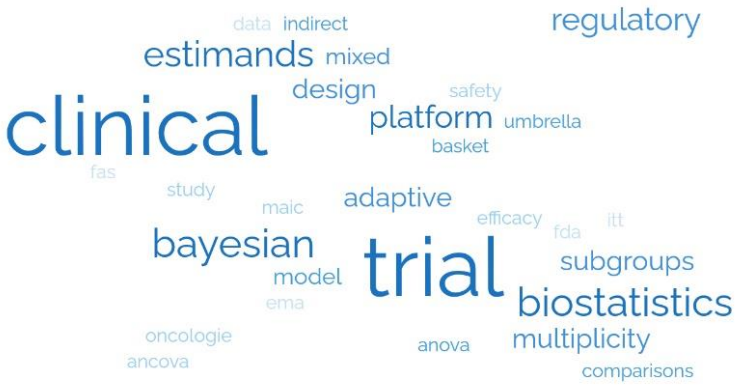


Training Catalog 2025

Data Management Methodology and Statistics

CATALOG 2025

METHODOLOGY AND STATISTICS

1-2025 BIOSTATISTICS AND METHODOLOGY FOR CRITICAL READING OF ARTICLES

2-2025 ESTIMANDS (ICHE9-Add) – In theory and practice

3-2025 MIXED LINEAR MODELS -Theory and Application on R and/or SAS

4-2025 SURVIVAL ANALYSIS IN CLINICAL STUDIES

5-2025 INTRODUCTION TO BAYESIAN STATISTICS

6-2025 INTRODUCTION TO ADAPTIVE METHODS

7-2025 ONCOLOGY PHASE I TRIAL METHODOLOGY

8-2025 INDIRECT COMPARISONS -Theory and Application on R and/or SAS

9-2025 REGULATORY BIOSTATISTICS – Review of EMA/FDA guidelines

10-2025 PERSONALIZED MEDICINE, SUBGROUPS AND BIOMARKER-DRIVEN TRIALS

11-2025 QUANTITATIVE DECISION MAKING (QDM)

12-2025 HANDLING MISSING DATA IN CLINICAL TRIALS

13-2025 DRUG BENEFIT-RISK ASSESSMENT (BRA)

14-2025 MULTI-REGIONAL CLINICAL TRIALS

15-2025 USE OF HISTORICAL / EXTERNAL DATA IN CLINICAL TRIALS

16-2025 CAUSAL INFERENCE IN CLINICAL TRIALS

DATA MANAGEMENT

17-2025 UNDERSTANDING CLINICAL DATA MANAGEMENT: FROM COLLECTION TO DATA SUBMISSION

18-2025 DEMYSTIFYING CDISC: A PRACTICAL INTRODUCTION TO CDASH AND SDTM STANDARDS

1-2025 BIOSTATISTICS AND METHODOLOGY FOR CRITICAL READING OF ARTICLES

OBJECTIVES

Gain a comprehensive yet accurate understanding of clinical trial methodology
Knowing the key issues and possible solutions during statistical analysis
Knowing how to quickly assess the methodological quality of a published article

TARGET AUDIENCE / PREREQUISITES

Clinical Project Managers, Researchers, Regulators, Medical Directors
General knowledge of clinical trials.

DURATION / LOCATION

1 day (7 hours) / Paris, Lyon or in-house
Accessibility PSH: contact us in case of disability or potential difficulty

REGISTRATIONS

Registrations possible up to one week before the scheduled training date

PROGRAM *For in-house training, the program can be tailored to meet your needs*

Introduction to Clinical Trials

- Presentation of the various reference documents (ICHE9, EMA Guidelines, FDA)
- Review of the content of key documents and processes : CRF, Blind-review report, SAP
- Why stats in clinical trials?

Review of the main methodological points

- Methodology of comparative superiority and non-inferiority trials, difference between the two, notion of 95%CI and role of the confidence interval versus p-value.
- Role and definition of populations (ITT, FAS, Per Protocol, Safety Set)

Calculating the number of patients – The power of a study

- How to define the assumptions needed to calculate a sample size
- Alpha risk, beta risk, calculation and understanding of the notion of power of a study

Review of the main statistical methods

- Presentation of the main statistical models and tests (t-test, chi2, Wilcoxon, logistic regression, ANCOVA, MMRM, Kaplan-Meyer model)
- Difference between a test and a model, introduction of covariates
- Awareness of the problems of missing data and multiplicity (why should we no longer use LOCF! Why choose a main criterion? what about subgroup analyses)

Practical Application – Critical Review of Clinical Articles

1h30 of practical application to implement the knowledge acquired during the day
The articles can be chosen in relation to the interests of the participants (therapeutic areas, phases)

PEDAGOGICAL, TECHNICAL AND SUPERVISORY RESOURCES

Classroom training session, PDF of the presentation given at the beginning of the training. Alternation of theoretical and practical presentations, interactive exchanges between the participants and the trainer. The training will be provided by Maeva Dupuis, methodologist.

FOLLOW-UP AND EVALUATION

Before/after knowledge assessment, training certificate, satisfaction questionnaire.

CONTACT

formation@exystat.com, maeva@mdstatconsulting.fr

2-2025 ESTIMANDS (ICHE9-Add) – In theory and practice

OBJECTIVES

Understanding the concept of estimand, its interest and its application
Being able to write a synopsis or a clinical study protocol using estimates
Knowing and anticipating regulatory expectations (EMA and FDA)

DURATION / LOCATION

1 day (7 hours) / Paris, Lyon or intra-company
Accessibility PSH: contact us in case of disability or potential difficulty

REGISTRATIONS

Registrations possible up to one week before the scheduled training date

TARGET AUDIENCE / PREREQUISITES

Clinical Project Managers – Biostatisticians – Possibility of pairing (20% discount) – 1 clinician + 1 biostatistician / General knowledge of phase 2-3 clinical trials

PROGRAM *For in-house training, the program can be tailored to meet your needs*

Regulatory context

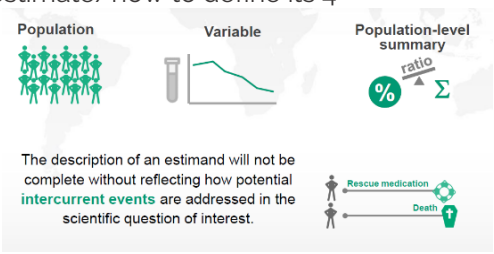
- Presentation of the various reference documents (ICHE9, EMA Guidelines, FDA)
- Guideline and estimand concept: Why this novelty?

State of the art Pre-Estimand

- Review of Population Definitions (FAS/PP) – Role, Interest, Limitations
- Data gaps: review of existing recommendations.
- Why the increasing complexity of methods has reached its limits and does not solve the problems

The estimand in theory

- Presentation of the content of the guideline (what is an estimate/how to define its 4 attributes)
- Role and definition of sensitivity analyses
- Interest of the approach



Estimands in practice – Working in small groups

A specific time for practical application in groups on the writing of synopses of clinical studies will be planned to apply the guideline.

PEDAGOGICAL, TECHNICAL AND SUPERVISORY RESOURCES

Classroom training session, PDF of the presentation given at the beginning of the training. The feedback sessions will be an opportunity to exchange, ask questions and dig into certain complicated points (for example, the management of intercurrent events).

FOLLOW-UP AND EVALUATION

Before/after knowledge assessment, training certificate, satisfaction questionnaire.

CONTACT

formation@exystat.com, maeva@mdstatconsulting.fr

3-2025 MIXED LINEAR MODELS -Theory and Application on R and/or SAS

OBJECTIVES

Know the theoretical basis of mixed models and know how to implement it on the R software (and/or SAS), and in particular:
- Understand the differences between a fixed-effects model and a random-effects or mixed-effects model, know how to choose a model adapted to your data.

TARGET AUDIENCE

Statisticians, students or staff working on statistical studies

PREREQUISITE

Good basics in statistics, mastery of linear models, ANOVA, ANCOVA, and basic statistical tests. Regular use of statistical software (R preferred)

DURATION/LOCATION

2 days in person (2 pm) / eXYSTAT, 4 rue Ernest Renan 92240 MALAKOFF
Accessibility PSH: contact us in case of disability or potential difficulty

REGISTRATIONS

Registrations possible up to one week before the scheduled training date

PROGRAM *For in-house training, the program can be tailored to meet your needs*

Each theoretical part will be followed by a practical part of applying the theory under R. The R software and the Rstudio interface are used for importing, manipulating data, and writing models. The corresponding orders under SAS will be discussed

Reminders about linear models with fixed effects:

- Linear models: linear regression, ANOVA, ANCOVA,
- Generalized linear models

Linear mixed models

- Theoretical presentation of the model (matrix writing, parameter estimation methods) and examples. Interpretation of the parameters of the mixed model.
- Selection of variables in the mixed model, comparison of several fixed-effect and/or random-effect models.
- Analysis of longitudinal or "repeated-measures" data: contribution of mixed models, different covariance structures
- Hierarchical or multi-level data analysis: hierarchical effect models

Mixed nonlinear models

- Extension to generalized models
- Model constructions and interpretation of mixed model parameters
- Commands and interpretation in R

PEDAGOGICAL, TECHNICAL AND SUPERVISORY RESOURCES

Classroom training session, PDF of the presentation given at the end of the training. Alternation of theoretical and practical presentations, interactive exchanges between the participants and the trainer.

FOLLOW-UP AND EVALUATION

Training certificate, satisfaction questionnaire

CONTACT

formation@exystat.com,

4-2025 SURVIVAL ANALYSIS IN CLINICAL STUDIES

OBJECTIVES

Appropriate survival analysis methods with applications in clinical research. Know how to manipulate, analyze and interpret data as part of a survival analysis.

TARGET AUDIENCE

Statisticians in clinical research or epidemiology

PREREQUISITE

Basics of statistics

DURATION / LOCATION

2 days in person (2 pm) / eXYSTAT, 4 rue Ernest Renan 92240 MALAKOFF
Accessibility PSH: contact us in case of disability or potential difficulty

REGISTRATIONS

Registrations possible up to one week before the scheduled training date

PROGRAM *For in-house training, the program can be tailored to meet your needs*

Efficacy criteria in oncology
Survival data

- Terminology
- Notion of Censorship
- Survival curve: Kaplan Meier's method
- Comparison of survival curves: Log-rank test
- Cox proportional hazard model
- Proportionality of risks and its consequences

Introduction to recurrent events (Pisces, Binomial negative)
Practical exercises under SAS (and initiation under R)

PEDAGOGICAL, TECHNICAL AND SUPERVISORY RESOURCES

Classroom training session. Alternation of presentations, discussions with the trainer and between participants. Provision of educational documentation. The training will be provided by Mr François MONTESTRUC, statistician and teacher of the "Survival Analysis" module of the Master 2 Mathematical Engineering of the University of Paris V.

FOLLOW-UP AND EVALUATION

Compulsory attendance (attendance sheet), evaluation by MCQ, training certificate, satisfaction questionnaire

CONTACT

formation@exystat.com, francois.montestruc@exystat.com

5-2025 INTRODUCTION TO BAYESIAN STATISTICS

OBJECTIVES

Explore Bayesian statistics and learn how it differs from frequentist approaches
Build confidence in applying the key principles of Bayesian analysis

TARGET AUDIENCE/ PREREQUISITE

Statisticians in the field of clinical trials

DURATION/LOCATION

2 days (14 hours) / France (in-house orpublic training)
Accessibility for persons with disabilities: contact us in case of disability or potential difficulties

REGISTRATIONS

Up to one week before the scheduled training date

PROGRAM

For in-house training, the program can be tailored to meet your needs

Introduction

- Bayesian thinking
- Bayesian vs Frequentist
- Probabilities: reminder

Prior Elicitation

Inference

- Bayes Factor
- Predictive Probability
- Credibility interval

MCMC Methods (Monte Carlo Markov Chains)

- Gibbs sampler
- Metropolis-Hasting algorithm
- Hamiltonian Monte Carlo

Practical examples and applications

- Using R or SAS

PEDAGOGICAL, TECHNICAL AND SUPERVISORY RESOURCES

Classroom training session, slides (.pdf) of the presentation provided at the beginning of the session. The course alternates between theoretical lectures and practical exercises, with interactive discussions between participants and the trainer.
The training will be provided by Laure Montané, Biostatistician and Methodologist.

FOLLOW-UP AND EVALUATION

Training certificate, satisfaction questionnaire

CONTACT

formation@exystat.com, lmontane@oxalis-statconsulting.com

6-2025 INTRODUCTION TO ADAPTIVE METHODS

OBJECTIVES

Gain the methodological foundations needed to understand and effectively apply adaptive methods.

TARGET AUDIENCE / PREREQUISITE

Statisticians in the field of clinical trials with experience using R

DURATION / LOCATION

2 days (14 hours) / France (in-house orpublic training)
Accessibility for persons with disabilities: contact us in case of disability or potential difficulties

REGISTRATIONS

Up to one week before the scheduled training date

PROGRAM

For in-house training, the program can be tailored to meet your needs

Each theory section will be followed by a practical session applying the concepts in R.

Introduction

- Definitions
- Pros and Cons
- Regulator's view
- Guidelines (EMA/FDA) and DMC

Methodology

- General considerations
- Multiplicity

RCommon adaptive designs

- Group Sequential Designs
- Sample Size Reassessment
- Adaptive Enrichment designs
- Adaptive Randomization
- MAMS/ Seamless

Case study

PEDAGOGICAL, TECHNICAL AND SUPERVISORY RESOURCES

Classroom training session, slides (.pdf) of the presentation provided at the beginning of the session. The course alternates between theoretical lectures and practical exercises, with interactive discussions between participants and the trainer. The training will be provided by Laure Montané, Biostatistician and Methodologist.

FOLLOW-UP AND EVALUATION

Training certificate, satisfaction questionnaire

CONTACT

formation@exystat.com, lmontane@oxalis-statconsulting.com

7-2025 ONCOLOGY PHASE I TRIAL METHODOLOGY

OBJECTIVES

Understand the specific features of Phase I oncology trials and the associated methodologies

TARGET AUDIENCE / PREREQUISITE

Statisticians in the field of clinical trials, with basic knowledge of phase I trials

DURATION / LOCATION

1 day (7 hours) / France (in-house or public trainings)
Accessibility for persons with disabilities: please contact us in case of disability or potential difficulties

REGISTRATIONS

Registrations available up to one week before the scheduled training date

PROGRAM

For in-house training, the program can be tailored to meet your needs

Introduction

- Phase I, specificities and limitations in oncology
- Definitions: DLT, MTD, RP2D...

Single Agent Escalation Methods

- Rule based methods: 3+3, accelerated titration
- Model based methods: CRM, titeCRM, EWOC, BLRM
- Interval based methods : mTPI, keyboard, BOIN, i3+3
- Comparison of the methods and recommendations

Phase I-II designs

- MTD vs OBD
- Optimus project
- Efficacy/Toxicity Models
- Assisted designs : BOIN12, U-BOIN

PEDAGOGICAL, TECHNICAL AND SUPERVISORY RESOURCES

Classroom training session, slides (.pdf) of the presentation provided at the beginning of the session.
The course alternates between theoretical lectures and practical exercises, with interactive discussions between participants and the trainer.
The training will be provided by Laure Montané, Biostatistician and Methodologist.

FOLLOW-UP AND EVALUATION

Training certificate, satisfaction questionnaire.

CONTACT

formation@exystat.com, lmontane@oxalis-statconsulting.com

8-2025 INDIRECT COMPARISONS -Theory and Application on R and/or SAS

OBJECTIVES

To know the theoretical basis of indirect comparisons and their applications and to know how to implement them on the R software (and/or SAS), and in particular:
- Understand the differences between indirect comparison methods.
- Know the most common functions in R/SAS to make indirect comparisons

TARGET AUDIENCE

Statisticians, students or staff working on statistical studies

PREREQUISITE

Good foundation in statistics and epidemiology, proficiency in propensity scores and basic statistical tests. Regular use of statistical software (R or SAS)

DURATION / LOCATION

1 day in person (7h) / eXYSTAT, 4 rue Ernest Renan 92240 MALAKOFF
Accessibility PSH: contact us in case of disability or potential difficulty

REGISTRATIONS

Registrations possible up to one week before the scheduled training date

PROGRAM *For in-house training, the program can be tailored to meet your needs*

Each theoretical part will be followed by a practical part of the application of the theory under R or SAS. The R software and the Rstudio interface are used for importing, manipulating data, and writing models. The corresponding orders under SAS will be mentioned.

Definition of Indirect Comparisons:

- Direct, indirect or mixed comparison
- Form of indirect comparisons (anchored unanchored)
- Propensity Score and ESS
- Meta Analysis (Principle and Application)

Network meta-analysis (NMA)

- General idea
- Classification of NMAs
- Steps to follow and presentation of the results
- Hypothesis Testing
- Published Examples and Exercises

Matching adjustment indirect comparison (MAIC)

- General idea
- Population reweighting and estimation
- Published Examples and Exercises

PEDAGOGICAL, TECHNICAL AND SUPERVISORY RESOURCES

Theoretical and practical approach, participatory and interactive method. PDF Training Material.

FOLLOW-UP AND EVALUATION

Training certificate, satisfaction questionnaire

CONTACT

formation@exystat.com, francois.montestruc@exystat.com

9-2025 REGULATORY BIOSTATISTICS – Review of EMA/FDA guidelines

OBJECTIVES

Acquire a good knowledge of international methodological guidelines to promote exchanges with agencies (FDA/EMA). To know the key issues and possible solutions during the statistical analysis of a pivotal study. Anticipate questions.

TARGET AUDIENCE / PREREQUISITES

CRO or biotech biostatisticians with a few years of experience

DURATION / LOCATION

1 day (7h) / intra-company
Accessibility PSH: contact us in case of disability or potential difficulty

PROGRAM *For in-house training, the program can be tailored to meet your needs*

Choice of 2 workshops among the 5 below.

REGISTRATIONS

Registrations possible up to one week before the scheduled training date

INTRODUCTION

- Background (pivotal dossiers, confirmatory trials, Europe/FDA)
- Presentation of the EMA website, where and how to find the methodology guidelines but also the guidelines specific to each therapeutic area

Workshop 1 – BASELINE COVARIATES

- Reference article 1 – "Subgroup analyses and other misuses of baseline data..."
- Discussions around the issue: baseline comparisons, choice of endpoints (raw value or change from baseline?), choice of covariates, stratification and link with randomization
- ***Guideline on Adjustment for Baseline Covariates (EMA-2015)*** – point-by-point review, discussion, consolidation/ ***Adjusting for covariates in RCTs (FDA-2021***)

Workshop 2 – MULTIPLICITY

- ***Point to consider on Multiplicity issues (EMA-2002)*** – point-by-point review, discussion
- Presentation of the main adjustment methods, practical cases: Hierarchical method, Hochberg, Dunnett, FDR - Case of co-primary endpoints, case of secondary endpoints.
- Problem specific to intermediate analyses (adaptive design).

Workshop 3 – MISSING DATA

- Problem of missing data – Recent developments, link with Estimands
- ***Guideline on missing data in confirmatory clinical trials (EMA-2010) – point-by-point*** review, discussion/**NAS Report FDA (2010)** - discussion - Examples of methods and interpretation, sensitivity analyses, Tipping point.

Workshop 4 – INVESTIGATION OF SUBGROUPS

- ***Guideline on the investigation of subgroups in confirmatory clinical trials (EMA - 2019)*** – point-by-point review, discussion, consolidation
- Should we do analyses in subgroups? If so, which ones, for what purpose and how to present them?

Workshop 5 – ESTIMANDS

- Introduction to Estimands – Links and evolutions in relation to the guidelines discussed.
- Why and How to Use Estimates - Practical applications based on a synopsis of a real protocol: Defining Intercurrent Events / Knowing the 5 strategies for their consideration in the definition of an Estimand.

PEDAGOGICAL, TECHNICAL AND SUPERVISORY RESOURCES

Theoretical and practical approach, participatory and interactive method. PDF Training Material.

FOLLOW-UP AND EVALUATION

Training certificate, satisfaction questionnaire

CONTACT

formation@exystat.com maeva@mdstatconsulting.fr

10-2025 PERSONALIZED MEDICINE, SUBGROUPS AND BIOMARKER-DRIVEN TRIALS

OBJECTIVES

Acquiring expertise in statistical methods and trial designs for subgroup detection and the implementation of biomarker-driven clinical trials

TARGET AUDIENCE / PREREQUISITES

Statisticians in the field of clinical trials

DURATION / LOCATION

2 days / France (in-house or public trainings)
Accessibility for persons with disabilities: please contact us in case of disability or potential difficulties

REGISTRATIONS

Registrations available up to one week before the scheduled training date

PROGRAM *For in-house training, the program can be tailored to meet your needs*

Subgroup identification

- Predefined vs adaptive cutoffs
- Continuous vs categorical biomarkers
- Statistical methods for cutoff selection and subgroup identification (e.g. SIDES)
- Treatment effect estimation
- Sample size considerations

Trial design strategies

- Based on the stage of the development
- Based on the level of confidence in the biomarker

Regulatory perspective

Practical examples and applications

- Using R

PEDAGOGICAL, TECHNICAL, AND SUPERVISORY RESOURCES

Classroom training session, slides (.pdf) of the presentation provided at the beginning of the session. The course alternates between theoretical lectures and practical exercises, with interactive discussions between participants and the trainer.
The training will be provided by statistical methodologists from SARYGA.

FOLLOW-UP AND EVALUATION

Training certificate, satisfaction questionnaire.

CONTACT

formation@exystat.com, gaelle.saint-hilary@saryga.com

11-2025 QUANTITATIVE DECISION MAKING (QDM)

OBJECTIVES

Acquiring expertise in statistical methods for evidence-based decision-making in clinical development

TARGET AUDIENCE / PREREQUISITES

Statisticians in the field of clinical trials

DURATION / LOCATION

2 days / France (in-house or public trainings)
Accessibility for persons with disabilities: please contact us in case of disability or potential difficulties

REGISTRATIONS

Registrations available up to one week before the scheduled training date

PROGRAM *For in-house training, the program can be tailored to meet your needs*

Probabilities of Success
- Posterior Probability of Success
- Predictive Probability of Success aka Assurance

Expert elicitation
- Overview of different approaches
- Focus on the Sheffield Elicitation Framework (SHELF)

Quantitative decision-making frameworks (Go / No-Go / Consider)
- Hypothesis testing and QDM framework
- One criterion, three outcomes QDM frameworks
- Two criteria, three outcomes QDM frameworks
- Operating characteristics
- More complex settings

Practical examples and applications
- Using R

PEDAGOGICAL, TECHNICAL, AND SUPERVISORY RESOURCES

Classroom training session, slides (.pdf) of the presentation provided at the beginning of the session.
The course alternates between theoretical lectures and practical exercises, with interactive discussions between participants and the trainer.
The training will be provided by statistical methodologists from SARYGA.

FOLLOW-UP AND EVALUATION

Training certificate, satisfaction questionnaire.

CONTACT

formation@exystat.com, gaelle.saint-hilary@saryga.com

12-2025 HANDLING MISSING DATA IN CLINICAL TRIALS

OBJECTIVES

Acquiring expertise in statistical techniques for dealing with missing data in clinical trials

TARGET AUDIENCE / PREREQUISITES

Statisticians in the field of clinical trials

DURATION / LOCATION

1 day / France (in-house or public trainings)
Accessibility for persons with disabilities: please contact us in case of disability or potential difficulties

REGISTRATIONS

Registrations available up to one week before the scheduled training date

PROGRAM *For in-house training, the program can be tailored to meet your needs*

Types of missing data
- MCAR, MAR, MNAR

Imputation methods and sensitivity analyses
- Classical methods: (Modified) Complete-Case Analysis, Last Observation Carried Forward (LOCF), Worst Value Imputation, Unconditional/Conditional Mean Imputation
- Principles of Multiple Imputation: Joint Modeling (JM), Fully Conditional Specification (FCS)
- Rubin's rules

Regulatory guidelines

Practical examples and applications
- Using R

PEDAGOGICAL, TECHNICAL, AND SUPERVISORY RESOURCES

Classroom training session, slides (.pdf) of the presentation provided at the beginning of the session.
The course alternates between theoretical lectures and practical exercises, with interactive discussions between participants and the trainer.
The training will be provided by statistical methodologists from SARYGA.

FOLLOW-UP AND EVALUATION

Training certificate, satisfaction questionnaire.

CONTACT

formation@exystat.com, gaelle.saint-hilary@saryga.com

13-2025 DRUG BENEFIT-RISK ASSESSMENT (BRA)

OBJECTIVES

Acquiring expertise in methodologies for evaluating benefit-risk trade-offs in drug development

TARGET AUDIENCE / PREREQUISITES

Statisticians in the field of clinical trials

DURATION / LOCATION

1 day / France (in-house or public trainings)
Accessibility for persons with disabilities: please contact us in case of disability or potential difficulties

REGISTRATIONS

Registrations available up to one week before the scheduled training date

PROGRAM *For in-house training, the program can be tailored to meet your needs*

Qualitative assessment: structured frameworks for drug benefit-risk assessment

- Define key Benefits and Risks
- Summary of treatment performance for each criterion

Quantitative approaches

- Standardization of performance across criteria on a common scale
- Integration of criterion importance through weighting
- Multi-Criteria Decision Analysis (MCDA)
    - Linear or non-linear model
    - Consideration of uncertainty in the assessment

Operational considerations

Practical examples and applications

- Using R

PEDAGOGICAL, TECHNICAL, AND SUPERVISORY RESOURCES

Classroom training session, slides (.pdf) of the presentation provided at the beginning of the session.
The course alternates between theoretical lectures and practical exercises, with interactive discussions between participants and the trainer.
The training will be provided by statistical methodologists from SARYGA.

FOLLOW-UP AND EVALUATION

Training certificate, satisfaction questionnaire.

CONTACT

formation@exystat.com, gaelle.saint-hilary@saryga.com

14-2025 MULTI-REGIONAL CLINICAL TRIALS

OBJECTIVES

Overview of the statistical and regulatory considerations involved in the design and analysis of Multi-Regional Clinical Trials (MRCTs)

TARGET AUDIENCE / PREREQUISITES

Statisticians in the field of clinical trials

DURATION / LOCATION

1 day / France (in-house or public trainings)
Accessibility for persons with disabilities: please contact us in case of disability or potential difficulties

REGISTRATIONS

Registrations available up to one week before the scheduled training date

PROGRAM *For in-house training, the program can be tailored to meet your needs*

Regulatory guidelines and requirements
Models and sample size considerations
Quantifying regional treatment effects
Assessing consistency of treatments effects

- Shrinkage estimators, local consistency assessments

Special case of treatment effect consistency and sample size calculation for Japanese patients in MRCTs (PMDA requirements)
Practical examples and applications

- Using R

PEDAGOGICAL, TECHNICAL, AND SUPERVISORY RESOURCES

Classroom training session, slides (.pdf) of the presentation provided at the beginning of the session.
The course alternates between theoretical lectures and practical exercises, with interactive discussions between participants and the trainer.
The training will be provided by statistical methodologists from SARYGA.

FOLLOW-UP AND EVALUATION

Training certificate, satisfaction questionnaire.

CONTACT

formation@exystat.com, gaelle.saint-hilary@saryga.com

15-2025 USE OF HISTORICAL / EXTERNAL DATA IN CLINICAL TRIALS

OBJECTIVES

Acquiring expertise in methodologies for integrating historical or external data into clinical trials in a robust manner, and learn from examples of their application in practice

TARGET AUDIENCE / PREREQUISITES

Statisticians in the field of clinical trials. Knowledge of Bayesian statistics is desirable.

DURATION / LOCATION

2 days / France (in-house or public trainings)
Accessibility for persons with disabilities: please contact us in case of disability or potential difficulties

REGISTRATIONS

Registrations available up to one week before the scheduled training date

PROGRAM *For in-house training, the program can be tailored to meet your needs*

General principles of historical / external data borrowing
Dynamic Bayesian borrowing approaches
- Meta-analytic predictive (MAP) model
- Robustification for dynamic borrowing
- Design planning, operating characteristics, and final analysis

Propensity score methods
- Estimate the propensity score
- Matching methods
- Weighting methods

Regulatory perspective
Practical examples and applications
- Using R

PEDAGOGICAL, TECHNICAL, AND SUPERVISORY RESOURCES

Classroom training session, slides (.pdf) of the presentation provided at the beginning of the session.
The course alternates between theoretical lectures and practical exercises, with interactive discussions between participants and the trainer.
The training will be provided by statistical methodologists from SARYGA.

FOLLOW-UP AND EVALUATION

Training certificate, satisfaction questionnaire.

CONTACT

formation@exystat.com, gaelle.saint-hilary@saryga.com

16-2025 CAUSAL INFERENCE IN CLINICAL TRIALS

OBJECTIVES

Acquiring basics of causal inference, emphasizing the distinction between correlation and causation in clinical trials

TARGET AUDIENCE / PREREQUISITES

Statisticians in the field of clinical trials

DURATION / LOCATION

2 days / France (in-house or public trainings)
Accessibility for persons with disabilities: please contact us in case of disability or potential difficulties

REGISTRATIONS

Registrations available up to one week before the scheduled training date

PROGRAM *For in-house training, the program can be tailored to meet your needs*

Potential outcomes framework
- Definition of causal effects based on counterfactual reasoning
- Individual Treatment Effects (ITE) and Average Treatment Effects (ATE)

Assignment mechanisms
- The role of treatment assignment in causal inference
- Randomization, probabilistic assignment, and unconfoundedness

Causal diagrams
- To identify confounding and biases

Propensity score methods, instrumental variables

Estimands and causal inference
- Defining treatment effects appropriately within the potential outcomes framework

Regulatory perspective

Practical examples and applications
- Using R

PEDAGOGICAL, TECHNICAL, AND SUPERVISORY RESOURCES

Classroom training session, slides (.pdf) of the presentation provided at the beginning of the session.
The course alternates between theoretical lectures and practical exercises, with interactive discussions between participants and the trainer.
The training will be provided by statistical methodologists from SARYGA.

FOLLOW-UP AND EVALUATION

Training certificate, satisfaction questionnaire.

CONTACT

formation@exystat.com, gaelle.saint-hilary@saryga.com

17-2025 UNDERSTANDING CLINICAL DATA MANAGEMENT: FROM COLLECTION TO DATA SUBMISSION

OBJECTIVES
Acquiring basics of Data Management process in clinical trials

TARGET AUDIENCE / PREREQUISITES
Project managers, CRAs, QA, students or staff working on clinical studies

DURATION / LOCATION
1 day / France (in-house or public trainings)
Accessibility for persons with disabilities: please contact us in case of disability or potential difficulties

REGISTRATIONS
Registrations available up to one week before the scheduled training date

PROGRAM *For in-house training, the program can be tailored to meet your needs*

Generalities
- Objectives, évolutions and regulatory context

Data Management activities
- Planification/ set-up
- Data collection
- Data cleaning / Database structure with practical examples
- Database lock, archiving

Sponsor responsabilities
Quality and compliance
Tools and technologies
GDPR, Data security
Challenges and perspectives

PEDAGOGICAL, TECHNICAL, AND SUPERVISORY RESOURCES
Classroom training session, slides (.pdf) of the presentation provided at the beginning of the session.
The course alternates between theoretical lectures and practical exercises, with interactive discussions between participants and the trainer.
The training will be provided by data managers from eXYSTAT.

FOLLOW-UP AND EVALUATION
Training certificate, satisfaction questionnaire.

CONTACT
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18-2025 DEMYSTIFYING CDISC: A PRACTICAL INTRODUCTION TO CDASH AND SDTM STANDARDS

OBJECTIVES

Acquiring basics of CDISC standards in clinical trials

TARGET AUDIENCE / PREREQUISITES

Project managers, CRAs, QA, students or staff working on clinical studies

DURATION / LOCATION

1 day / France (in-house or public trainings)
Accessibility for persons with disabilities: please contact us in case of disability or potential difficulties

REGISTRATIONS

Registrations available up to one week before the scheduled training date

PROGRAM *For in-house training, the program can be tailored to meet your needs*

General Information
- History and objectives of CDISC, impact of CDISC on the evolution of Data Management
- Regulatory context
- CDISC website – Structure / How to find documentation

CDASH Format
- Concepts related to data collection format
- Principles and implementation
- Validation of CDASH documentation

SDTM Format
- Concepts related to the Data Management database format
- Principles and implementation of SAS-based mapping
- Validation of SDTM documentation

Define.xml
- Definition, key concepts, principles

PEDAGOGICAL, TECHNICAL, AND SUPERVISORY RESOURCES

Classroom training session, slides (.pdf) of the presentation provided at the beginning of the session.
The course alternates between theoretical lectures and practical exercises, with interactive discussions between participants and the trainer.
The training will be provided by data managers from eXYSTAT.

FOLLOW-UP AND EVALUATION

Training certificate, satisfaction questionnaire.

CONTACT

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REFERENCES

Maëva Dupuis created MDSTAT Consulting in 2011. Maeva is regularly called upon to supervise statistical analyses as a biostatistician-consultant/methodologist for the clinical development of new drug candidates, including protocol development, representation in regulatory statistics to agencies, statistical modeling, reporting across a wide range of therapeutic areas. Prior to founding MDSTAT, Maëva was Head of Statistics at SOLADIS, Keyrus Biopharma and Thériamis, and held a position as Senior Statistician in Clinical Development at SANOFI-AVENTIS. Maëva has represented her clients several times at meetings with the FDA, the EMA and local European agencies, and regularly participates in Data Monitoring Committees (DMCs), as a methodologist for adaptive trials. Within MDSTAT, she is a consultant for many Biotechs and has been regularly leading training courses for more than 10 years, for both statisticians and non-statisticians, on the subject of regulatory clinical statistics. Maeva currently holds the position of Associate Director, Biostatistics, at ALEXION (Astra Zeneca Rare Diseases) in Barcelona.
She was elected as a member of the executive committee, responsible for training, in the Biopharmacy section of the French Statistical Society from 2005 to 2012.

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Laure Montané is a biostatistician and methodologist in the field of clinical trials, she has worked for more than 13 years in structures of varying sizes: pharmaceutical laboratories, French healthcare establishments and CRO. After graduating as an engineer in mathematics and scientific computing, she joined Soladis and carried out statistical consulting for various clients including Sanofi, Pasteur, L'Oréal and Servier. She then took over the management of the preclinical biostatistics department at Servier and provided methodological support for in vitro and in vivo studies. She then held a position as a biostatistician and senior methodologist at the Léon Bérard Center where she was involved in phase I to III trials and was a member of the statistical committee of the GINECO group. She created Oxalis in 2021 and brings to her clients (Biotechs, CROs) an expertise that calls for in-depth knowledge of complex methods, including adaptive designs, multiplicity problems and the Bayesian approach. She regularly participates in DMCs as a voting member or as an independent statistician. His skills allow him to cover many therapeutic areas with a strong experience in oncology, and to intervene at all stages of drug development, from the preclinical phase to phase III.

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François Montestruc has expertise in methodology, statistics and data-management of clinical studies. François has been working in the health industry for more than 25 years and has built a Biometrics department within Roche and then an epidemiological studies department. He was involved in all of Roche France's epidemiological studies until 2008. From 2008 to 2013, he joined a biotechnology company and again built the Biometrics department of a parent company and thus expanded his skills in the development of molecules in many indications. These two experiences led him to create eXYSTAT in 2013 to share his expertise with all healthcare stakeholders.
François also has an in-depth knowledge of the ANSM, MHRA, BfArM, Transparency Commission, EMA and FDA regulatory processes, having participated in numerous "scientific advices" or in the constitution of marketing authorization dossiers.
Finally, his expertise has led him to teach university courses, particularly in survival analysis, epidemiology or probabilities and to participate in the creation of the professional degree in "Statistics and Health" at the University of Paris V. He is a speaker at numerous training courses and seminars, for example at the Institut Pasteur, the University of Geneva, the ESIEE engineering school and at statistical congresses. Advising on the design of new clinical trials has remained passionately unchanged since the beginning of his career.

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Gaëlle Saint-Hilary is a statistical methodologist and the founder and CEO of Saryga, a consultancy dedicated to supporting innovation in healthcare through advanced statistical methodologies and data-driven decision-making. With 20 years of experience in the pharmaceutical industry – including leadership and scientific roles at Servier and Novartis – she has established herself as a recognized expert in Bayesian statistics, quantitative decision-making, and benefit-risk assessment.

Gaëlle has led methodological innovations across all stages of drug development, from early-phase design and dose-finding to portfolio-level decision-making. Her expertise spans adaptive designs, historical data integration, biomarkers, and the development of quantitative tools to improve the success and efficiency of clinical programs. She has also served as an expert on advisory boards, steering committees and to support regulatory submissions.

Holding a Master in Biostatistics from ENSAI and a PhD in Mathematics from the Polytechnic University of Turin, Gaëlle has authored numerous peer-reviewed publications and regularly contributes to academic and industry conferences. Her company Saryga provides consultancy, training, and strategic support to pharmaceutical companies and biotechnology companies, while maintaining strong collaborations with academic researchers and international consortia.

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Julie Le Boulicaut is CEO of eXYSTAT and a data manager with over 20 years of experience in the pharmaceutical and biotechnology industries. Before co-founding eXYSTAT, she held data management positions in both big pharma and biotech companies, where she led clinical data activities across various therapeutic areas. These roles allowed her to develop strong expertise in clinical data, regulatory compliance, and cross-functional collaboration.

She has worked on numerous clinical and epidemiological studies, with a particular focus on data quality and the implementation of CDISC standards (CDASH, SDTM and ADaM) to support regulatory submissions to authorities. At eXYSTAT, she now leads data management operations and helps sponsors improve the structure, reliability, and value of their clinical data. Julie also contributes to training initiatives, sharing her practical experience in data management processes.

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