

CTN-POL-021	DESIGN & ANALYSIS WORKGROUP CHARTER	Date Approved: 4/3/2002
Approved by: Steering Committee	Date Revised: 3/5/2002 Revised by:	Page 1 of 1

Purpose

The purpose of the Design and Analysis Workgroup is to serve as a resource and consulting group to the Protocol Development Teams and Steering Committee regarding the design and analysis of CTN s clinical trials, so that:

- The designs are based on sound scientific, clinical and statistical principles;
- The designs are feasible and sustainable;
- The planned analyses are based on the most appropriate statistical models and tests.

Responsibilities

The responsibilities of the Design and Analysis Workgroup are:

- To be instrumental and actively involved in the development of the first version of all CTN protocols regarding their design and analytic plan.
- To facilitate and assist in the design and analysis of all CTN protocols at all stages of the review process.
- To address general and important design and analysis issues that are common to several CTN protocols, or could potentially emerge in future protocols; and prepare guidelines (not necessarily SOPs) that describe the Workgroup s recommendations for dealing with these issues.