



## **CDISC Operating Procedure CDISC-COP-004 CDISC Registered Solutions Providers**

### **Revision History**

<b>Date</b>	<b>Revision</b>	<b>Description</b>	<b>Author</b>
23 April 2002	0.1	Original Draft	Wayne Kubick
10 June 2002	0.2	Final Draft	Wayne Kubick
19 June 2002	1.0	Approved	Board of Directors
1 January 2006	1.1	Revisions required to align with current CDISC organization and procedures	CDISC Operations

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# CDISC Operating Procedure CDISC-COP-004

## CDISC Registered Solutions Providers

### 1 Introduction

#### 1.1 Purpose

The purpose of this CDISC Operating Procedure is to describe the policy for qualifying and registering vendors and service providers who work with CDISC models.

#### 1.2 Background

The mission of CDISC is to develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare.

CDISC has developed standards for use in Clinical Research, and many organizations participating in data interchange activities have requested qualified assistance for implementing these standards for specific applications. Accordingly, CDISC has established a program for registering qualified consultants, system integrators, and subject matter experts who are believed by CDISC to have sufficient knowledge and experience implementing the various CDISC standards. These service providers will be recognized by CDISC as a CDISC “Registered CDISC Solutions Provider” (RSP).

For more information on CDISC objectives and principles, please see the CDISC website at [www.cdisc.org](http://www.cdisc.org).

#### 1.3 Authority

This document is approved by the CDISC President and should be followed by all CDISC Operations staff, team/project leaders, CDISC consultants and representatives, including volunteers participating in teams/projects or in user networks.

#### 1.4 References

The following information sources are referenced in this document:

- **CDISC Website:** [www.cdisc.org](http://www.cdisc.org)

### 2 Criteria and Requirements for CDISC Registered Solutions Providers

In order to become an RSP, a service provider must complete a registration form (Attachment 1) which must be reviewed and approved by the CDISC Technical Coordinating Committee, endorsed by at least one member of the CDISC Board of Directors, and meet the following minimum criteria:

- Adhere to all CDISC policies and procedures, including the CDISC Code of Conduct and Professional Ethics and the Intellectual Property Policy.
- Have a positive overall reputation for services in some aspect of clinical research

- Be Involved in CDISC as a sponsor, member, benefactor, associate, or active team participant
- Demonstrate expertise in one or more CDISC models, as evidenced in at least one of the following ways:
  - Completion of advanced, model-related activities or applications such as controlled testing of CDISC models or demonstrations.
  - Delivery of commercial products that are based substantially on CDISC Standards, have been recommended and reviewed by at least two CDISC Board or TCC members, and that have a copy of product documentation filed with the CDISC office.
  - Active participation on a modeling team for a period of at least one year with at least 75% attendance (as determined by team leaders), combined with a relevant and clearly defined service offering resulting from team participation.

The registration form must be updated annually. RSPs who are not in good standing or who have not kept registration forms up to date will be removed from the Registered Solution Providers list.

CDISC will publish a list of RSPs for each of the CDISC models. RSPs will need to demonstrate qualifications in each individual model area supported by CDISC.

CDISC believes that all RSPs are especially qualified to provide products or consulting services for projects related to CDISC models; however, CDISC does not express any warranty or guarantee any products or services provided by RSPs. Contract details (e.g., cost, timing) should be negotiated directly between the RSP and the customer.

### 3 Authorization

This document has been authorized by:

Date	Representation	Name
1 January 2006	CDISC President	Rebecca Kush

## 4 Attachment 1 – CDISC Registered Solutions Provider Application Form

Date	
Company Name	
Address	
Phone	
E-mail	
Website URL	
Company Contact	
Name of technical consultants or staff members with CDISC expertise (please e-mail CVs of all listed to swilliams@cdisc.org)	
Description of CDISC-related products or services offered (list the appropriate CDISC model supported in each case)	
Description and length of experience with CDISC models and related process areas: SDTM, ODM, LAB, ADaM, SEND OTHER	
Model(s) to which you are applying for (list all that apply)	
CDISC References (3 are preferred)	