# Cayuga Consulting

### Medical Writing ~ Clinical Research ~ Electronic Documents ~ Regulatory Affairs

### **Company Description**

Cayuga Consulting is a full-service Medical Writing and Clinical Research Consulting firm. Headquartered in Providence, RI, Cayuga Consulting provides contract medical writing, clinical development support, and electronic document services to the Pharmaceutical, Biotech and Device industries. President and Cayuga Consulting founder, Donna D. Walczak, Ph.D., leads the scientific and medical writing teams, provides clinical development expertise, and manages the Electronic Document Center.

### Large-Format Posters

Cayuga Consulting can produce high-quality, eye-catching and effective posters for scientific and medical meetings. We prepare quality-assured text, graphics and layouts to suit any presentation need - starting from raw data or using the client's prepared materials. Small, medium and large poster formats are available - up to 4' x 8'. Posters can be printed on heavyweight glossy paper, lightweight indoor banner material, or laminated for durability.

- Unitary and multipanel designs are easily accommodated.
- All posters are prepared in Adobe InDesign<sup>®</sup> or PageMaker<sup>®</sup> and rendered to PDF for printing. We can import text and graphics from standard software packages or create de novo charts and illustrations as needed, using Illustrator, Photoshop, Excel, and Word, and others graphing software packages.
- We can design the overall appearance of the poster, or use your electronic logos and background "wallpaper". Project-specific color schemes can be matched exactly.
- Don't have electronic files? We can recreate your illustrations from raw data or printed media.
- Proof copies are provided via e-mail or FedEx in either legal size (8.5" x 11") or tabloid-size prints (11" x 17") for client review and approval.
- Black and white handouts can also be provided in these sizes (color handouts incur an extra charge).
- We can ship the finished poster to you, to the presenter, or directly to the meeting/presentation venue.
- We also prepare hard-copy compendia of related posters, in a variety of styles (8.5" x 11" handouts, booklets, etc.).
- Turn-around time on production is exceptional, quality and satisfaction guaranteed.
- We also provide emergency service (72-hr plus print time) call us!

Sample Posters are provided on subsequent pages. Our competitive rates will please even the toughest budget negotiator. Call or e-mail for quotes.

## Let us help you make a great impression!

Want to know more? Contact:	Donna D. Walczak, Ph.D, President	
	Cayuga Consulting, 20 Dewey St, Providence, RI 02909	
	(401) 942-3458 office dwalczak@cayugaconsult.com	

# Sample Poster Styles

### Standard three-panel format with three graphs, no background

Title of Your Poster Here: Panacea Cures All Ills in Weeks First Author, MD, Affiliation #1; Second Author MD, Affiliation #2; Third Aurhor PH.D., Affiliation #3; Fourth Author, RN, Affiliation #4

The choice of control group is always a critical decision in designing a clinical trial. That choice affects the inferences that can be drawn from the trial, the ethical acceptability of the trial, the degree to which bias in conducting and analyzing the trail, the degree to which bias in conducting and analyzing the study can be minimized, the types of subjects that can be recruited and the pace of recruitment, the kind of endpoints that can be studied, the public and scientific credibility of the results, the acceptability of the results by regulatory authori-ties, and many other features of the study, its conduct, and its interpretation

Introduction

#### Methods

The purpose of this guideance is to describe the general principles involved in choosing a control group for clinical trials intended to demonstrate the efficacy of a treatment and to discuss related trial design and conduct issues. This guidance does not address the regulatory requirements in any region, but describes what trials using each design can demonstrate. The general principles described in this guidance are relevant to any controlled trial but the choice of control group is of particularly critical importance to clinical trials carried out during drug development to demonstrate efficacy. The choice of the control group should be considered in the context of available standard therapies, the adequacy of the evidence to support the chosen design, and ethical considerations

This guidance first describes the purpose of the control group and the types of control groups commonly employed to demonstrate efficacy. It then discusses the critical design and interpretation issues associated with the use of an active control trial to demonstrate efficacy by showing non-infe-riority or equivalence to the control (Section 1.5). There are circumstances in which a finding of noninferiority cannot be interpreted as evidence of efficacy. Specifically, for a finding of non-inferiority to be interpreted as showing efficacy, the trial needs

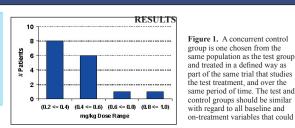
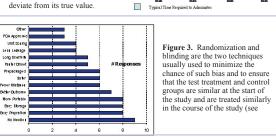


Figure 2. Failure to achieve this similarity can introduce a bias into the study Bias here (and as used in ICH E9) means the systematic tendency of any aspects of the design, conduct, analysis, and interpretation of the results of clinical trials to make the estimate of a treatment effect deviate from its true value



60 min

120 min

180 min

>240 min

Control groups have one major purpose: to allow discrimination of patient outcomes (for example, changes in symptoms, signs, or other morbidity) caused by the test treatment from outcomes caused by other factors, such as the natural progression of the disease, observer or patient expectations, or other treatment

The control group experience tells us what would have happened to patients if they had not received the test treatment or if they had received a different treatment known to be effective

If the course of a disease were uniform in a given patient population, or predictable from patient characteristics such that outcome could be predicted reliably for any given subject or group of subjects, results of treatment could simply be compared with the known outcome without treatment.

For example, one could assume that pain would have persisted for a defined time, blood pressure would not have changed, depression would have lasted for a defined time, tumors would have pro-gressed, or the mortality after an acute infarction would have been the same as previously seen. (see

#### Conclusions

- · Panacea was effective and well-tolerated with minimal adverse effects in a rural pediatric population with acute prolonged seizures and seizure clusters.
- Numerous advantages were identified by the families and caregivers for Panacea use com-pared to other treatments
- Most issues of concern can be handled by adequate caregiver training in recognition of prolonged or cluster seizures and administration techniques for Panacea.

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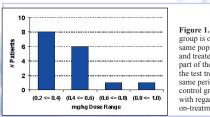
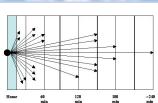


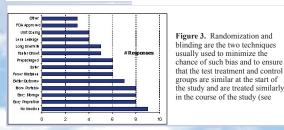
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60 min

min min Typical Time Required to Adr

deviate from its true value



#### RESULTS

Figure 1. A concurrent control group is one chosen from the same population as the test group and treated in a defined way as part of the same trial that studies the test treatment, and over the same period of time. The test and control groups should be similar with regard to all baseline and on-treatment variables that could

180 min

>240

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### Cayuga Consulting 2017 Process Schedule and Charges Poster Production

All services are provided on an hourly basis; typical estimated hours required are indicated below. Real time estimates are in parentheses and are based on 20-30 hours/week

**Description of Deliverables:** Develop and prepare print-ready copy of presentation posters for medical or scientific conferences.

- All work will be done in PC format
- Poster text and graphics will be typeset using Adobe InDesign
- All text will be prepared in Microsoft Word and imported into the poster
- Graphs and Charts will be prepared in Microsoft Graph, PowerPoint, Excel, Illustrator, GraphPad Prism, or similar software
- Cayuga Consulting will print the final poster unless otherwise requested by client

### **Typical Poster Development Schedule\***

Process	Time Required**
Create Poster from study report or data tables and protocol	
Review Study Report	8-10 hours
Select Poster Message and Prepare Text	8-12 hours
Create Tables, Graphs and Charts	
Estimated Charges	
<ul> <li>Create Poster from Sponsor-approved text and charts</li> <li>Create Poster Format to Meet Sponsor</li> </ul>	
Format Specifications	
<ul> <li>Typeset Poster Text and Figures</li> </ul>	
<ul> <li>Make Revisions as Needed (assume 2 rounds of review)</li> </ul>	8-10 hours
<ul> <li>QA Page Proofs and Make Revisions</li> </ul>	6 hours
<ul> <li>Estimated Charges</li> </ul>	\$3,000 - \$4,000
Printing, Proofing and Ancillary Services	
Submit to Printer	1 hour
<ul> <li>Review and Proof Print</li> </ul>	2-3 hours
Estimated Charges	\$500 - \$1,000
Total Projected Hours from Review of Study Report (Real Time)	40 - 60 hours** (2 – 3 weeks)
Total Hours from Approved Graphs, Charts and Text Real Time	10- 25 hours** (1-2 weeks)
Total Projected Charges per Poster	\$8,000.00 - \$12,000.00

\*Typically, 2 - 3 weeks advance notice is preferred for poster development, although every effort will be made to meet emergency situations.

\*\*These are estimates for a typical poster and are based on the assumption of a 30-hour work week. Emergency work, weekend work or schedules compressed beyond 30% will have a 20% surcharge added to the hourly total.

\*\*Multiple posters employing similar formats may allow savings in overall project time and charges.

### Schedule of Charges for Ancillary Services:

<ul> <li>Subcontract specialty graphic design if needed</li> <li>Provide Sample print of fonts, colors, and finish (1 foot section)</li> <li>Provide Final Poster on CD (PDF or InDesign or both)</li> <li>Tabloid Size Handouts, 100 copies, per side</li> <li>Compendia of related posters for Hospitality Suites</li> <li>Poster Printing Charges (unlaminated)</li> </ul>	\$85/hr \$100.00 \$100.00 \$5.00/sheet \$150/hr
<ul> <li>3' x 5' poster</li> <li>4' x 7' poster</li> </ul>	~\$500.00 ~\$600.00

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