



**DRUG DEVELOPMENT
SOLUTIONS**

Alliance Pharma, Inc.

Data Management

We are experienced in supporting a variety of data management requests, tailoring services to our client's needs.

This ranges from providing datasets directly from Watson LIMS™, to supplying SDTM/SEND conforming files. Our team of data management specialists work collaboratively with our bioanalysis teams and our clients. They provide expert advice on the setup of Data Transfer Specifications, to ensure that data is formatted according to our client's needs.

All data manipulations and data transfers follow our Standard Operating Procedures (SOPs). Comprehensive quality control checks ensure that data integrity and data quality is maintained throughout the life-cycle of the data.

Direct export from Watson LIMS™

Bioanalytical datasets generated by Drug Development Solutions are provided as a direct export from the validated LIMS, Watson™, without any further transformations. This can support fast, results driven, decision making.

Watson LIMS™ exported data contains information used to track and identify a sample throughout the analytical lifecycle. This includes subject/animal ID, time-point, treatment, with the associated data value and units, providing traceability and confidence in data reporting.

SDTM/SEND standards

Data is processed using specialist software to apply the format and content requirements relevant to the SDTM or SEND standards.

Example datasets are available for both direct Watson exports and SDTM/SEND data standards.

Specialist software tools

Specialist software may also be used to provide customised data content and formats. This can minimise downstream processing and may include:

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| » Incorporation of externally provided data with data originating from Drug Development Solutions | » Formatting of Watson LIMS™ or TK/PK data to bespoke requirements |
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SAS® software is used for its reproducible and extensive data transformation capabilities, including the incorporation of externally provided data such as sample demographics (e.g. collection dates and times). It is also used to provide SAS format datasets and submission ready formats (SAS transport files).

Certara Phoenix WinNonlin® may also be used as an end to end solution for the management of Toxicokinetic (TK), Pharmacokinetic (PK) and anti-drug antibody (ADA) datasets.

Technical specifications and service levels

Service lead	Fast turnaround compatible	Customisable	Demographics compatible	Submission compatible	Supported formats		
					Excel (.xls, .xlsx)	ASCII (.csv, .txt, .dat)	SAS (.sas7bdat, .xpt)
Watson LIMS™ export*	✓	✓			✓	✓	
Specialist software		✓	✓		✓	✓	✓
SDTM/SEND standard			✓	✓	✓	✓	✓

*Customisable applies only to data captured and available in LIMS™.

SDTM and SEND standards

SDTM and SEND standardised formats provide a streamlined method for sharing and receiving data from multiple contributors, across studies and study components. Drug Development Solutions offers support for the compilation of our high quality bioanalytical and PK/TK data to SDTM or SEND standards.

- » Pharmacokinetics Concentrations (PC)
- » Pharmacokinetics Parameters (PP)
- » Laboratory Test Results (LB)
- » Immunogenicity (LB/IS)
- » Related Records (RELREC), Pooling (POOLDEF), Comments (CO) as required

In addition

- » Drug Development Solutions provides information for the compilation of Define files and the Study Data Reviewer's Guide for the accurate use and interpretation of SDTM/SEND datasets
- » Pinnacle21 Community software is used to validate conformance to SDTM/SEND data standards

Dataset formats

Multiple output formats are supported to meet our client's needs. These include:

- » Excel and ASCII files allow for easy access without the need for specialist viewing software
- » SAS datasets and transport files capture descriptor information such as data types and lengths, contributing to the build of submission datasets

Data transfers

Datasets are typically transferred by email using a password protected and zipped folder.

We also operate File Tray, a SharePoint based service, which allows us to share files with our clients and external partners. This service supports shared access to files within the site, controlled by user name and password. The information is also encrypted, ensuring the security of the information. Use of third party systems (including FTP) are also supported.

Let's discuss your project:

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