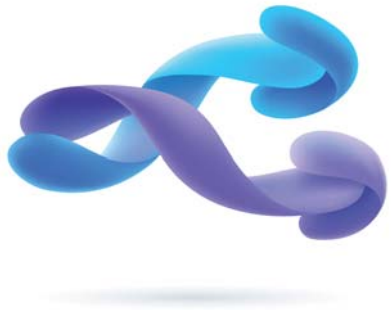
AdClin® **SDTM/ADaM**
Data Conversion Solution



New Challenges for Clinical Data Submission

Today, clinical data must be submitted to the FDA using standards developed by CDISC®: SDTM and ADaM. These standards allow the FDA to easily integrate the received data into its review and analysis system, thus becoming for any laboratory an unavoidable prerequisite to access its target market.

Therefore, laboratories face new challenges: integrating conversion towards SDTM/ADaM models into their existing processes, while maintaining maximum productivity; avoiding possible information loss or alteration during the data transformation phase.

AdClin: A Unique Expertise in CDISC® Standards

In order to face these challenges, AdClin offers pharmaceutical laboratories a unique know-how along two major lines of action:

- **A data conversion service,** with the creation of SDTM/ADaM packages.
- **A consultancy service,** tackling current processes and CDISC® standard conformity requirements, along with a **support service** to define and deploy new processes, thanks to innovative methods and tailored tools.

Conversion Service
to SDTM/ADaM Standards

SDTM/ADaM Package Creation

Thanks to its well known expertise and its unparalleled quality of service, AdClin offers high performance conversion to CDISC® formats:

Mapping to SDTM/ADaM standards, annotated CRFs, .xpt file generation from SDTM/ADaM definitions, define.xml and define.pdf file creation, validation of data and define files (OpenCDISC®, AdClin), creation of the reviewer's guide, pooling of studies for ISS/ISE.

Knowledge at the Service of Strategic Plans

Thanks to ten years of experience in clinical data standardization for major players in the pharmaceutical industry, AdClin can apply its expertise to strategic projects: quickly converting significant volumes of legacy studies, or efficiently creating SDTM/ADaM submission packages (notably for pivotal studies).

Our proactivity allows us **upstream identification of potential problems** caused by an inadequate definition of target standards, thus guaranteeing delivery of the best possible results, and on schedule.

In addition, our pioneering methods and tools allow total control over the data transformation process, resulting in **optimal traceability from the original data to their target format**.

Consultancy and Support Service
for the Deployment of CDISC® Standards

Are You in Compliance with the FDA's Expectations?

How do you incorporate the activity of conversion to SDTM/ADaM models into your operations? Can these standards be easily interfaced to existing tools and methods, or will they require more extensive reorganization? At which operational stage should they be incorporated in order to respect the FDA's current and future requirements?

Making the Best Possible Decisions

AdClin's unique experience in the transformation of data into well-defined or adjustable models enables us to help you make the best decisions:

- By analyzing the discrepancy between your current processes and those you should put in place in the face of CDISC® and FDA requirements.
- By setting out the different solutions that will allow you to comply with these requirements first in the short term, and then in the longer term.

Deployment of Suitable Procedures and Software

Finally, AdClin can advise you on putting in place a **work environment including, light, powerful and inexpensive computer tools**, and innovative work procedures. Easy to deploy and user-friendly, this environment will deliver **significant data processing productivity and quality gains**: version control software for traceability, integration server, various tools to work faster with SAS®, etc.

AdClin
The Data Experts

AdClin has standardized and centralized more than a hundred studies for various pharmaceutical companies. We have notably converted pivotal studies to SDTM/ ADaM formats, which were subsequently approved by the FDA.

Other AdClin solutions include:

- **AdClin Table Production Framework™** - software allowing easy production of statistical tables and listings with SAS®.
- **AdClin Report Builder™** - a tool enabling automatic integration and pagination of tables and graphics in Microsoft Word™.
- **AdClin SEM™** - a work environment including software and procedures, allowing productivity gains and improved traceability in data processing.
- High added value **ad-hoc programming**, and custom **consulting services.**

AdClin is an active member of **CDISC®**. Our clients include major companies like **Sanofi**, **Pierre Fabre**, **L'Oréal**, **Parexel** or **BNP Paribas**.

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