SAS Programs Copied from C Drive m-Mead M-MICUSAS...</li> <li>○ SAS Tables</li> </ul> </li> <li>● M_TDEMO SAS B1 VM/IS RELEASE 4.0 CMS</li> <li>● M_MCH SAS B1 VM/IS RELEASE 4.0 CMS</li> <li>● M_MEANO SAS B1 VM/IS RELEASE 4.0 CMS</li> <li>● M_MEAN SAS B1 VM/IS RELEASE 4.0 CMS</li> <li>● M_MEANO</li> <li>● M_TDEMO</li> <li>● Drug vs. Placebo vs. Active</li> <li>● Listing of Week 0 Data Set "Derived"</li> <li>● M_MCHSAS</li> <li>● M_MEAN</li> <li>● SAS Table 1 Descriptive Statistics of Seven Primary Efficacy Variables at Baseline (B)</li> <li>● SAS ® Proprietary Software Release 6.03</li> <li>● Fax 1991</li> <li>● VSHIELD Version 3.6V77</li> <li>● BRCI's Systems Configuration Flow Chart</li> <li>● Program TAB16FIN.PRG</li> </ul>	24	12

<ul style="list-style-type: none"> <li>● Program TAB15FIN.PRG</li> <li>● Program TAB9FIN.PRG</li> <li>● Summary Statistics for TRT BY GLRSPV2 Controlling for INVNO</li> <li>● % Pagenum Instructions</li> <li>● Floppy Disks (3.5") <ul style="list-style-type: none"> <li>○ Maureen Simmonds Ts. PRN</li> <li>○ Untitled (3)</li> </ul> </li> <li>● The Coding Symbol is for a Thesaurus of Adverse Reaction Terms (COSTART)</li> <li>● Code (2)</li> </ul>		
On Using One Coefficient Variation for Sampling Size Determination	24	13
Ulcer <ul style="list-style-type: none"> <li>● Usefulness of Anti-Ulcer Drugs for the Prevention and Treatment of Peptic Ulcers Induced by Low Doses of Aspirin</li> </ul>	24	14
What a World Class Community Research Program Would Look Like	24	15
Design Considerations of Ongoing Trails TTE November 23, 1985 <ul style="list-style-type: none"> <li>● Definitions of Risks</li> <li>● Design Overview</li> </ul>	24	16
Design and Cost Considerations of One Trial K Comparisons vs. K Trails with one Comparisons	24	17
Correspondence and Papers <ul style="list-style-type: none"> <li>● Effect of Two Cimetidine Regimens on Prothrombin Time and Warfarin Pharmacokinetic During Long Term Warfarin Therapy</li> <li>● American Society for Clinical Pharmacology and Therapeutics Abstract Form American College of Gastroenterology</li> <li>● Correspondence 1983; 1989</li> <li>● An Evaluation of Triprolidine and Pseudoephedrine in the Treatment of Allergic Rhinitis</li> <li>● Course/ Colloquy Proposal Form</li> <li>● Protocol for Warner-Lambert/Parke-Davis Clinical Trial</li> <li>● Warner-Lambert/Parke-Davis Pharmaceutical Research Division CI-719-GEMFIBROZIL</li> <li>● Levene Test for Homogeneity of Variance</li> <li>● Randomization Test for Schuirmann's Two One-sided Tests T-Test for AUC</li> </ul>	24	18
SNRT Data Analysis <ul style="list-style-type: none"> <li>● Statistical Analysis System July 10, 1978</li> </ul>	24	19

<ul style="list-style-type: none"> <li>• Data Female SNRT Data Input</li> </ul>		
Wright State University <ul style="list-style-type: none"> <li>• Problems to be Presented in Clinical Session on Biometrics</li> <li>• C. R. Rao: Weighted Discrete Distributions</li> </ul>	24	20
Helsinki Heart Study <ul style="list-style-type: none"> <li>• Helsinki Heart Study: Coronary Heart Disease Incidence During an Extended Follow-Up</li> <li>• Helsinki Heart Study: An 8.5 Year Safety and Mortality Follow-up</li> <li>• Correspondence 1992-1993</li> <li>• Efficacy of Gemfibrozil in Dyslipidaemic Subjects with Suspected Heart Disease. An Ancillary Study in the Helsinki Heart Study Frame Population</li> <li>• Statistical Analysis Methods for Providing Inferences Between Primary Response Measures and Exposure to Study Medication in the Helsinki Heart Study: Double Blind and Open Label Periods</li> </ul>	24	21
An Alternative Way of Calculating the $\chi^2$ Independence or Association Test Statistic for a $2 \times k$ Contingency Table	24	22
PNAS Manuscripts Review and Revisions <ul style="list-style-type: none"> <li>• Classification: Medical Sciences Tacrine in Alzheimer's Disease: A Population Pharmacodynamic Model for Cognitive Effects; Methods, Part 1 of 2</li> <li>• Classification: Medical Sciences Tacrine in Alzheimer's Disease: A Population Pharmacodynamic Model for Cognitive Effects; Methods, Part 2 of 2</li> <li>• Correspondence 1992</li> </ul>	24	23
Correspondence and Data <ul style="list-style-type: none"> <li>• Efficacy Summary File for the Bacteriologic Response Visit</li> <li>• Correspondence 1985</li> <li>• Data Set M030EFF.DAT <ul style="list-style-type: none"> <li>◦ Floppy Disk (5 1/2)</li> </ul> </li> <li>• M85-129</li> </ul>	24	24
Transparencies and Papers <ul style="list-style-type: none"> <li>• Correspondence 1984</li> <li>• Distribution List</li> </ul>	24	25
Non-sequential Analysis of time to Event Data Seminar July 1984	24	26
Non-sequential Analysis of time to Event Data Seminar July 23, 1984 <ul style="list-style-type: none"> <li>• Transparencies</li> </ul>	24	27

<ul style="list-style-type: none"> <li>• Data Analysis</li> </ul>		
Survival Data Analysis Methodology April 25, 1984	24	28
Colon Carcinoma Exercise <ul style="list-style-type: none"> <li>• Clinical Trial Analysis Colon Rectal Cancer</li> <li>• Correspondence 1984</li> <li>• Distribution List</li> <li>• Current Research on Antineoplastic Agents</li> <li>• Antibiotics Screen</li> <li>• Dual Process</li> </ul>	24	29
Survival Data Analysis Seminar II	24	30

**Box 25: 0200106500164**

<b>Manuscripts</b>	<b><u>Box Number</u></b>	<b><u>Folder Number</u></b>
Correspondence and Papers <ul style="list-style-type: none"> <li>• Survival Data Analysis Correspondence 1982-1983</li> <li>• Lectures 1-7</li> <li>• Independent Study with Bobbi Scueftler 1983</li> <li>• VM/SP Conversational Monitor System</li> <li>• G.M.T. Was the Origin</li> <li>• Lectures 7-11</li> <li>• Survival Analysis: Midterm Exam October 20, 1981 MCU Biostatistics</li> <li>• Re Goodness of Fit</li> <li>• Use of the Modified Sausage Statistics in Testing Sequentially the Equality of Two Survival Distribution</li> <li>• BIS: 600: Final Examination: MCV Richmond, Virginia 23298</li> <li>• Analysis of Survival Data Chapters and Bibliocist</li> <li>• Mortality Table</li> <li>• The Mean and Variance of <math>\hat{S}_{LT}</math></li> <li>• Connection Between the Mantel-Haenszel and Cox Procedures for Two Sample Case December 17, 1979</li> <li>• Test of Hypothesis in 2x2 Tables</li> <li>• Situation</li> <li>• Computation</li> <li>• Marginal Likelihood of Kalbfleisch and Prentice (1973) for continuous Time and Non censored Case</li> <li>• Test of Significance</li> <li>• The Feigl and Zelen Data</li> </ul>	25	1
Susan Arnold Memorial Project	25	2

Memorial Shelly Helmstrom	25	3
Memorial Melissa Giariatataro	25	4
Memorial Peter Settevendemie	25	5
Heidi Oh Memorial Consulting	25	6
Iffath Hogkins	25	7
Melissa Decker	25	8
SEGACA: Survey Methodology Group	25	9
Memorial Consulting: Dr. Eunice Bell	25	10
Memorial Consulting Michelle Stevens	25	11
Research Protocol with Bill (William) Hoskins	25	12
NCIR 25 Grant Norma Sheridan-Leos	25	13
Comprehensive Screening and Management of Distress Norma Sheridan- Leos	25	14
Biostatistical Aspects of Clinical Drug Development	25	15
Chapters <ul style="list-style-type: none"> <li>● Chapter 6 Overview of Bayesian Inferential Methods Including Time-to-Event Endpoints</li> <li>● Chapter 13 Design and Analysis of Cardiovascular Prevention Trials</li> <li>● Chapter 14 Design and Analysis of Antiviral Trials <ul style="list-style-type: none"> <li>○ Includes a CD</li> </ul> </li> </ul>	25	16
Maximum Likelihood Estimation and Efficiency Assessments of Tests of Hypotheses on Survival Parameters	25	17
Eric V. Slud <ul style="list-style-type: none"> <li>● Chapter 5 Overview of Inferential Methods for Categorical Time-To-Event Data <ul style="list-style-type: none"> <li>○ Includes a Floppy Disc</li> </ul> </li> </ul>	25	18
Clinical Trials Methodology <ul style="list-style-type: none"> <li>● Clinical Trials Methodology: A Graduate Course in Biostatistics for Medical Personnel <ul style="list-style-type: none"> <li>○ Includes Transparencies</li> </ul> </li> <li>● An Overview of the Processes of Discovery, Basic Research, Clinical Development and Manufacturing, In Pharmaceutical</li> </ul>	25	19



Development		
PowerPoint Presentations <ul style="list-style-type: none"> <li>• IV. a: Bioavailability and Bioequivalence of Pharmaceutical Formulations</li> <li>• The Design and Analysis of Pivotal Clinical Trials to Assess the Efficacy of Drugs to Treat Panic Disorder</li> <li>• Clinical Trials in the prevention of NSAID Induced Gastric Ulceration</li> <li>• The Importance of Numbers (of Patients) in Cancer Clinical Trials</li> <li>• Biostatistical Aspects of the Design of Cancer Clinical Trials</li> <li>• Biostatistical Aspects of the Analysis and Interpretation of Cancer Clinical Trials</li> </ul>	25	20

**Box 26:0200106500172**

<b>MISC</b>	<b><u>Box Number</u></b>	<b><u>Folder Number</u></b>
Framed Photos and Awards <ul style="list-style-type: none"> <li>• Tito Mijares Lifetime Achievement Award</li> <li>• Georgia House of Representatives 2008</li> <li>• Thank-You Letter</li> <li>• Dr. Bill Hoskins</li> <li>• Dr. Phil Geetia</li> <li>• Letter April 18, 2006</li> </ul>	26	1
Statesboro Magazine January/February 2011 <ul style="list-style-type: none"> <li>• Contains an Article about Karl Peace</li> </ul>	26	2
PowerPoint Presentations 1 <ul style="list-style-type: none"> <li>• Introduction to Design of Genomic Clinical Trials</li> <li>• Targeted (Enrichment) Design</li> <li>• Categorical Data Analysis using SAS</li> <li>• Quantal Bioassay Analysis</li> <li>• The Final Session: Recent Topics in Categorical Data Analysis</li> <li>• Biomarker Adaptive Threshold Design</li> <li>• Development and Validation of Predictive Classifiers Using high Dimensional Data</li> <li>• Proportional Odds and Generalized Logits Models</li> <li>• Weighted Least Squares for Mean Scores</li> <li>• Poisson Regression</li> </ul>	26	3
Considerations for Colorectal Cancer Screening	26	4

**Box 27:0200106500180**

<b>Jiann-Ping Hsu</b>	<b><u>Box Number</u></b>	<b><u>Folder Number</u></b>
Framed <ul style="list-style-type: none"> <li>• Congratulatory Letter from Georgia Southern University</li> <li>• Photo of Karl Peace's Home from Age 10-18</li> <li>• Elsie Peace 1974 Sketch of Home Karl Peace (son) was Born</li> <li>• Philippine Statistical Association Certificate of Appreciation</li> </ul>	27	1
BASS Short Courses and Tutorials	27	2
Magazines <ul style="list-style-type: none"> <li>• Amstat News December 2013-March 2014</li> <li>• Newsboy March-April 2014</li> <li>• International Chinese Statistical Association January 2014</li> <li>• Nature Methods December 2013- March 2014</li> <li>• Drug and Development January 2014 and March 2014</li> <li>• International BioPharm November 2013- February 2014</li> <li>• Applied Clinical Trials December 2013-March 2014</li> <li>• Significance December 2013 and February 2014</li> <li>• Georgia Back Roads Summer 2012 and Spring 2014</li> </ul>	27	3
Investing in Public Health 85 th Annual Meeting and Conference of the Georgia Public Health Association	27	4
Graduate School Correspondence for Jiann-Ping Hsii	27	5

**Box 28:0200106500198**

<b>Misc Framed</b>	<b><u>Box Number</u></b>	<b><u>Folder Number</u></b>
<ul style="list-style-type: none"> <li>• Ernest Karl Peace High School Diploma 1959</li> <li>• Vanderbilt University Graduate Summer Session of Statistics in the Health Sciences 1975</li> <li>• Karl Ernest Peace Clemson University Master of Science Degree 1964</li> <li>• Thank you from AAPS Atlanta October 1989</li> <li>• Alumni Award</li> <li>• Omicron Delta Kappa Certificate 2000</li> <li>• Letter about the Philippine Statistician's Tito Mijares Lifetime Achievement Award</li> <li>• Georgia Southern College Bachelor of Science Degree 1963</li> </ul>	<b>28</b>	<b>1</b>

<ul style="list-style-type: none"> <li>• Who's Who Among Students in American Universities and Colleges 1962-63</li> <li>• Georgia Southern College Excellent Scholarship 1962</li> <li>• Letter about Virginia Commonwealth University's Founders' Society</li> <li>• The Philippine Statistical Association Certificate of Appreciation 2004</li> <li>• Regulatory Affairs Professionals Society (RAPS) Membership Certificate 1989</li> <li>• Letter from Jiann-Ping Hsu</li> <li>• Letter about Chair-Elect Position from American Public Health Association 2009</li> <li>• The Drug Information Association Certificate 2003</li> </ul>		
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**Box 29:0200106500206**

<b>Books</b>	<b><u>Box Number</u></b>	<b><u>Folder Number</u></b>
Reference books o SAS reference books x 7 (Different Volumes and Topics) o User's Guide to Survival Data Analysis o Biopharmaceutical Statistics for Drug Development o Statxact User's Guide o Resampling Stats o Teledata Manager	29	
Misc books o Various magazines mentioning Karl Peace and the JPH College of Public Health o Auto Auction Magazine o Pencil Broadside Sketchbook o User's Digest 4 th ed.	29	

**Box 30:0200106500214**

<b>Framed Materials</b>	<b><u>Box Number</u></b>	<b><u>Folder Number</u></b>
Awards x10	30	
Photographs x5	30	

**Box 31:0200106500222**

<b>MISC Books</b>	<b><u>Box Number</u></b>	<b><u>Folder Number</u></b>
<ul style="list-style-type: none"> <li>o Idyll's of the King</li> <li>o Key to Robinson's Progressive Practical Arithmetic</li> <li>o Tennyson's Princess</li> <li>o Irving's Sketchbook</li> <li>o Condensed Books (A collection of stories)</li> <li>o Course in General Chemistry</li> <li>o Trigonometry for Secondary Schools</li> <li>o High School Physics</li> <li>o College Trigonometry</li> </ul>	31	

**Box 32: 0200106500230**

<b>MISC</b>	<b><u>Box Number</u></b>	<b><u>Folder Number</u></b>
<p>Cassette Tapes</p> <ul style="list-style-type: none"> <li>• Session 1: Integration of Popln PK/PD Modeling</li> <li>• Session 1: Beyond Observational Data Analysis</li> <li>• A DIA PK/PD Workshop; Session 1 Basic Concepts and Applications</li> <li>• Sequence of period Effects</li> <li>• Log Transformation for Bioan. Bioeg Data</li> <li>• Outlier Analysis</li> <li>• A Session II: Individual Ratio Analysis</li> <li>• Log Transform</li> <li>• Sequence and Period Effects</li> <li>• Session IV: Impact on Drug Development</li> <li>• Session III: Design for Population PK/PD</li> <li>• Session II Modeling and Estimation Tape 2</li> <li>• Response to Industry Concerns on Early Termination of Clinical Trials</li> <li>• Session III: Simple Design Strategies for Poplu PK Model</li> <li>• Session II: Modeling and Estimation Tape 1</li> <li>• Session II: Appl. Of Popln PK/PD Analysis to Determine Optimal Dosing</li> </ul>	32	
<p>VHS Tapes</p> <ul style="list-style-type: none"> <li>• Gardner Communications "Vision"</li> <li>• Gardner Communications "Animation"</li> <li>• Health Care Industry</li> <li>• Gardner Communications "Imagination"</li> </ul>	32	

<ul style="list-style-type: none"> <li>• Demo Tape</li> <li>• Fresh Daily</li> <li>• S-Plus; Unopened/Still wrapped VHS</li> </ul>		
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**Box 33: 0200106500248**

	<u>Box Number</u>	<u>Folder Number</u>
Mathematical physiology: Summary of semester's work	33	1
Mathematical physiology: Summary of semester's work continued	33	2
Genetics 516 – Population genetics	33	3
Population genetics continued	33	4
Topics in Biostatistics	33	5
ASA course: Analysis of survival data	33	6
Comprehensives	33	7
Continuous Form Paper	33	8
Unbound notes	33	9
BIY 646 – Nonparametrical statistics – notes	33	10
BIY 646 – Nonparametrical statistics – problems	33	11
BIY 600 – Hypothesis testing	33	12
BIY 600 – Hypothesis testing – Notes, Roll, Reprints	33	13
BIY 600 – Hypothesis testing – Notes, Roll, Reprints continued	33	14
BIY 600 – Hypothesis testing – Notes, Roll, Reprints (3) continued	33	15
BIY 600 – Hypothesis testing – Notes, Roll, Reprints (4) continued	33	16
Gen 620	33	17

**Box 34:0200106500255**

	<u>Box Number</u>	<u>Folder Number</u>

30 th Annual Princeton Conference on Applied Statistics	34	1
Dissertation draft	34	2
Dissertation – Ch. 4 + 5 (draft)	34	3
BIY 537 – Sampling theory	34	4
Statistics 301 – Bayesian Interference	34	5
Statistics 5020 – Time Series Analysis	34	6
Statistics 5020 – Time Series Analysis continued	34	7
Dissertation – Ch. 3 (draft)	34	8
Exploratory Data Analysis	34	9
Decision theory – Colloquy 254	34	10
BIY 511 – Statistical Methods	34	11
BIY 512 – Experimental design - notes	34	12
BIY 512 – Experimental design – problems	34	13
BIY 546 – Linear models – notes	34	14
Folder 15: BIY 546 – Linear models – problems	34	15

**Box 35:0200106500263**

	<b><u>Box Number</u></b>	<b><u>Folder Number</u></b>
BIY 650 – Response Surface methodology	35	1
BIY 650 – Response Surface methodology continued	35	2
BIY 650 – Response Surface methodology (3) continued	35	3
BIY 641 – Advanced inference	35	4
BIY 641 – Advanced inference continued	35	5
BIY 642 – Multivariate analysis	35	6
BIY 642 – Multivariate analysis continued	35	7

Statistics 300 – Actuarial functions – notes	35	8
Statistics 300 – Actuarial functions – exercises	35	9
Math 105 - Finite	35	10
Colloquy 218 – Methods of Optimization	35	11
Math 353 – complex variables	35	12
Math 411 – Linear Algebra	35	13
Math 453 – Advanced Calculus	35	14
Math 453 – Advanced Calculus continued	35	15
Math 371 – Probability	35	16
Math 503 – Complex variables	35	17
Math 505 – Problems and verification	35	18
Math 504 – Complex variables	35	19
Math 505 – Numerical analysis	35	20
Math 505 – Numerical analysis – problem assignments	35	21
Math 505 – Numerical analysis – Solved problem assignments	35	22
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**Folder 1: (Oversize) Room 2224, Mapcase A- Drawer 15**

**Karl E. Peace Certificate of Appreciation 1991-1994**

**Karl E. Peace Pharmaceutical Manufacturers Association Recognition Award**

**Karl E. Peace; Commonwealth of Virginia General Assembly**

**Karl E Peace Medical College of Virginia Doctorate Degree**

**Poster- Nature Reviews: Molecular Cell Biology**

**Poster- Nature Reviews: Cancer**

**Poster- Statesboro Magazine October, November 2007**