

# Computational Tools for Clinical Research - CLR0501: Class Topics 2018

Alan Weinberg – SAS System Software

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## Lecture 1

Introduction to SAS: Starting-up SAS software, SAS Windows, opening files, reading in data, i.e. small data sets and large (EXCEL files or ASCII text), the SAS editor, writing SAS code, saving files, job/commands, character and numeric variables, generating frequencies and means, sorting data, using ODS for output. The LOG window.

## Lecture 2 – LAB plus short lecture

Introduction to SAS cont'd: TITLES, LABELS, Comments, Creating new variables, Rounding,

## Lecture 3

DO loops.

Performing t-tests and chi squares in SAS, generating relative risks, odds ratios, confidence intervals.

## Lecture 4

Introducing 'Date' variables: Calculating the time between two events.

Calculating Kaplan-Meier survival estimates and generating survival curves in SAS.

FORMAT statements.

## Lecture 5

Working with SAS datasets: invoking the Commands APPEND, MERGE, KEEP, DROP, LRECL for large files to append or merge files. Creating permanent SAS data sets.

Converting a horizontal file to a vertical one, especially for repeated measures analyses.

Adding ID's. Numbering repeated events. Finding Duplicate records.

## Lecture 6

Plotting group means over time.

SAS Programming: Writing code to translate equations and calculate values.

SAS and Missing Data.

EXPORTING a SAS file to EXCEL.

%INCLUDE: Incorporating one SAS file within another.

Using Memory variables

## Lecture 7

Converting a Vertical file to Horizontal.

SAS Graphics

SAS Macros

If time permits:

Power and Sample Size Code.

Logistic Regression, Topics to be announced

Final Review.

## **Ron Levitan, Richa Deshpande: Data Security and Electronic Data Capture (EDC) Tools**

### **Lecture 1: Data Security**

Data privacy and security, HIPAA and IRB requirements, tools for protecting and transporting data securely, Mount Sinai policies for storage and transport of research data. Developing a regulatory-compliant data management plan.

### **Lecture 2, 3: Electronic Data Capture (EDC) Tools: REDCAP**

A survey of desktop and web-based systems for capturing data for clinical research projects. Students will use a web-based Electronic Data Capture (EDC) system in class to perform a set of typical data import/entry operations for a clinical trial, and will develop a web-based data collection tool using the REDCap EDC system. Students will then learn how to integrate collected data with SAS and will use SAS to visualize and describe those data.

## **Ron Levitan, Richa Deshpande: Databases, Data Security and Electronic Data Capture (EDC) Tools**

### **Lecture 1: Relational Databases; Data Security**

1. Introduction to relational databases. An in-class assignment will implement a relational model of patient demographics and encounter data using an open source SQL database (sqlite).
2. Data privacy and security, HIPAA and IRB requirements, tools for protecting and transporting data securely, Mount Sinai policies for storage and transport of research data. Developing a regulatory-compliant data management plan.

### **Lecture 2: Electronic Data Capture (EDC) Tools: REDCap**

A survey of desktop and web-based systems for capturing data for clinical research projects. Students will develop two small web-based REDCap projects to implement a survey tool and a longitudinal study.

### **Lecture 3: Working with REDCap data**

Students will learn how to import and export REDCap data as well as how to integrate, visualize and describe REDCap data with SAS.

## **Lopa Gupta: Case Report Forms**

### **Lecture: Case Report Forms**

Purpose of CRFs in clinical trials, factors to consider when designing CRFs.  
Reviewing samples of real life CRFs, Impact of optimal/suboptimal CRF design,  
Standardization of CRFs.

