
PHARMASTAT LLC



SAS Programmer – CDISC REQ'D – What Does This Mean and How to Be a Competitive Candidate

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San Diego CDISC Users Network

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TODAY

- How CDISC impacts programmer roles
- Types of CDISC programmer roles
- Based on one's current level of experience, opportunities for growth to increase one's contribution to their team and improve one's marketability

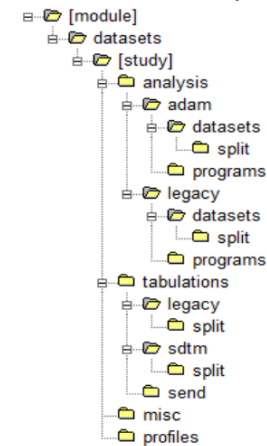
NEW DRUG APPLICATIONS (NDA)

Then



Now

Figure 1: Folder Structure for Study Datasets



DS (Disposition) DSCAT = PROTOCOL MILESTONE
INFORMED CONSENT DSTERM / DSDECOD = INFORMED CONSENT OBTAINED
Informed Consent Date
DM (Demographics) DSSTDTC
DEMOGRAPHICS RFICDTC
Birth Year BRTHDTC

	DOMAIN	USUBJID	VSSEQ	VSTESTCD	VSTEST	VSPOS	VSORRES	VSORRESU	VSSTRESC	VSSTRESH	VSSTRESU
12	VS	CDISC001	12	DIABP	Diastolic	SUPINE	68	mmHg	68		68 mmHg
13	VS	CDISC001	13	DIABP	Diastolic	STANDING	72	mmHg	72		72 mmHg
14	VS	CDISC001	14	DIABP	Diastolic	STANDING	68	mmHg	68		68 mmHg
15	VS	CDISC001	15	HEIGHT	Height		71.5	in	181.61		181.61 cm
16	VS	CDISC001	16	PULSE	Pulse Rat	STANDING	51	beats/min	51		51 beats/min
17	VS	CDISC001	17	PULSE	Pulse Rat	STANDING	50	beats/min	50		50 beats/min
18	VS	CDISC001	18	PULSE	Pulse Rat	STANDING	50	beats/min	50		50 beats/min

Table 14-3.01

Display	Table 14-3.01 [2 of 3] Primary Endpoint Analysis: ADAS-Cog - Summary at Week 24 - LOCF (Efficacy Population)
Analysis Result	Dose response analysis for ADAS-Cog changes from baseline
Analysis Parameter(s)	PARAMCD = "ACTOT" (Adas-Cog11) Subscore
Analysis Variable(s)	ADOSADAS.CHG (Change from Baseline)
Analysis Reason	SPECIFIED IN SAP
Analysis Purpose	PRIMARY OUTCOME MEASURE
Data References (incl. Selection Criteria)	ADOSADAS (PARAMCD = "ACTOT" and AVISIT = "Week 24" and EFFFL = "Y" and ANLO1FL = "Y")
Documentation	Linear model analysis of CHG for dose response; using randomized dose (0 for placebo; 54 for low dose; 81 for high dose) and site group in model. Used PROC GLM in SAS to produce p-value (from Type III SS for treatment dose). SAP Section 10.1.1 [4 of 9]
Programming Statements	[SAS version 9.2] proc glm data = ADOSADAS; where EFFFL="Y" and ANLO1FL="Y" and AVISIT="Week 24" and PARAMCD="ACTOT"; class SITEGR1; model CHG = DOSE * SITEGR1; run;

CDISC FOR PROGRAMMERS

Data Collection

- Data collection tools (CRFs)
CDASH

Tabulations Data

- SDTM for submission & analysis dataset source
- acrf.pdf
- define.xml
- csdrg.pdf

Analysis Data and Analysis

- ADaM for submission & TLF source
- define.xml
- Analysis results metadata
- adrg.pdf

WHAT DOES IT MEAN

- Because CDISC is so intertwined in a clinical/statistical programmers role, it's not a surprise that job postings list CDISC experience specifically. It's nearly impossible to avoid.
- But what does it really mean? What does this look like for programmers?

STANDARDS/CONCEPTS TO KNOW

- eCTD
- CDASH
- SDTM, SDTMIG
- TAUGs
- ADaM, ADaMIG
- Metadata Submission Guidelines
- Define.xml
- Reviewers Guides
- acrf.pdf
- Conformance

DOCUMENTS/CORRESPONDENCE

- FDA Guidances
- Implementation Guides (IGs)
- Metadata Guidelines
- Therapeutic Area User Guides (TAUGs)
- Data Standards Catalogs
- Controlled Terminology
- FDA Business Rules
- CDISC announcements
- Industry Templates and Completion Guidelines

IS THIS WHAT IS MEANT BY PROGRAMMER-CDISC REQ'D?!?!?!?

There is so much to know, does a programmer need to know it all?

GOOD NEWS

- It depends on
 - The position, role, company need
- If you don't know it all, you are still marketable and
there are ways to build on what you know

TYPES OF CDISC TASKS & ROLES

- Submission Strategy/Prepare Study Data Submission Plans
- End to end implementation of the standards and production of deliverables
- Subject matter expert
- Governance
- Project standards lead
- Program SDTM or ADaM based on specifications provided by a subject matter expert/team lead
- Use conformance validation tools to evaluate CDISC deliverables
- Quality control-program based on specifications + adhoc checks
- Program TLFs from ADaM or SDTM
- Programmatically or manually prepare SDTM define.xml content
- Prepare acrf.pdf based on SDTM database
- Prepare csdrg.pdf based on SDTM database
- Programmatically or manually prepare ADaM define.xml content
- Prepare adrg.pdf to support analysis datasets and analysis

WE ALL HAVE TO START SOMEWHERE

- There are so many opportunities to contribute and there are always opportunities to grow
- Resources to learn are plentiful

NEW PROGRAMMER OR PROGRAMMER WHO HAS NOT WORKED WITH CDISC

- Finds themselves still learning about the industry, mastering their programming skills, and may be hearing about and seeing CDISC for the first time.
- May be programming TLFs, ADaM, or SDTM from specifications written by someone else
- Level of responsibility and expectation to be a CDISC expert is low
- General understanding of standards may be high level and they know that rules need to be followed and that there are conformance validation tools to use (and their goal is just to minimize diagnostics :0/)
- May not understand their work in relation to other tasks
- This is a place that some programmers may want to stay – **low risk, low responsibility = safe** when you are not an expert who knows everything

PROGRAMMER WITH SOME CDISC EXPERIENCE

- Know about the industry and has a good handle on their programming skills
- Has worked on a number of projects that require submission standards deliverables and has provided support. They may be producing CDISC deliverables from specifications written by a more experienced analyst or SME or and SME is providing oversight.
- They feel pretty comfortable referencing CDISC documents such as the Implementation Guides and they can question or improve specification documents. They know some of the nuances and unwritten conventions.
- They can provide informed quality control comments for CDISC deliverables
- Level of responsibility and expectation to be a CDISC expert is medium
- This is a place that programmers struggle to define themselves **“I have experience but I wouldn’t say I’m an expert”**

EXPERIENCED CDISC IMPLEMENTER

- Good industry knowledge and understanding of CDISC and its role in regulatory submissions
- Has worked on a number of projects that require submission standards deliverables and has experience leading implementations.
 - Probably writes production and validation specification documents
 - Probably trains and/or provides oversight
 - Can quickly resolve conformance issues
 - Can tackle implementation challenges
 - Has a library of reference tools at their fingertips. They know many of the nuances and unwritten conventions
 - Probably hears “can I ask a quick question” quite a bit
- They can provide informed quality control comments for CDISC deliverables
- Level of responsibility and expectation to be a CDISC expert is high
- Can pretty confidently say **“my area of expertise in XX but I have a lot of experience in YY”**

CDISC SUPER IMPLEMENTER

- Multiple implementations. Possibly multiple indications and different versions of standards. Likely multiple phases of trials.
- Advanced understanding of the eCTD and regulatory submissions
- If standards governance team exists, participates in team
- SME for their organization in at least one area
- May or may not be a full time hands on programmer
- Often involved in process development
- Level of responsibility and expectation to be a CDISC expert is high
- Others often refer to them as the “Guru”

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- As we can see, *“SAS Programmer-CDISC Req’d”* can mean a number of things
 - What an employer is looking for and your programming and CDISC skill set will determine whether this is a match

Whatever stage of your CDISC journey, there are always opportunities to contribute and grow

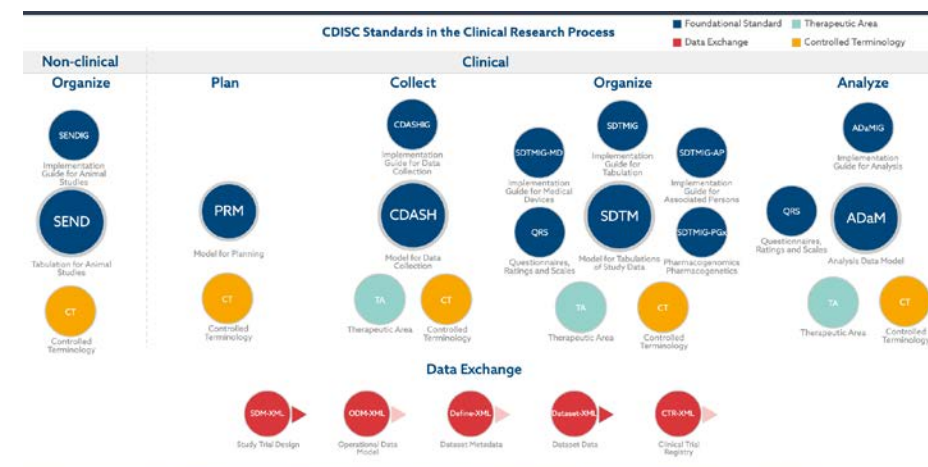
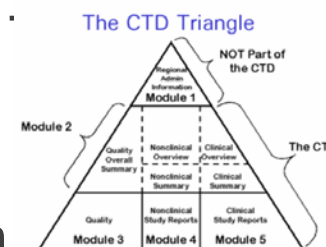
NEW PROGRAMMER OR PROGRAMMER WHO HAS NOT WORKED WITH CDISC

- Build your foundation

- Read or watch online presentations about the eCTD, CDISC, and CSR programming

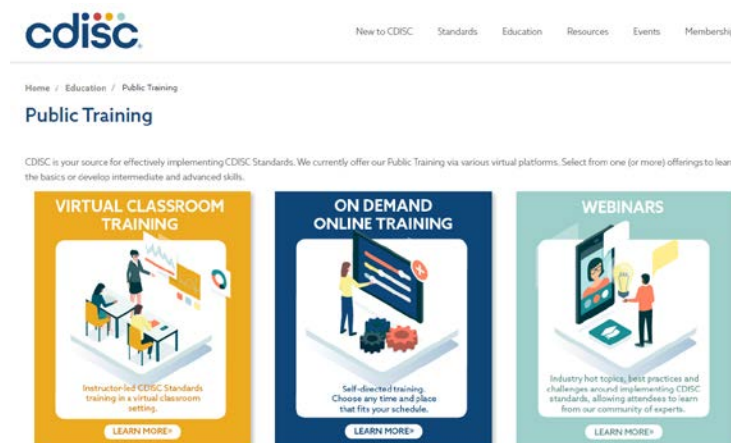
- The standards do not exist in a vacuum. They are part of a larger picture of data handling and representation for regulatory submissions. Having a firm understanding of the submission landscape will do several things

- 1) It will give you context for everything that you do
- 2) will influence good practices and decision making



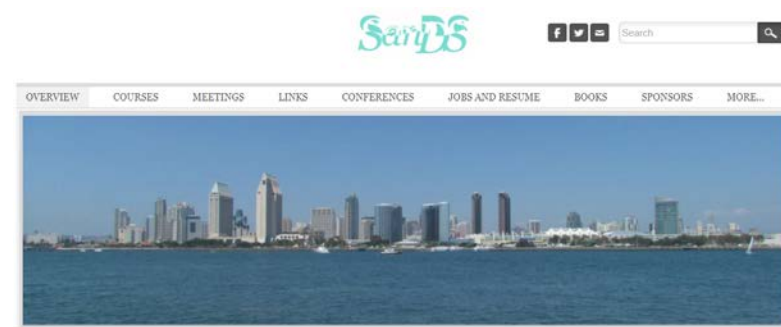
NEW PROGRAMMER OR PROGRAMMER WHO HAS NOT WORKED WITH CDISC

- Trainings
 - CDISC offered (individual or organization)
 - Choose topics at conferences that are CDISC related
 - Fortunately SAS conferences has tracks for data standards so you can focus on both SAS and CDISC as you keep building your programming skills (WUSS, PharmaSUG, etc.)
- Online trainings
 - If you are interested in SDTM, start reviewing topics from the CDISC Tabulate Exam Scope



NEW PROGRAMMER OR PROGRAMMER WHO HAS NOT WORKED WITH CDISC

- Network
 - Attend local users network events (SANDs, San Diego CDISC Users Network)
 - Join LinkedIn groups in your areas of interest. You will find posts and conversations about topics you may be interested in
- Find a mentor
 - Don't unnecessarily wade in the ocean alone
- Embrace opportunities
 - Try to touch as many things as possible
 - Present at local users group on small topics
 - Don't be scared



PROGRAMMER WITH SOME CDISC EXPERIENCE

- Keep building foundational understanding
 - Stay current on FDA Guidances, Technical Conformance Guide, Data Standards Catalog, and CDISC documents

Full description of column headings is given in Table 1 . Column Descriptions table. Rows with data models are in bold with blue font. Dependent programs (i.e., R, RStudio, Jupyter, etc.) are listed in the last column.											
	Study	Platform	OS	Language	Program	Request	Response	Request	Response	Request	Response
Clinical study	AD-M	APP	COSMIC	AD-M-H1	CERES, CERES	Replay				INTERVIEW 10	INTERVIEW 10
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Clinical study (AD-M)	AD-M	APP	COSMIC	AD-M-H1.3	CERES, CERES	Replay				INTERVIEW 10	INTERVIEW 10
AD-M	APP	COSMIC	AD-M-H1	CERES, CERES	Replay					INTERVIEW 10	INTERVIEW 10
AD-M	APP	COSMIC	AD-M-H1.0	CERES, CERES	Replay					INTERVIEW 10	INTERVIEW 10
Non-clinical study	AD-M	APP	COSMIC	AD-M-H1	CERES, CERES	Replay				INTERVIEW 10	INTERVIEW 10
Non-clinical study (AD-M)	AD-M	APP	COSMIC	AD-M-H1.0	CERES, CERES	Replay				INTERVIEW 10	INTERVIEW 10
Clinical study (AD-M)	AD-M	APP	COSMIC	AD-M-H1.1	CERES, CERES	Replay				INTERVIEW 10	INTERVIEW 10
Clinical study (AD-M)	AD-M	APP	COSMIC	AD-M-H1.2	CERES, CERES	Replay				INTERVIEW 10	INTERVIEW 10
Clinical study (AD-M)	AD-M	APP	COSMIC	AD-M-H1.3	CERES, CERES	Replay				INTERVIEW 10	INTERVIEW 10
AD-M	APP	COSMIC	AD-M-H1	CERES, CERES	Replay					INTERVIEW 10	INTERVIEW 10
AD-M	APP	COSMIC	AD-M-H1.0	CERES, CERES	Replay						



Analysis Data Model Implementation Guide

Version 1.3 (Final)

Providing Regulatory Submissions In Electronic Format — Standardized Study Data Guidance for Industry

- Offer to mentor or help train
 - Nothing will sharpen your understanding more than trying to explain to someone else
- Offer to lead or write specifications when you can
- Think of ways to improve your process or your company's processes

PROGRAMMER WITH SOME CDISC EXPERIENCE

- Trainings
 - CDISC offered (individual or organization)
 - Choose topics at conferences that are CDISC related or attend conferences that are more CDISC focused (CDISC Interchange)
 - Online trainings
- Present
 - Internally, at a local user group (SANDS, San Diego CDISC Users Network), and when you feel you are ready, at a large conference (write a paper). **Your struggles and experience can help others!**
 - If you are interested in SDTM, consider studying for the CDISC Tabulate Certification



EXPERIENCED CDISC IMPLEMENTER

- Keep building foundational understanding
 - Be familiar with FDA Guidance documents, Technical Conformance Guide, Data Standards Catalog
- Mentor
 - If you are the quiet type, mentor through templates and work instructions
- Take responsibility for specifications, processes and review of work products

EXPERIENCED CDISC IMPLEMENTER

- Trainings
 - Choose topics at conferences that are CDISC related or attend conferences and events that are more CDISC focused (CDISC Interchange)
 - Attend “What’s New?” online presentations
- If you are an SDTM implementer, consider working towards CDISC Tabulate Certification
- Present
 - Periodically present at local users events. Present at a large conference (write a paper).
- Attend and participate in PhUSE’s CSS. Join a working group
- Volunteer for a conference

CDISC SUPER IMPLEMENTER

- Do not get stagnant
 - Stay current on FDA Guidance documents, Technical Conformance Guide, Data Standards Catalog
 - Stay current on CDISC and FDA communications and initiatives
- MENTOR (someone probably mentored you)
- Be involved in process development, internal standards
- Write work instructions or SOPs
 - Participate in/recommend/lead governance

CDISC SUPER IMPLEMENTER



- If you are an SDTM implementer, get CDISC Tabulate Certified
- Present/Write Papers at larger conferences
- Attend and participate in PhUSE's CSS. Commit to a working group.
- Become a conference/user group executive committee member in your area of specialty

PROGRAMMER-CDISC REQ'D CAN MEAN ANY NUMBER OF THINGS SO...

New programmers or programmers who have not worked with CDISC

- Remember that it's a major learning curve for newer analysts but be encouraged that there are many resources and opportunities for your growth
- There are many different roles at different levels within companies. Be encouraged that as long as you are trying to improve using the various opportunities available to you, you can make a contribution and you will improve
- Don't be discouraged and don't undersell yourself

PROGRAMMER-CDISC REQ'D CAN MEAN ANY NUMBER OF THINGS SO...

Programmers with some CDISC experience

- Don't undersell yourself. You probably know a lot more than you think you do.
- Your learning curve is less steep however there is work to do for you to feel confident and to make your greatest impact
- Don't stop learning
- Share your knowledge

PROGRAMMER-CDISC REQ'D CAN MEAN ANY NUMBER OF THINGS SO...

EXPERIENCED CDISC IMPLEMENTERS

- Don't get complacent. Your value is both in your past experience as well as your ability to stay abreast of developments and adapt
- Share your experience and offer your talents to your current or future team
- With experience under your belt, you have the freedom to start broadening your experience

PROGRAMMER-CDISC REQ'D CAN MEAN ANY NUMBER OF THINGS SO...

CDISC SUPER IMPLEMENTER

- MENTOR !
- Make your mark. At your company and in the industry.
- Be an “influencer”

ALL PROGRAMMERS USING CDISC

- Get on e-mail the key distributions lists (CDISC, FDA, PhUSE)
- Join groups on LinkedIn with content of interest
- Attend conferences when possible
- Keep an eye out for online or single day events
- Keep in touch with your contacts and seek to meet new people
- Stay involved

THANK YOU

Micky Salgado-Gomez

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Founder of San Diego CDISC Users Network

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