



AdClin Reporting System™

01 Navigator / 02 Table Production Framework / 03 Report Builder



Streamlining the process from programming and statistics to medical writing

AdClin Reporting System™ software has been carefully designed to allow programmers, statisticians, medical writers and physicians to integrate their work and to stay in tune with their business objectives.

Freeing users from constraints due to database structures and underlying tools

Whatever the database structure and the complexity of required reporting tables, AdClin Reporting System™ frees users to only spend their time on the true semantic, value-added part of their job.

Matching the requirements of various users in the organization, thanks to its modular architecture:

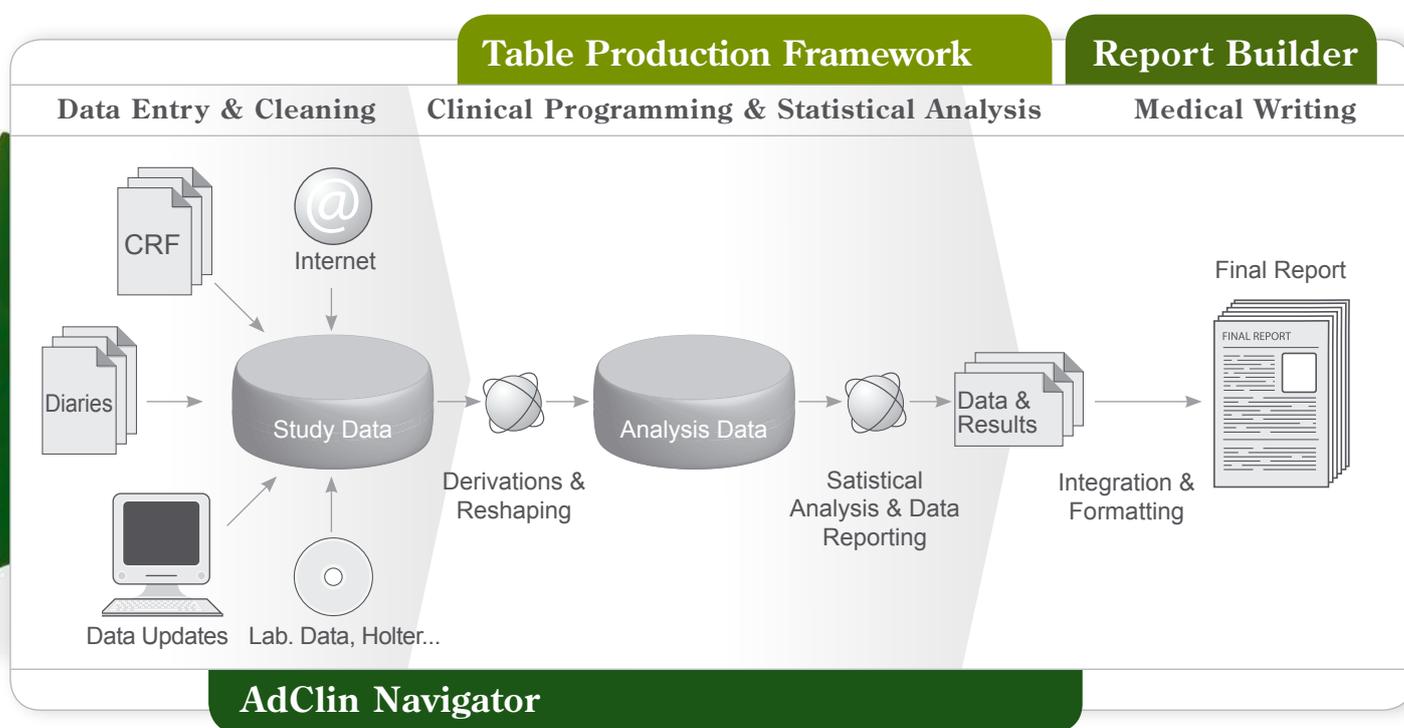
- > **AdClin Navigator™**, to instantly view and navigate SAS® clinical databases, making information just a click away.
- > **AdClin Table Production Framework™**, a unique SAS®-based productivity framework that produces 100% of summary tables and data listings.
- > **AdClin Report Builder™**, an innovative tool automating the integration of tables and listings into Word documents.



AdClin Reporting System™

A new generation software tool maximizing the efficiency and security of clinical data reporting.

AdClin Reporting System™ is based on an innovative approach not bound to underlying tools limitations, **designed to match the whole process for producing clinical reports**. The results are great improvements of productivity, quality and validation, allowing users to stay focused on their business objectives.



Easy Data Access: AdClin Navigator™ provides instant and comfortable data access, while AdClin Table Production Framework™ allows generating easily any kind of table or listing, that are then easily integrated into reports thanks to AdClin Report Builder™.

Increased Productivity: Lengthy manual operations are reduced to a few mouse clicks, and daunting programs turned into concise and safe macro invocations.

Better Validation: Data otherwise concealed in SAS® databases can be made available to all professionals involved in the clinical trial, regardless of their technical skills, and shorter programs make validation much faster.

Easy Integration: All modules integrate seamlessly into any existing process, can be rolled out extremely quickly, and are immediately usable and productive.

AdClin Reporting System™

AdClin Navigator™

AdClin Navigator™ is a point-and-click, user-friendly tool to navigate clinical databases for both non-technical users and SAS® experts.

Thanks to the use of industry-standard, well known, feature-rich Microsoft Excel® interface, AdClin Navigator™ is the tool of choice to easily access and navigate clinical data in various situations:

Physicians

Clinical data concealed in SAS® databases becomes accessible and readable by all the non-technical staff in a few clicks, avoiding lengthy and inflexible printed data listings.

Blind Reviews

Attached to a video projector, AdClin Navigator™ makes blind reviews more attractive and consistent: instant access to readable data allows rapid and easy exchange of information.

Programming

Instant access to datasets, variables and formats, easy filtering give optimal understanding of the data and reduces the risk of programming errors.

Quality Control

Data from a third-party can be reviewed and validated very easily, tracking related data in a few mouse clicks.

Adverse events are only a click away from related concomitant medications

Subid	AENO	Serious	AETerm	Sev	Rel	AES	D	OnGoing	AEE	D	Death
1	102	1	0 VERTIGO FEELING	1	0	14-Feb-00		0	18-Feb-00		
2	102	2	0 HEADACHE	2	0	14-Feb-00		0	18-Feb-00		
3	104	1	0 ACUTE BRONCHITIS	1	0	18					
4	104	1	0 VERTIGO FEELING	1	0	30					
5	104	2	0 HEADACHE	1	0	18					
6	104	3	0 HEADACHE	1	0	18					
7	106	1	0 HEADACHE	2	0	30					
8	106	2	0 ACUTE BRONCHITIS	1	0	14					
9	108	1	0 VERTIGO FEELING	1	0	14					

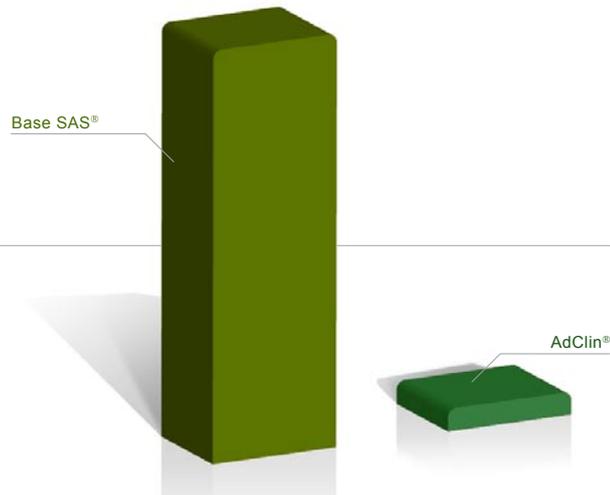
AdClin Reporting System™

AdClin Table Production Framework™

A unique productivity framework based on SAS®, allowing clinical programmers to easily, securely and effectively produce tables in the exact way they are needed.

AdClin Table Production Framework™ inherited from AdClin's advanced vision and in-depth understanding of clinical business process and requirements. It frees programmers and statisticians from SAS® limitations, and helps them stay focused on their business objectives.

Typical volume of code



Key benefits

Productive and Secure: because it allows a dramatic decrease of the amount of code needed to produce listings and tables, programs are both written and validated much more quickly.

Exhaustive Scope, Environment-Neutral: it allows producing any kind of data listing and summary table, regardless of input data structure, output layout, and customer reporting process.

Usable and Evolving: its functional and technical design makes it quick to deploy, immediately usable, and at the same time open to the most various improvements, and to the evolution of standards (e.g., XML).

AdClin Reporting System™

AdClin Table Production Framework™

Unique Features

Independence versus the input data structure: changing from “vertical” to “horizontal” input shape or vice-versa just involves tuning the notation used to access the data, not preprocessing it.

Reporting data from various datasets together requires no more than specifying where the data should be taken (automatic and safe “merge” of datasets).

Ability to include any kind of statistical result computed by the user together with or in lieu of the statistics and results computed by the product.

Ability to compute any kind of percentage (any kind of denominator) without any preprocessing.

Table 12.2 Demographic Characteristics

	Treatment A N=7	Treatment B N=7	All N=14
Sex			
Male	4 (57.1%)	6 (85.7%)	10 (71.4%)
Female	3 (42.9%)	1 (14.3%)	4 (28.6%)
Age (Years)			
N	7	7	14
Mean (Std)	70.3 (6.07)	68.7 (14.19)	69.5 (10.52)
Median	70.0	66.0	69.5
Min / Max	59 / 77	53 / 88	53 / 88
Race			
Caucasian	5 (71.4%)	6 (85.7%)	11 (78.6%)
Black	2 (28.6%)	0 (0.0%)	2 (14.3%)
Asian	0 (0.0%)	0 (0.0%)	0 (0.0%)
Other	0 (0.0%)	1 (14.3%)	1 (7.1%)

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Other	0 (0.0%)	1 (14.3%)	1 (7.1%)

Table presentation is controlled outside of programs to easily match corporate standards

Subject Counts	Placebo	100 µg	300 µg	Subtotal	All
	N=10	N=22	N=16	N=160	N=200
33 (77.8%)	43 (69.4%)	68 (68.4%)	111 (69.4%)	143 (71.0%)	
Any Event	8 (20.0%)	10 (45.5%)	22 (22.4%)	32 (20.0%)	40 (20.0%)
Any Peritriptin Incidence > Placebo	8 (20.0%)	11 (17.7%)	20 (20.4%)	31 (19.4%)	39 (19.5%)
Nervous System Disorders	4 (10.0%)	3 (4.9%)	17 (17.2%)	24 (15.0%)	18 (9.0%)
Gastrointestinal Disorders	5 (12.5%)	1 (4.5%)	8 (8.2%)	14 (8.8%)	11 (5.5%)
Respiratory, Thoracic and Mediastinal Disorders	2 (5.0%)	1 (4.5%)	0 (0.0%)	3 (1.9%)	3 (1.5%)
General Disorders and Administration Site Conditions	0 (0.0%)	2 (2.2%)	4 (4.1%)	6 (3.8%)	4 (2.0%)
Cardiac Disorders	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Hematology and Hematology Disorders	1 (2.5%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.5%)
Immune System Disorders	0 (0.0%)	1 (4.5%)	2 (2.0%)	3 (1.9%)	3 (1.5%)
Renal and Urinary Disorders	0 (0.0%)	1 (4.5%)	0 (0.0%)	1 (0.6%)	1 (0.5%)
Neoplasms Benign, Malignant and Unspecified	1 (2.5%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.5%)
Reproductive System and Breast Disorders	0 (0.0%)	1 (4.5%)	1 (1.0%)	2 (1.2%)	2 (1.0%)
Ear and Labyrinthine Disorders	0 (0.0%)	1 (4.5%)	0 (0.0%)	1 (0.6%)	1 (0.5%)
Surgical and Medical Procedures	1 (2.5%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.5%)
Conjunctival, Fungal and Genetic Disorders	0 (0.0%)	1 (4.5%)	0 (0.0%)	1 (0.6%)	1 (0.5%)
Eye Disorders	0 (0.0%)	1 (4.5%)	0 (0.0%)	1 (0.6%)	1 (0.5%)
Hypertension	1 (2.5%)	0 (0.0%)	0 (0.0%)	1 (0.6%)	1 (0.5%)
All Peritriptin Incidences < Placebo	18 (45.0%)	24 (68.2%)	33 (33.7%)	57 (35.6%)	75 (37.5%)
Infections and Infestations	2 (5.0%)	11 (17.7%)	22 (22.4%)	35 (21.6%)	42 (21.0%)
Psychiatric Disorders	1 (2.5%)	3 (4.9%)	8 (8.2%)	12 (7.5%)	15 (7.5%)
Musculoskeletal and Connective Tissue Disorders	2 (5.0%)	3 (4.9%)	4 (4.1%)	9 (5.6%)	8 (4.0%)
Skin and Subcutaneous Tissue Disorders	2 (5.0%)	3 (4.9%)	4 (4.1%)	9 (5.6%)	10 (5.0%)
Injury, Poisoning and Procedural Complications	1 (2.5%)	2 (2.2%)	0 (0.0%)	3 (1.9%)	3 (1.5%)
Vascular Disorders	1 (2.5%)	1 (4.5%)	1 (1.0%)	3 (1.9%)	3 (1.5%)
Investigations	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

All listings and tables available for review using an Internet browser

AdClin Reporting System™

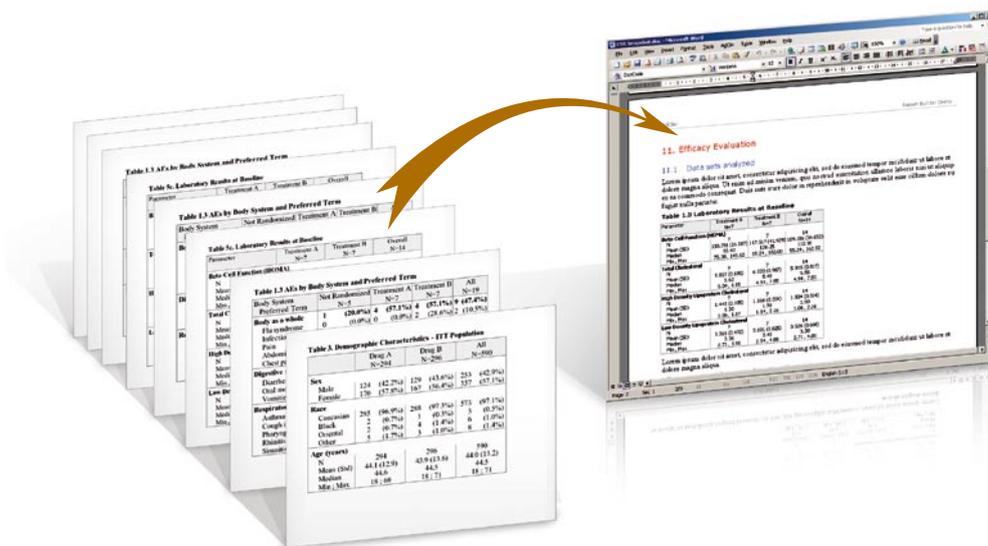
AdClin Report Builder™

AdClin Report Builder™ allows instant inclusion and formatting of any number of tables and listings into submission-ready documents.

AdClin Report Builder™ has been designed to dramatically reduce the workload associated with including tables and listings into clinical study reports.

Fully automated, it provides state-of-the-art quality assurance, as results need not be manually reformatted (or even worse, retyped) into documents.

Thanks to its simple, point-and-click interface, AdClin Report Builder™ brings an unmatched comfort of use for creating high quality documents.



Tedious manual pasting of tables in clinical study reports is over

Unique Features

Mass integration of all tables and listings in Word documents, at their final location, with one mouse click.

Easy switch to landscape of tables or listings that do not fit in portrait.

Automatic and fully customizable pagination of tables and listings.

Advanced features such as automatic bookmarking for cross-references or instant renumbering.

Requirements:
SAS® version 8.2 or later, BASE and STAT modules

AdClin® / Smart Clinical Software™

Since 1999, AdClin has provided the pharmaceutical industry with innovative clinical data software products and services which dramatically increase both productivity and compliance to 21 CFR Part 11, thus safely shortening time to market.

Addressing the Needs of Pharmaceutical Companies and CROs

AdClin was founded to provide answers in identified areas where there is room for significant improvements through adequate productivity tools.

To date, AdClin has been providing two innovative clinical data software product suites matching the business needs of renowned pharmaceutical companies and CROs:

- > AdClin Reporting System™, streamlining the overall clinical data reporting process.
- > AdClin Study Normalizer™, easily converting multiple databases to CDISC-compliant format.

Key References

Sanofi-Aventis, Fournier Pharma, Orphan Europe, Sanofi-Pasteur, Centelion, Novartis, MDS Pharma Services, MAPI Group, Guerbet Group, L'Oréal.



AdClin SA - 11, rue des Petites Ecuries / F-75010 Paris, France
Phone +33 1 56 82 03 00 - Fax: +33 1 56 82 03 09
<http://www.adclin.com> / Email: sales@adclin.com

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