

# Perfecting Your Company Core Data Sheets

## A Guide for Authoring and Updating the CCDS

---

### Table of Contents

Background.....	3
Origin of the Core Data Sheet: CIOMS.....	5
Core Data Sheet Basics.....	7
The CCDS Format.....	13
Updating an Existing CCDS.....	19
Developing Company Core Safety Information (CCSI).....	27
SBR Use Encouraged to Lighten Product Safety Paperwork.....	41
Conclusion.....	43
Appendices <i>(can be found on the CD in the back of this report)</i>	
A. CIOMS I Reporting Form	
B. ICH E2C Revision 1	
C. Crestor CCDS	
D. The Process for Creating a CCDS	
E. Format for a CCDS	
F. EMA 9a Guidance	
G. FDA's Investigational New Drug Safety Reporting Requirements	
H. Addendum to E2C Clinical Safety Data Management	