

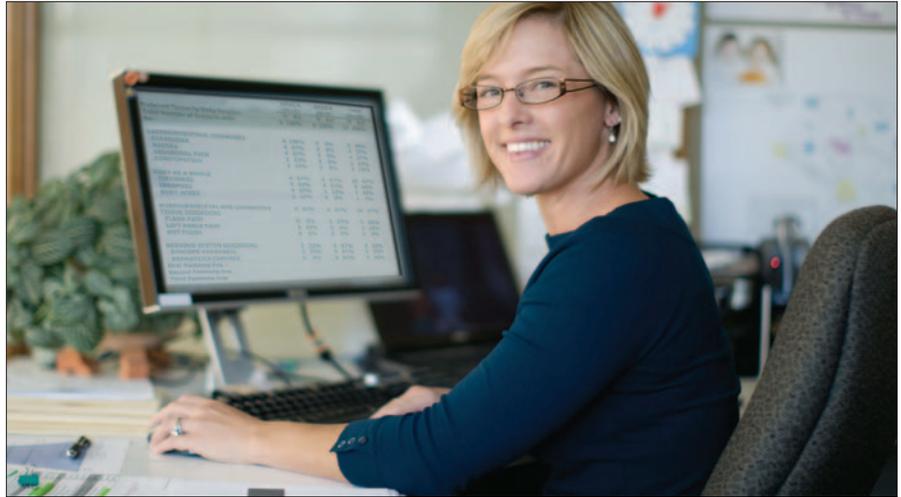


Technology | Consulting | Outsourcing

ClinPlus[®] Report

- Create high-quality statistical tables and listings
- An industry-proven authoring tool
- Ensure consistency across different programmers
- Extensive Template Library included
- Powerful CDISC/SDTM/ADaM conversion capability

Preferred Terms by Body System	DRUG A (N=6)		DRUG B (N=9)		-Total (N=15)	
	N	Pct	N	Pct	N	Pct
Total Number of Subjects with Ae	6	100%	9	100%	15	100%
GASTROINTESTINAL DISORDERS	6	100%	0	0%	6	40%
DIARRHOEA	4	67%	0	0%	4	27%
NAUSEA	4	67%	0	0%	4	27%
ABDOMINAL PAIN	2	33%	0	0%	2	13%
CONSTIPATION	2	33%	0	0%	2	13%
BODY AS A WHOLE	4	67%	6	67%	10	67%
TIREDFNESS	3	50%	6	67%	9	60%
INSOMNIA	4	67%	3	33%	7	47%
BODY ACHEs	1	17%	0	0%	1	7%
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	4	67%	6	67%	10	67%
FLANK PAIN	0	0%	6	67%	6	40%
LEFT ANKLE PAIN	2	33%	0	0%	2	13%
HOT FLUSH	0	0%	0	0%	0	0%
NERVOUS SYSTEM DISORDERS	2	33%	6	67%	8	53%
SYNCOPE VASOVAGAL	2	33%	6	67%	8	53%
DERMATITIS CONTACT	0	0%	6	67%	6	40%
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Second Footnote line						
Third Footnote line						



ClinPlus[®] Report

EXECUTIVE OVERVIEW

The goal of biostatisticians and clinical data managers is to implement consistent internal processes to monitor and maintain data management compliance. At the same time, along with medical writers and programmers, they must produce accurate and consistent statistical tables and listings. Because they operate in a demanding and ever-changing environment, they must accomplish their goals while struggling with the ambiguities of current regulations.

With the Clinical Data Interchange Standards Consortium (CDISC) setting out additional standards — the Study Data Tabulation Module (SDTM) and the Analysis Data Model (ADaM) — the situation becomes ever more daunting. However, adhering to and properly managing these data standards among workgroups, between departments and across the enterprise, can result in dramatic time-savings, increased productivity and earlier visibility to reliable clinical data.

DZS Software Solutions ClinPlus[®]

Report has emerged as the Industry's most widely-proven, SAS[®]-based, statistical table and listing authoring tool for creating the highest quality statistical tables and listings from any type of clinical data.

With unmatched versatility to create simple data listings as well as complex statistical summary tables, it has been adopted as a standard by over

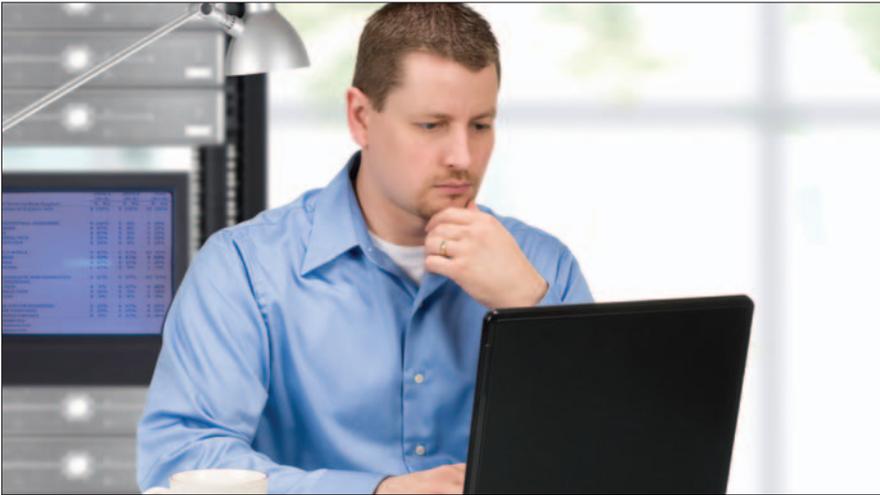
50 organizations, including most of the top ten pharmaceutical companies worldwide.

Our latest enhancement of the software, the **ClinPlus ADaM Data Conversion and Report Toolkit and Template Library**, is a powerful solution for generating safety tables and listings and providing supporting documentation in a validated, standardized CDISC/ADaM-compliant manner.

ADVERSE EVENTS TABLE

Preferred Terms by Body System	DRUG A (N=6)		DRUG B (N=9)		-Total (N=15)	
	N	Pct	N	Pct	N	Pct
Total Number of Subjects with Ae	6	100%	9	100%	15	100%
GASTROINTESTINAL DISORDERS	6	100%	0	0%	6	40%
DIARRHOEA	4	67%	0	0%	4	27%
NAUSEA	4	67%	0	0%	4	27%
ABDOMINAL PAIN	2	33%	0	0%	2	13%
CONSTIPATION	2	33%	0	0%	2	13%
BODY AS A WHOLE	4	67%	6	67%	10	67%
TIREDNESS	3	50%	6	67%	9	60%
INSOMNIA	4	67%	3	33%	7	47%
BODY ACHES	1	17%	0	0%	1	7%
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	4	67%	6	67%	10	67%
FLANK PAIN	0	0%	6	67%	6	40%
LEFT ANKLE PAIN	2	33%	0	0%	2	13%
HOT FLUSH	0	0%	0	0%	0	0%
NERVOUS SYSTEM DISORDERS	2	33%	6	67%	8	53%
SYNCOPE VASOVAGAL	2	33%	6	67%	8	53%
DERMATITIS CONTACT	0	0%	6	67%	6	40%
First Footnote line						
Second Footnote line						
Third Footnote line						

ClinPlus Report allows you to build tables easily and even combine incongruent information neatly and efficiently in the same table.



The system has three major components:

1 | **The Report Engine**, the foundation of the system, has been used by pharmaceutical companies in the U.S. and internationally since 1989. The Report engine does not rely on canned procedures such as Proc Report, Proc Tabulate or Proc Print, for report presentation. This eliminates many limitations inherent in those procedures while retaining complete reusability.

2 | **The Report GUI** (Graphical User Interface) provides point-and-click access to the Report Engine. This eliminates syntax errors and extends the system to a wide range of users. The Report GUI allows you to create and manage pure metadata templates that can be recalled, modified and used to create stand-alone SAS programs.

Other features, such as a global titles and footnotes library and format builder, are also included.

Many leading pharmaceutical companies are leveraging this capability in a post-marketing capacity to provide insight into drug safety and efficacy trends, and to track unusual values and other relationships within patient data.

3 | **The RTF Engine** is used to generate true RTF (Rich Text Format) tables for your final report without any modification. This proprietary engine, which does not rely on SAS's ODS, was designed with the complex formatting demands of medical writers in mind. A single RTF style sheet may be used for all data presentations.

*"Using **ClinPlus Report** has helped me, and my team produce quality reports in a short amount of time. The functionality and flexibility of **ClinPlus Report** is remarkable."*

— Raman Bassi, PhD, Senior Project Manager, ClinPro, Inc.

TABLE 33. DEMOGRAPHIC BASELINE STATISTICS FOR EACH TREATMENT GROUPS IN THE STUDY OF QYC-123

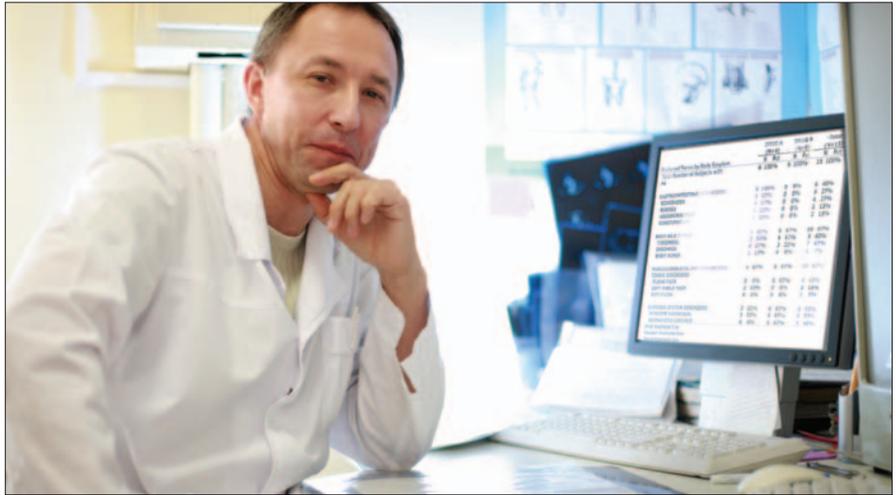
Variable	Total Pat#	Treatment Definition					
		XYZ Treatment ⁽¹⁾		ABC Treatment ⁽²⁾		All Treatments ⁽³⁾	
		Pat#	Rate (95% CI)	Cases*	Rate (95% CI)	Cases*	Rate (95% CI)
Total Cases(N)							
N	3,178	1,315	41.4% (0.12, 0.33)	823	0.000% (0.43, 0.61)	1,040	0.003% (0.31, 0.36)
Gender							
Male	2,091	642	30.7% (0.43, 0.77)	279	0.000% (0.66, 0.77)	764	0.002% (0.15, 0.25)
Female	1,087	673	61.9% (0.18, 0.22)	544	0.001% (0.34, 0.82)	376	0.004% (0.24, 0.35)
Age [Category]							
<30	795	423	78.4% (0.09, 0.11)	136	0.000% (0.11, 0.22)	316	0.001% (0.13, 0.15)
31-50	1,442	632	0.080% (0.56, 0.81)	357	0.000% (0.21, 0.31)	153	0.005% (0.14, 0.23)
>50	1,941	933	0.018% (0.16, 0.20)	556	0.001% (0.43, 0.55)	452	0.001% (0.01, 0.02)

⁽¹⁾ Treatment Definitions are based on the Study Protocol. XYZ Treatment is considered as Double Blind Drug AA administered as outpatient.

⁽²⁾ ABC Treatment is considered as Double Blind Drug BB administered in Clinics during visits of the Study three times a week intravenous route.

⁽³⁾ All Treatments column is a combination of XYZ and ABC Treatment events.

ClinPlus Report allows you to make style changes on any text within a table such as bolding, superscript, italic to highlight significant P-values.



"We have used **ClinPlus Report** for many years and it continues to make our work more productive. The technical support we received from DZS Software Solutions is excellent. They are very professional and the response is always quick and helpful."

— Jun Wang

Procter & Gamble Pharmaceuticals

ClinPlus Report allows you to:

1 Produce complex FDA-ready tables and listings with NDA quality

ClinPlus Report produces effective statistical tables, and utilizes over 70 different statistics across numerous SAS/STAT procedures.

You choose precision, group and class variables, sub-setting, or subtotals, you always have the final word in controlling the appearance of the table. **ClinPlus Report's** format control features assist in preparing any summary you want in any format you require.

DEMOGRAPHIC CHARACTERISTICS SUMMARY						
Protocol: XYZ123	Draft Demographic Characteristics Summary All Treated Subjects				Page: 1 of 1	
	DRUG A (N=57)	DRUG B (N=65)	DRUG C (N=16)	PLACEBO (N=62)	-Total (N=200)	P-values
Age	57	65	16	62	200	
MEAN	52.7	54.8	52.4	55.5	54.2	0.365
MEDIAN	55.0	55.0	57.0	58.0	55.5	
MIN MAX	[23 , 68]	[27 , 70]	[26 , 69]	[27 , 70]	[23 , 70]	
STANDARD DEVIATION	9.95	9.64	13.46	8.88	9.85	
<65	50 (88)	53 (82)	13 (81)	54 (87)	170 (85)	
>=65	7 (12)	12 (18)	3 (19)	8 (13)	30 (15)	
Sex (%)	57	65	16	62	200	
Male	37 (65)	36 (55)	10 (63)	47 (76)	130 (65)	0.118
Female	20 (35)	29 (45)	6 (38)	15 (24)	70 (35)	
Race (%)	57	65	16	62	200	
ASIAN/NOT PACIFIC ISLANDER	1 (2)	1 (2)	0	2 (3)	4 (2)	0.276
BLACK/AFRICAN AMERICAN	4 (7)	12 (18)	1 (6)	8 (13)	25 (13)	
OTHER: EAST INDIAN	0	1 (2)	1 (6)	0	2 (1)	
WHITE	52 (91)	51 (78)	14 (88)	52 (84)	169 (85)	
Ethnicity (%)	57	65	16	62	200	
HISPANIC/LATINO	5 (9)	7 (11)	2 (13)	1 (2)	15 (8)	0.186
NOT HISPANIC/LATINO	52 (91)	58 (89)	14 (88)	61 (98)	185 (93)	
Program Source: D:\Training\Demog.sas						04DEC08

Unlike any other authoring tool, ClinPlus Report allows you to stack and word wrap variables within columns, reducing page count yet retaining table integrity.

2 Standardize the appearance of your data

RTF (rich text format) is produced directly from **ClinPlus Report** for inclusion in word processing programs as native tables. Using RTF style sheets, you control font, point size, color, shading, border styles, etc., eliminating the need to reformat your tables in the final report. Titles and foot-

notes can appear in table cells and may contain RTF tags for Table of Contents (TOC) or in-line style changes such as single word bolding. Automatic bolding of significant p-values, separate style for group headings, fine tuning down to 1/100th on an inch for title and footnote alignment, are just a few features that set this system apart.



3 | Gain unrivaled flexibility with CDISC standardization —

Other report generation systems rely on a library of pre-designed templates, requiring your data structures to conform to their templates and potentially requiring additional programming. **ClinPlus Report** is designed with a different philosophy to be a true data-driven report authoring tool that can produce an endless variety of reports using any data structure, including the CDISC standard. Users need only specify the location of datasets, views and formats. In fact, **ClinPlus Report** is so flexible you can use it for marketing, financial or any other type of data analysis.

4 | Streamline table and listing production without sacrificing quality —

Generating tables and listings can be a costly and an extremely time-consuming undertaking. **ClinPlus Report** streamlines the process by enabling a broad range of users to produce identically formatted tables and listings without knowing the SAS programming language. The point-and-click user interface is easy to learn and operate, and provides immediate access to your data, significantly reducing the time it takes to create a table or listing.

5 | Customize tables and listings to suit your needs —

ClinPlus Report has many features to address the complex requirements of clinical reporting. Below are just some of the options that allow you to control:

- Inclusion/exclusion of columns, not present in the data
- The joining of categorical and continuous statistics within a single cell
- Decimal point alignment
- Text-wrapping on word boundaries
- Variable stacking within a column
- Multiple justification within a single title/footnote line
- Flexible page-numbering (n of tot, n (Last), etc.)
- Conditional footnotes
- Extensive page-handling intelligence and much more

6 | Create Customized Patient Profile Listings —

ClinPlus Report has additional applications within an organization and supports Data Management's QC requirements to produce random sample, patient profiles and clearly formatted summary information after database lock to ascertain accuracy.

"ClinPlus Report give the programmers another option for developing quick listings and summary tables. It is very easy for users to get used to ClinPlus Report after completing the training, and the customer support is second to none."

— Anonymous
Novartis Pharmaceuticals



MORE FROM CLINPLUS

ClinPlus also offers a complete range of support services to help you maximize your software investment and assure your success. Our dedicated staff average over 10 years experience in the clinical trials arena, and can provide immediate support in the following areas:

- Training
- Hosting
- Study Set-Up
- Screen Design
- Coding
- Template Design
- Table & Listing Design
- CDISC/ SDTM/ADaM Conversion
- SAS Programming

7 QC and Third-Party Execution — ClinPlus Report produces a separate executable SAS program containing only the SAS procedure code used when creating your table. When executed, it produces raw procedure output showing

your calculations as they appear in your table. This can be used for QC or documentation. All CPR programs are stand-alone SAS programs, and may be delivered to a third-party along with the Report Engine macro catalog for execution.

PATIENT PROFILE LISTING

1 02/23/09
 Q2S Software Solutions, Inc.
 Patient Profile Listing
 Center: 95 Patient Number: 9003
 Patient Initials=NVL Treatment=Placebo

Demographics

Visit Date	Age at Visit	Birth Date	Sex	Race
09/06/94	81	07/18/13	Female	CAUCASIAN

Medical History

Line No.	Body System	Description	Onset Year	Current Condition
1	OTHER BODY SYSTEM	INFECTION	30	NO
2	H.E.E.N.T.	TONSILLECTOMY	30	NO
3	GASTROINTESTINAL	APPENDECTOMY	40	NO
4	HEPATIC/BILIARY	CHOLESTECTOMY	56	NO
6	ENDOCRINE/METABOLIC	PARATHYROIDECTOMY	73	NO
7	GENITOURINARY	DILATION AND CURETTAGE	73	NO
8	RESPIRATORY	POSITIVE PPD	94	YES

Previous Meds

Med. No.	Med Name Preferred Name	Drug Code ATC Code	Dose Unit	Freq Route	Reason Specify	Start	End	Continue
1	INH ISONIAZID	0003021002 J04AC	300 MG	ONCE A DAY ORAL	CONCOMITANT DISEASE + PPD	5/24/94		YES
2	VITAMIN B6 B-KOMPLEX	00003501002 A11EA	50 MG	ONCE A DAY ORAL	CONCOMITANT DISEASE + PPD	5/24/94		YES
3	PREMARIN CREAM ESTROGENS CONJUGATED	00073001002 G03CA	1000 MG	OTHER OTHER	CONCOMITANT DISEASE MENOPAUSE	--/--/99		YES

ClinPlus Report has uses beyond just statistical tables and listings used in Clinical Study Reports. In QC, the software is often used to create random sample Patient Profiles Listings to check data quality before database lockdown.

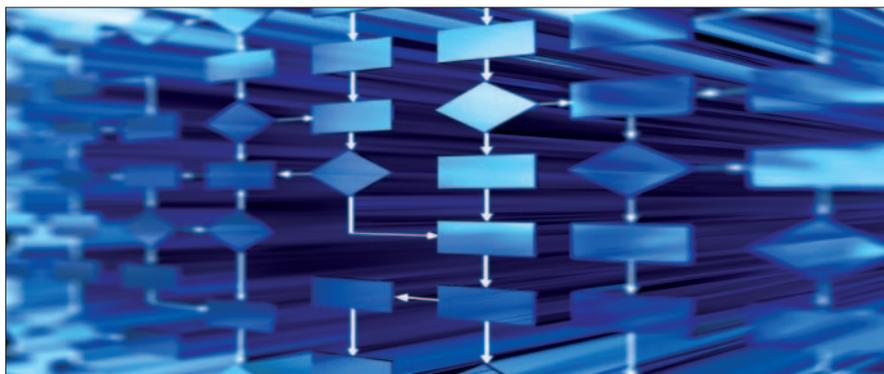
ADVERSE EVENT — ALL TREATED SUBJECTS

Protocol: CLIN001 Page: 1 of 91

DRAFT Adverse Event All Treated Subjects

Treatment Group: Drug A	Subject Id.	Period	Start Date	End Date	Body System or Organ Class	Ref. to SDr	Serious An
	Age/Sex	Visit	End Date	Preferred Term		Outcome	Severity
	Race	Study Day	Dur.(Years)				
CLIN001-006116	(52/M)	Baseline	29AUG2003	22MAY2196	GASTROINTESTINAL DISORDERS	Not Related	Not Serious
	White	-25	29AUG2003	22MAY2196	ABDOMINAL PAIN	Resolved	Mild
		Lead-in	29AUG2003	22MAY2196	NERVOUS SYSTEM DISORDERS	Not Related	Not Serious
		Visit 2	29AUG2003	22MAY2196	SYNCOPE VASOVAGAL	Resolved	Severe
		Double Blind	29AUG2003	22MAY2196	SKIN AND SUBCUTANEOUS TISSUE DISORDERS	Not Related	Not Serious
		10	29AUG2003	22MAY2196	SKIN DISORDERS	Resolved	Mild
		63	29AUG2003	22MAY2196	LIP DRY	Resolved	Mild
CLIN001-006315	(60/M)	Pre-RX	12DEC2003	22MAY2196	GASTROINTESTINAL DISORDERS	Not Related	Not Serious
	White	9	12DEC2003	22MAY2196	PHARYNGITIS STREPTOCOCCAL	Resolved	Mild
		Lead-in	12DEC2003	22MAY2196	INFECTIONS AND INFESTATIONS	Not Related	Not Serious
		Visit 1	12DEC2003	22MAY2196	PHARYNGITIS STREPTOCOCCAL	Resolved	Mild
		Double Blind	12DEC2003	22MAY2196	SKIN AND SUBCUTANEOUS TISSUE DISORDERS	Not Related	Not Serious
		9	12DEC2003	22MAY2196	SKIN CHAPPED	Resolved	Mild
		46	12DEC2003	22MAY2196	INFECTIONS AND INFESTATIONS	Not Related	Not Serious
		Follow-up	12DEC2003	22MAY2196	HERPES ZOSTER	Resolved	Mild
		14	12DEC2003	22MAY2196	HERPES ZOSTER	Resolved	Mild
		103	12DEC2003	22MAY2196	SKIN CHAPPED	Resolved	Mild
CLIN001-008818	(67/M)	Pre-RX	04FEB2004	22MAY2196	INFECTIONS AND INFESTATIONS	Not Likely	Not Serious
	White	5	04FEB2004	22MAY2196	GASTROENTERITIS	Resolved	Moderate
		44	04FEB2004	22MAY2196	INFECTIONS AND INFESTATIONS	Not Likely	Not Serious
		Visit 1	04FEB2004	22MAY2196	NASOPHARYNGITIS	Resolved	Mild
		11	04FEB2004	22MAY2196	NASOPHARYNGITIS	Resolved	Mild

ClinPlus Report provides multiple ways to sort and list data, word wrap data within columns, sequence columns and control logical groupings of data..



Converting SDTM to ADaM Using ClinPlus ADaM Data Conversion and Report Toolkit and Template Library

Adhering to CDISC standards has proven to facilitate efficient data integration and transport as well as access and review. Ideally, the FDA will want to perform analytic review using ADaM standards. Converting your SDTM data to ADaM data, and then to submission-ready tables, as well as accurately documenting the process, can present numerous challenges.

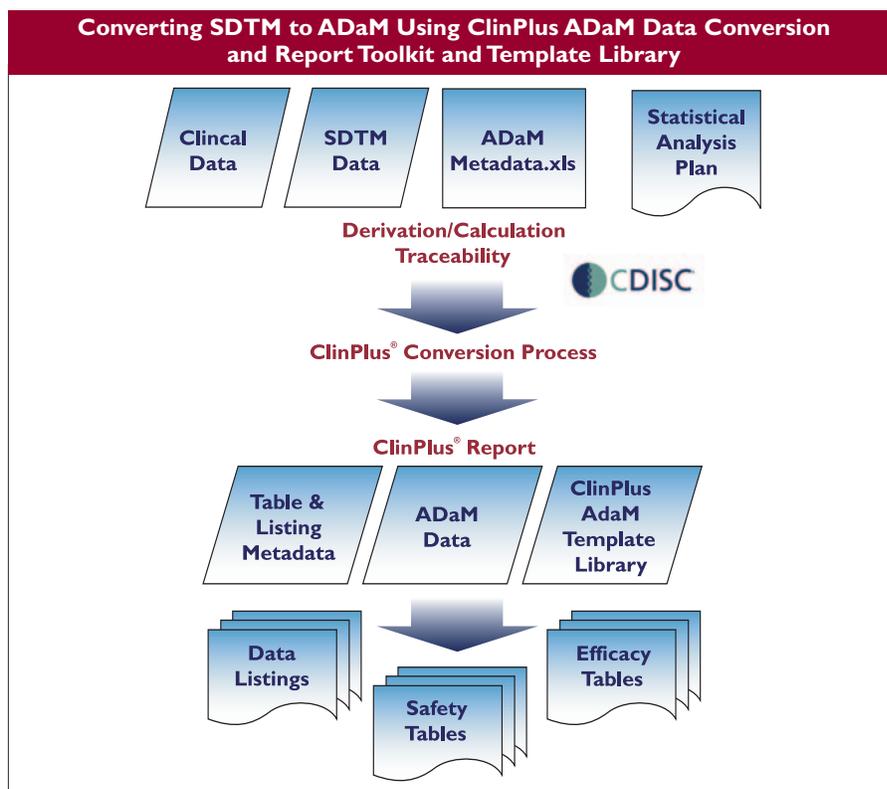
One of the primary challenges is providing reviewers with complete documentation with clear descriptions of the usage, structure, contents and attributes of all submitted datasets and variables.

A second challenge when creating tables and listings is to provide traceability as to how the ADaM datasets were derived or calculated. This process tracks each variable in the ADaM dataset back to its original source. CDISC specifications also indicate that any variables copied or derived from an SDTM domain into an ADaM dataset must retain the integrity of the data in the SDTM domain. This allows reviewers to replicate most analysis, tables, graphs and listings with minimal or no transformations and to enable them to easily view and subset the data used to generate any analysis, table, graph or listing without complex programming.

The final challenge is to produce and present in-text tables and data listings in a highly readable manner with consistent formatting from table-to-table and study-to-study.

To answer these challenges, DZS Software Solutions has enhanced **ClinPlus** Report with the **ClinPlus** ADaM Data Conversion and Report Toolkit and Template Library. This enhancement

responds to the needs for both metadata-driven conversion of SDTM data to ADaM data and the flexible production of metadata-driven safety tables and listings from the ADaM data. A complete library of more than 50 commonly used templates is provided, totally customizable for any other table needs. DZS also provides Custom Template Design services as required.



Let us help

DZS's professional staff of statistical programmers and trainers can assist your organization with consulting services, set-up of your standard template libraries, on-site training, the construction of new, custom templates, and final validation of your system. Our programmers have an average of 15 years of SAS programming experience in the pharmaceutical industry and are expert **ClinPlus Report** users. In addition to successfully supporting global implementations of **ClinPlus Report** for several top 10 pharmaceutical companies, we provide world-class customer care to organizations of all sizes.

Flexible Delivery Methods —

ClinPlus Report can be easily implemented, getting you up and running quickly, whether you decide to purchase the software, lease it or have DZS do the work for you. We also provide complete validation scripts or perform the validation for you.

Your decision is easy! — **ClinPlus**

Report is simply the most flexible and powerful statistical table and listing production system available in the industry today. Your organization will realize dramatic cost-savings benefits in T&L development, Quality Control and final report assembly time. Reports generated with **ClinPlus Report** promise to be consistent, of superior quality and based on your standards, even across disparate programmers. And you will benefit from the peace of mind that comes with knowing the reports you deliver were produced using a validated product and will be totally CDISC-compliant when transported to eventual NDA, eCTD, NeeS and any other marketing authorization applications.

To see for yourself why so many major pharmaceutical companies, biotech, medical device manufacturers and CROs have adopted **ClinPlus Report** as their standard, contact us today, or visit our website, www.clinplus.com.



About DZS Software Solutions, Inc.

DZS Software Solutions, Inc.

(www.clinplus.com) is a privately held company founded in 1996 providing clinical trials software for clinical data management and analysis to the biotech and pharmaceutical industry worldwide. Over 50 clients globally presently use **ClinPlus** software for data collection and capture, data cleansing, coding, analysis, clinical trial management and reporting. When the software is coupled with DZS services and training, many **ClinPlus** clients have dramatically improved productivity and maximized the value of clinical research investments and gained a competitive advantage to get medicines and products to market faster.

The **ClinPlus Software Solutions Suite for Clinical Trials** provides premium tools required by pharmaceutical companies, contract research organizations

(CROs), biotech, and medical device manufacturers to expedite clinical trials and meet the strict data formatting requirements of the FDA and other global regulatory agencies.

The **ClinPlus Software Solutions Suite's** unmatched cost-of-entry, scalability, flexible delivery options and exceptional training and support have gained DZS a reputation for delivering exacting quality and helping clients achieve early visibility to reliable clinical data.

DZS software engineers possess decades of statistical analysis, clinical data management, and ADE/Drug coding and table/list/report building experience.

This real-world experience is incorporated into every **ClinPlus** system design and is evident in the reliability and enhanced features found in all.



DZS Software Solutions, Inc.
+1 732.764.6969

For more information please visit:
www.clinplus.com



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